

# TITAN MEDICAL

TITAN MEDICAL INC.

Management's  
Discussion and Analysis  
for the three and nine  
months ended September  
30, 2021

November 11, 2021

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## INTRODUCTION

The following Management's Discussion and Analysis ("MD&A") is prepared as of November 10, 2021 and should be read in conjunction with the unaudited condensed interim consolidated statements of financial position and the related notes thereto for the three and nine months ended September 30, 2021 (the "Interim Financial Statements") of Titan Medical Inc. (referred to hereinafter as "**Titan**", the "**Company**", "**we**", "**us**" and "**our**") and the annual audited financial statements for the year ended December 31, 2020. The Interim Financial Statements have been prepared in accordance with International Financial Reporting Standards ("**IFRS**") 34, Interim Financial Reporting ("**IAS 34**") as issued by the International Accounting Standards Board. Unless otherwise indicated, all financial information in this MD&A is reported in thousands of US dollars except for share and earnings (loss) per share data which is reported in number of shares and US dollars respectively. The tables and charts included in this document form an integral part of this MD&A.

The common shares of the Company (the "**Common Shares**") are listed under the symbol "**TMDI**" on The Nasdaq Capital Market (the "**Nasdaq**") and "**TMD**" on the Toronto Stock Exchange (the "**TSX**").

This MD&A has been prepared with reference to National Instrument 51-102 – Continuous Disclosure Obligations. Additional information related to Titan, including our Annual Information Form ("**AIF**") and Annual Report ("**Annual Report**") on Form 40-F for the year ended December 31, 2020, is available via our website at [www.titanmedicalinc.com](http://www.titanmedicalinc.com), on SEDAR at [www.sedar.com](http://www.sedar.com), and on the EDGAR section of the SEC's website at [www.sec.gov](http://www.sec.gov).

This MD&A includes references to the Company's trade-marks and trade names, such as Titan, Titan Medical, and Enos, some of which may be protected under applicable intellectual property laws of one or more countries and which the Company believes is its property. Solely for convenience, the Company's trade-marks referred to in this MD&A may appear without the TM or ® symbols, but such references are not intended to indicate, in any way, that the Company will not assert, to the fullest extent under applicable law, its rights to these trade-marks and trade names.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This discussion includes certain statements that may be deemed "forward-looking statements". All statements in this discussion other than statements of historical facts that address future events, developments, or transactions that the Company expects, are forward-looking statements. These forward-looking statements are made as of the date of this MD&A. Forward-looking statements are frequently, but not always, identified by words such as "expect", "anticipate", "estimate", "may", "could", "might", "will", "would", "should", "intend", "believe", "target", "budget", "plan", "strategy", "goals", "objectives", "predicts", "potential", "projects", "possible", "milestones", "projection" or the negative of any of these words and similar expressions, although these words may not be present in all forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties, assumptions and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include, but are not limited to, the factors discussed in the section entitled "Risk Factors" in this MD&A and in the section entitled "Risk Factors" in the Company's AIF or Annual Report for the year ended December 31, 2020 dated March 31, 2021. Although the Company has attempted to identify

important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. Forward-looking statements contained herein are made as of the date of this MD&A and, other than as required by law, the Company disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or results or otherwise. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Forward-looking statements are based on a number of assumptions, which may prove to be incorrect, including but not limited to the assumptions discussed in the section entitled “Caution Regarding Forward Looking Statements” in the Company’s AIF. Accordingly, readers should not place undue reliance on forward-looking statements.

This MD&A also includes market data and forecasts. Although the Company is responsible for all of the disclosure contained in this MD&A, in some cases the Company relies on and refers to market data and certain industry forecasts that were obtained from third party surveys, market research, consultant surveys, publicly available information and industry publications and surveys that it believes to be reliable. Unless otherwise indicated, all market and industry data and other statistical information and forecasts contained in this MD&A are based on independent industry publications, reports by market research firms or other published independent sources and other externally obtained data that the Company believes to be reliable. Any such market data, information or forecast may prove to be inaccurate because of the method by which it was obtained or because it cannot always be verified with complete certainty given the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties, including those discussed in the AIF and Annual Report under the heading “Risk Factors”. As a result, although the Company believes that these sources are reliable, it has not independently verified the information.

Please also refer to the risk factors set forth in the Company’s Annual Report for the 2020 fiscal year available on the EDGAR section of the SEC’s website at [www.sec.gov](http://www.sec.gov) and the Company’s AIF for the 2020 fiscal year available on SEDAR at [www.sedar.com](http://www.sedar.com), which are expressly incorporated by reference into this MD&A.

## NON-IFRS FINANCIAL MEASURES

The Company discloses non-IFRS measures (such as adjusted General & Administration (“**G&A**”) expenses) that do not have standardized meanings prescribed by IFRS. The Company believes that shareholders, investment analysts and other readers find such measures helpful in understanding the Company’s financial performance. Non-IFRS financial measures do not have any standardized meaning prescribed by IFRS and may not have been calculated in the same way as similarly named financial measures presented by other reporting issuers and therefore are unlikely to be comparable to similar measures presented by other companies. Furthermore, these non-IFRS measures should not be considered in isolation or as a substitute for measures of performance or cash flows as prepared in accordance with IFRS. These measures should be considered as supplemental in nature and not as a substitute for related financial information prepared in accordance with IFRS.

## Adjusted G&A

G&A refers to expenses determined in accordance with IFRS. The Company defines adjusted G&A as G&A excluding stock-based compensation (“**SBC**”) expense and severance costs. Management believes adjusted G&A is a useful supplemental measure to determine the Company’s cash burn rate related to G&A so investors can understand the cash that is available for research and development (“**R&D**”).

## OVERVIEW

Titan is a Canadian company committed to enhancing robotic assisted surgery through technology that requires only a single patient access point. Titan is headquartered in Toronto, Ontario with product development and regulatory affairs activities in Chapel Hill, North Carolina. The Company is developing the Enos™ surgical system (the “**Enos System**”), a robotic single access surgical system to assist surgeons in performing certain procedures well suited for single access surgery. With the Enos System, the Company intends to improve patient outcomes and lower operating costs through the application of robotic technology that is designed to be safe, effective and easy to use, allowing medical professionals to perform their best. The Enos System derives its name from the Greek language, meaning ‘Of One’, signifying the system’s focus on “single access”. By focusing on a single access point, we believe that patient trauma, post-operative pain and scarring can be reduced, and patients may be able to recover from surgery faster. The Company’s innovations in robotic-assisted surgery, including those directed at the Enos System, are protected by a growing patent portfolio that has expanded from 12 issued patents at December 31, 2016, to 100 issued patents and 96 patent applications as of September 30, 2021.

While under development, the Enos System has not been cleared or approved by the U.S. Food and Drug Administration (“**FDA**”) or any other regulatory authority in any other jurisdiction and is not yet commercially available.

The Company is the successor corporation formed pursuant to two separate amalgamations under the *Business Corporations Act* (Ontario) on July 28, 2008. The address of the Company’s corporate office and its principal place of business is 155 University Avenue, Suite 750, Toronto, Ontario, Canada M5H 3B7. On May 29, 2020, the Company established Titan Medical USA Inc. (“**Titan USA**” or the “**Subsidiary**”), a Delaware corporation and a wholly owned subsidiary of the Company. Titan USA’s principal activity consists of R&D as well as the manufacturing of instruments and camera systems for the Enos System from its leased premises located in Chapel Hill.

In addition to leveraging in-house R&D capabilities for activities related to the Enos System and the development work pursuant to the agreement with Medtronic plc (see “*Significant Transactions - Development Agreement & License Agreement with Medtronic*”), the Company engages subcontractors and consultants to perform certain design and development, prototyping, and assembly and manufacturing activities.

## SIGNIFICANT TRANSACTIONS

### February 2021 Equity Offering

On February 24, 2021, the Company closed an offering of 9,585,250 units of the Company (“**February 2021 Units**”) sold on a “bought deal” basis, at a price of \$2.40 per February 2021 Unit for aggregate gross proceeds of \$23 million. Each February 2021 Unit consists of one Common Share and one half (1/2) of one Common Share purchase warrant (each whole warrant, a “**February 2021 Warrant**”). Each February 2021 Warrant is exercisable to acquire one Common Share at an exercise price of \$3.00 per Common Share until February 24, 2023. In connection with the February 2021 offering, the Company issued 670,967 broker warrants, each exercisable at \$3.00 until February 24, 2023 for one Common Share.

Anticipated use of proceeds from the offering is for general corporate purposes and funding working capital and capital expenditures. As previously disclosed, general corporate purposes includes the development of the Enos System (see “*Enos Robotic Single Access Surgical System - Development Plan*”) and there have been no variations in the proposed use of proceeds to date.

### January 2021 Equity Offering

On January 26, 2021, the Company closed an offering of 7,419,354 units of the Company (“**January 2021 Units**”) sold on a “bought deal” basis, at a price of \$1.55 per January 2021 Unit for aggregate gross proceeds of \$11.5 million. Each January 2021 Unit consists of one Common Share and one half (1/2) of one Common Share purchase warrant (each whole warrant, a “**January 2021 Warrant**”). Each January 2021 Warrant is exercisable to acquire one Common Share at an exercise price of \$2.00 per share until January 26, 2026. In connection with the January 2021 offering, the Company issued 518,234 broker warrants, each exercisable at \$1.9375 until January 26, 2023 for one Common Share.

Anticipated use of proceeds from the offering is for general corporate purposes and funding working capital and capital expenditures. As previously disclosed, general corporate purposes includes the development of the Enos System (see “*Enos Robotic Single Access Surgical System - Development Plan*”) and there have been no variations in the proposed use of proceeds to date.

### Development Agreement & License Agreement with Medtronic

On June 3, 2020, the Company entered into a development and license agreement (the “**Development Agreement**”) with a U.S. affiliate of Medtronic plc (“**Medtronic**”) in connection with the development of robotic assisted surgical technologies and a separate license agreement (the “**License Agreement**”, and together with the Development Agreement, the “**Medtronic Agreements**”) with Medtronic in respect of certain previously developed Company technologies.

Under the terms of the License Agreement, Titan granted Medtronic an exclusive license with regard to certain robotic assisted surgical technologies, including patents and know-how, for a one-time upfront royalty payment of \$10 million with no further royalty payments due thereunder. Under the terms of the Development Agreement, Titan has granted or will grant Medtronic an exclusive license with regard to the technologies developed under the Development Agreement in exchange for license fees totaling up to \$31 million with no further royalty payments due thereunder, \$20 million of which has already been received by Titan as described below. While the intellectual property licensed to Medtronic under the Medtronic Agreements may not be licensed to a third party, Titan has retained rights to continue to develop, commercialize and use

the licensed intellectual property and the licensed technologies for the Company's own business in single access robotic assisted surgery, including the Enos System. Furthermore, in connection with the sale of all or substantially all of the assets of the Company or a "change of control" (as such term is defined in the Medtronic Agreements), the Company may assign and transfer all of its rights under the Medtronic Agreements, allowing an acquirer to use the licensed intellectual property and technologies, as otherwise permitted under the Medtronic Agreements, for their own purposes.

On June 10, 2020, the Company received a \$10 million license payment pursuant to the License Agreement. Under the Development Agreement, on October 28, 2020, the Company received a \$10 million license payment for completion of Medtronic Milestone 1, and on May 28, 2021, the Company received a further \$10 million license payment for completion of Medtronic Milestone 3. The Company's entitlement to receive up to an additional \$11 million pursuant to the Development Agreement is conditional upon the completion of Medtronic Milestone 4 set forth in the Development Agreement. The technology development under Medtronic Milestone 4 involves complex electromechanical design and development and specialized components that may be challenging to source on a timely basis due to global supply chain constraints, and there is no assurance that the milestone will be satisfied on a timely basis or at all. The technology design and development require a combination of personnel with experience and expertise in robotic-assisted surgical technology and financial resources. Furthermore, there is no assurance that the Company will receive further license payments from Medtronic, including the payments related to Medtronic Milestone 4.

The Company is also dependent on the engagement of certain contractors and suppliers and there is no assurance that those parties will all be agreeable to engage throughout the project on terms satisfactory to the Company or at all.

The payments are to be provided as technology milestones are completed and evaluated by Medtronic and are further identified in the table below. The Development Start Date, as defined in the Development Agreement, was June 12, 2020.

Medtronic Milestone <sup>(1)</sup>	Deadline <sup>(2)</sup>	Payment <sup>(3)</sup> (US \$ 000's)	Milestone Achieved
Medtronic Milestone 1 <sup>(4) (5)</sup>	Four (4) months from Development Start Date	10,000	Q4 2020
Medtronic Milestone 2 <sup>(6)</sup>	Four (4) months from Development Start Date	-	-

Medtronic Milestone <sup>(1)</sup>	Deadline <sup>(2)</sup>	Payment <sup>(3)</sup> (US \$ 000's)	Milestone Achieved
Medtronic Milestone 3 <sup>(5)</sup>	Six (6) months from the later of: (a) receipt by us of Payment for Medtronic Milestone 1, (b) receipt by us from Medtronic of Medtronic deliverables required for Medtronic Milestone 3, and (c) receipt by us from Medtronic of confirmation of certain due diligence in respect of our deliverables for Medtronic Milestone 1	10,000	Q2 2021
Medtronic Milestone 4	Four (4) months from the later of: (a) receipt by us of Payment for Medtronic Milestone 3, (b) receipt by us of Medtronic deliverables for Medtronic Milestone 4, and (c) receipt by us from Medtronic of confirmation of certain due diligence in respect of our deliverables for Medtronic Milestone 3	11,000 <sup>(7) (8)</sup>	

Notes:

1. Medtronic Milestone 1, Medtronic Milestone 3 and Medtronic Milestone 4 are each defined in the Development Agreement and consist of the completion of the development of certain robotic assisted surgical technologies as described in the Development Agreement.
2. All as further described and qualified in the Development Agreement.
3. Each payment is conditional upon the corresponding milestone being completed on a timely basis. As of the date of this document, Medtronic Milestones 1, 2 and 3 have been completed.
4. "Development Start Date" has the meaning ascribed to it in the Development Agreement and was June 12, 2020.
5. As of the date of this document, Medtronic Milestones 1, 2 and 3 have been completed on schedule and the related payments were received.
6. Medtronic Milestone 2 is a non-technology milestone defined as Titan raising at least \$18.0 million of capital between the effective date of the Development Agreement and the date that is four months from the Development Start Date. Medtronic Milestone 2 was achieved ahead of the deadline in June 2020.
7. The amount of the payment will be the sum of \$10.0 million and the amount of the Legal Expenses (as defined below) to be paid to the Company up to a maximum of \$1.0 million pursuant to the Development Agreement and License Agreement.
8. The balance outstanding under the Medtronic Loan will be offset against the payment for Medtronic Milestone 4. See below under "Senior Secured Loan from Medtronic".

The Development Agreement provides for a steering committee comprising of an equal number of representatives from Titan and Medtronic established to provide oversight regarding the work toward achievement of the milestones. Either party may terminate the Development Agreement if the other party materially breaches the agreement and (if the breach is curable) fails to cure the breach within forty (40) business days after receipt of written notice.

## Senior Secured Loan from Medtronic

On April 28, 2020, Titan received gross proceeds of \$1.5 million from a senior secured loan (the “**Medtronic Loan**”) provided by an affiliate of Medtronic (“**Medtronic Lender**”). The Medtronic Loan is evidenced by an amended and restated senior secured promissory note (“**Note**”) dated June 3, 2020, in the principal amount of \$1.5 million plus an amount equal to certain legal, transaction and intellectual property related expenses (“**Legal Expenses**”) incurred by Medtronic in connection with the License Agreement and Development Agreement and will bear interest at the rate of 8% per annum. The unpaid principal balance owing under the Note, together with any accrued and unpaid interest and all other unpaid obligations under the Note, shall be due and payable in full on the earliest to occur of: (i) June 4, 2023, (ii) the completion of the last milestone under the Development Agreement, or (iii) a Change of Control (as defined in the Note), subject to an accelerated due date under certain adverse conditions. Until repayment of the loan, Medtronic may have one non-voting observer attend meetings of Titan’s Board of Directors.

While the Company may prepay the Note at any time, in whole or in part, without fee or penalty, the Company has maintained the Note to preserve capital as may be required for corporate purposes including for the development of the Enos System.

Titan has entered into a security agreement dated April 28, 2020 in favor of the Medtronic Lender (the “**Security Agreement**”) pursuant to which Titan has granted to the Medtronic Lender a security interest in all of the Company’s present and future property including all personal property, inventory, equipment and intellectual property. In addition, Medtronic Lender’s rights and powers under the Security Agreement include without limitation (a) exercising and enforcing all rights and remedies of a holder of collateral as if the Medtronic Lender were the absolute owner of the collateral, (b) collection of any proceeds arising in respect of all of our property pledged as security for the loan, (c) license or sublicense, whether on an exclusive or nonexclusive basis, of any of our intellectual property for such term and on such conditions and in such manner as Medtronic Lender in its sole judgement determines (taking into account such provisions as may be necessary to protect and preserve such intellectual property), and (d) the right to enforce its security in the event of a default which may include the appointment of a receiver by instrument or order of the court.

The Medtronic Loan and Note may limit or preclude the Company from arranging further debt financing. Under the terms of the Note and related Security Agreement, the Medtronic Lender has certain rights and powers that, if exercised, could have a material adverse effect on the Company’s business. Due to the senior ranking of the Medtronic Lender’s security interest in all of the Company’s assets under the Security Agreement, the Company may be limited in, or entirely precluded from, granting a security interest in its assets in support of any further debt financing the Company may seek from any other lender, unless the security interest under the further debt financing is subordinate to the Medtronic Lender’s security interest or the Medtronic Loan and the Note is paid in full satisfaction as permitted therein.

In the event that the Company were to seek further debt financing and if it were not possible to subordinate the further debt financing or otherwise pay the Medtronic Loan and the Note in full satisfaction, the Company would need to seek financing by way of equity financing and there is no assurance that further equity financing will be available or available on acceptable terms.

### June 2020 Financing

On June 10, 2020, the Company completed a registered offering of 6,500,000 Common Shares, 11,500,000 Common Share equivalents (each, a “**June 2020 Common Share Equivalent**”) and 9,000,000 Common Share purchase warrants (each, a “**June 2020 Warrant**”) for total gross proceeds of approximately \$18,000,000. Under the offering, the Common Shares, June 2020 Common Share Equivalent and June 2020 Warrants were sold in fixed combinations at an offering price of \$1.00, consisting of one Common Share and one-half June 2020 Warrant or one June 2020 Common Share Equivalent and one-half June 2020 Warrant. Each June 2020 Warrant is exercisable to acquire one Common Share at an exercise price of \$1.00 per Common Share until June 10, 2024. Each June 2020 Common Share Equivalent is convertible to one Common Share at a conversion price of \$0.0001 and will expire when exercised in full. All 11,500,000 June 2020 Common Share Equivalents have been converted to Common Shares at various dates from June 10, 2020 to September 30, 2020.

In connection with the June 2020 offering, broker warrants were issued to the placement agent entitling the holder to purchase 1,260,000 Common Shares at an exercise price of \$1.25 per share prior to expiry on June 10, 2024.

### May 2020 Financing

On May 6, 2020, the Company completed a registered direct offering of 5,514,500 Common Shares at an offering price of \$0.36268 per share and 2,757,252 unregistered Common Share purchase warrants (each, a “**May 2020 Warrant**”) for gross proceeds of \$2,000,000. Each May 2020 Warrant is exercisable to purchase one Common Share at an exercise price of \$0.3002 per Common Shares until November 6, 2025.

In connection with the May 2020 offering, broker warrants were issued to the placement agent entitling the holder to purchase 386,015 Common Shares at an exercise price of \$0.45335 per share prior to expiry on November 6, 2025.

### March 2020 Financing

On March 25, 2020, the Company completed a registered offering of 7,000,000 Common Shares and 3,500,000 Common Share purchase warrants (each, a “**March 2020 Warrant**”) for total gross proceeds of approximately \$1.2 million. Each March 2020 Warrant is exercisable to purchase one Common Share at an exercise price of \$0.19 per share until March 25, 2025.

In connection with the March 2020 offering, broker warrants were issued to the placement agent entitling the holder to purchase 490,000 Common Shares at an exercise price of \$0.2125 per share prior to expiry on March 25, 2025.

### Aspire Common Share Purchase Agreement

On December 23, 2019, the Company entered into an agreement with Aspire Capital Fund, LLC (“**Aspire**”). Under the terms of this agreement, Aspire committed to purchase up to \$35 million of Common Shares for a maximum of 9,729,777 Common Shares. To date, the Company has issued 6,981,048 Common Shares of Titan for total proceeds of \$5.2 million (\$0.2 million for the three months ended September 30, 2021 and \$2.7 million for the nine months ended September 30, 2021). The balance remaining on Aspire’s commitment is 2,748,729 Common Shares (with a

maximum value of \$29.8 million), accessible at the Company's request from time to time, until June 23, 2022, subject to the terms and conditions of the agreement.

## ENOS ROBOTIC SINGLE ACCESS SURGICAL SYSTEM

### Development

The Company's business consists of the design and development of robotic-assisted surgical technologies that require only a single patient access point for application in minimally invasive surgery ("MIS"). The Company is presently focused on the development of the Enos System, which comprises a surgeon-controlled patient cart with a 3D high-definition vision system and multi-articulating instruments for performing MIS procedures, and a surgeon workstation that provides the surgeon with an ergonomic interface to the patient cart and a 3D high-definition view of the MIS procedure. The Company intends to initially pursue gynecologic surgical indications for use of its Enos System.

Development of the Enos System has proceeded with input from various stakeholders including surgeons and operating room staff experienced in MIS, medical technology development firms and from the Company's surgeon advisory board. This approach has positioned the Company to design a robotic surgical system intended to include the traditional advantages of robotic-assisted surgery, including 3D stereoscopic imaging and restoration of instinctive control, as well as new and enhanced features, including an advanced surgeon workstation incorporating a 3D high-definition display providing a more ergonomic user interface and a patient cart facilitating the use of instruments with enhanced dexterity.

The Enos System patient cart has been developed with the goal of delivering multi-articulating instruments and a dual-view camera system into a patient's abdominal body cavity through a single access port. The dual-view camera system consists of a flexible 3D high-definition endoscopic camera along with a light source and an insertion tube with a diameter of approximately 25 millimeters that includes an integrated 2D high-definition camera along with an independent light source that, once inserted, provides visualization of the MIS surgical site for optimal surgical positioning of the patient cart. Once the insertion tube is positioned in the body, it is docked to a central drive unit of the patient cart and the 3D high-definition endoscopic camera is subsequently deployed in a manner that the endoscopic camera and multi-articulating instruments can be controlled by the surgeon via the surgeon workstation. The reusable multi-articulating instruments provide for highly dexterous movement in use and are designed to facilitate an assortment of permanent and detachable single patient use end effectors. The use of reusable robotic instruments for a specific number of uses that can be cleaned and sterilized between surgeries is intended to minimize the cost per procedure without compromising surgical performance. The design of the patient cart also incorporates multiple mechanical elements for surgical positioning allowing for configurability for a number of surgical indications and the ability to be maneuvered within the operating room, or redeployed within hospitals and ambulatory surgical centers, where applicable.

As part of the development of the Enos System, the Company plans on the continued development of a robust training curriculum and post-training assessment tools for surgeons and surgical teams. The training curriculum is planned to include cognitive pre-training, psychomotor skills training, surgery simulations, live animal and human cadaver lab training, surgical team training, troubleshooting and an overview of safety. Post-training assessment will include validation of the effectiveness of those assessment tools. A software training system developer

has produced an initial set of core surgical skills simulation modules customized for use with the surgeon workstation in the first phase of the comprehensive surgeon training curriculum that the Company plans for its Enos System.

The Company has worked to deepen its intellectual capital through the recruitment of an in-house technical team and continuously evaluates its technologies under development for intellectual property protection through a combination of trade secrets and patent application filings. The Company continues to focus on the filing and prosecution of patents that management believes validate the novelty of its unique technology, and in turn, support the value of the entire franchise.

### Regulatory Overview

Robotic assisted surgery systems are highly regulated, complex medical devices. The Company has used a combination of internal and external resources to execute the research, development and regulatory plans for the Enos System. Development objectives have been established to support a planned regulatory submission to the FDA for marketing authorization in the US, followed by submittal of a Technical File to a European Notified Body to obtain CE marking, which indicates that a product for sale within the European Economic Area has been assessed to conform to health safety and environmental protection requirements.

In the US, the regulatory clearance process includes a Q-Submission Program that provides companies an opportunity to interact with and obtain feedback from the FDA on specific aspects of the regulatory process, requirements and planned submissions including Investigational Device Exemption (“**IDE**”) applications, 510(k) applications and De Novo classification requests. Certain Q-Submissions, termed Pre-Submissions, typically include a request for written feedback, and if a company chooses, a meeting in which additional feedback and findings are documented in meeting minutes. The recommendations made by the FDA in response to a Pre-Submission are non-binding on the FDA, and circumstances related to a company’s product or potential risks identified through post-market surveillance of similar products in clinical use may further change the position of the FDA. Furthermore, while the FDA encourages Q-Submissions, there is no assurance that feedback provided from these communications will result in regulatory approval or clearance, nor does it preclude any identified future changes in regulatory pathways.

The Company has filed a number of Q-Submissions and based on ongoing communications with the FDA, expects that the Enos System will be classified as a Class II device and accordingly plans to obtain marketing authorization through a classification request for novel devices in accordance with section 513(f)(2) of the U.S. Federal Food, Drug and Cosmetic Act (the “**FD&C Act**”), commonly known as a De Novo classification submission. In 2020, the Company filed a Request for Information in response to communications the Company had with the FDA, in which the FDA raised the question of whether robotically-assisted surgical devices (“**RASD**”) would generally continue to be eligible for classification as Class II devices and the 510(k) submission pathway, or whether a De Novo submission would be more appropriate for such devices. While the Company had previously confirmed with the FDA that the Enos System would be suitable for marketing authorization through a 510(k) submission, in December 2020, it received a written response (the “**Written Response**”) from the FDA to its Request for Information in accordance with section 513(g) of the FD&C Act that indicated that the FDA believes, based on information provided to it, that the Enos System is appropriate for classification through the De Novo submission pathway. The FDA stated that the technological differences between the Enos System and robotically-assisted surgical devices previously cleared for marketing by the FDA raise new questions of safety and effectiveness, and that a 510(k) application submitted by the Company claiming substantial equivalence to any previously marketed RASD would most likely be

determined to be not substantially equivalent. In view of the Written Response and additional guidance provided by the FDA to the Company, the Company plans to proceed with a De Novo classification request for the Enos System following successful completion of the IDE clinical study as described below.

Requests for Information made pursuant to Section 513(g) of the FD&C Act require the FDA to provide information about the classification and the regulatory requirements that may be applicable to a particular device. FDA responses to such requests represent the FDA's best judgement about how a device would be regulated, based upon review of information provided by a requester, including the description of the device and its intended use. The FDA's response to a 513(g) request is not a classification decision for a device and does not constitute FDA clearance or approval for commercial distribution. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act, such as a classification obtained in response to a 510(k) submission or a De Novo submission.

The De Novo classification request provides a pathway for the FDA to classify novel medical devices for which general controls, or general and special controls, provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. The De Novo process allows the FDA to review a company's submission and reasons as to why the device should be a Class II device, including the review of the general and special controls that would provide reasonable assurance of the safety and effectiveness of the device. Included in such a classification request, clinical, non-clinical, test and design data may be provided to support a company's recommendation for the classification of the device as a Class II device. After the FDA receives and reviews a request, a determination (generally within 150 review days) is made to either grant or decline the request. Review days are calculated as the number of calendar days between the date the De Novo request was received by the FDA and the date of the FDA's decision, excluding the days a request was on hold for an additional information request. If the request is granted (i.e. the device is determined to be a Class II device), the device is authorized to be marketed and a new classification regulation will be established, ultimately allowing the novel device to serve as a predicate for 510(k) submissions of future devices of the same type. Should the De Novo classification request be declined, and the device is therefore classified as a Class III device, a premarket approval application under section 515 of the FD&C Act, also known as a PMA, would be required to market the device, involving a more expensive and time-consuming approval process.

Since the Enos System is presently under development and the Company has not submitted any regulatory applications, it is not possible to predict with certainty the outcome of any review by the FDA and the time required to complete activities necessary for regulatory approval or clearance is not quantifiable at this time. The FDA's recent review and response to the Company's proposed IDE clinical study general design and planning occurred during a video conference call held in September, 2021. While the general design of the Company's planned IDE clinical study was confirmed, more detailed communication will be required to reach agreement on the content of a complete IDE application, including the final clinical design, detailed risk analyses, extensive safety testing, human factors testing, and preclinical data. Accordingly, the Company plans on further communications and submissions with the FDA to clarify the requirements for the IDE application and to understand any special controls which the FDA may apply to the IDE clinical study. Additional Pre-Submissions will allow the FDA to review the state of the current design of the surgical system, and the inclusion of test data and more detailed proposals for clinical protocols would allow the FDA to provide additional feedback and/or suggest modifications.

The performance of human surgeries as part of the proposed clinical study with the Enos System will require an IDE from the FDA, which must be submitted and approved in advance. An IDE allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. Further, the recruitment of surgeons from multiple hospital sites will be necessary to perform the surgeries as well as the recruitment of patients willing to participate in the IDE study. Each of these sites will require approval of their independent Institutional Review Board (“**IRB**”) to approve the studies. Application to the IRB of each hospital can be made once the FDA has approved the Company’s IDE application. Only upon successful completion of the IDE clinical study will the Company be in a position to submit to the FDA an application for De Novo classification for marketing authorization.

Previous results achieved by surgeons in operating prototypes in numerous animal and cadaver studies have preliminarily validated the potential for single incision surgeries to be performed with the Enos System. Insights gained from these preclinical studies have directed the Company to make product improvements. In June 2019, the Company commenced preclinical live animal and cadaver studies according to Good Laboratory Practices (“**GLP**”) and subsequently, on July 18, 2019, announced the successful completion of those studies. Following the completion of the GLP procedures, the Company proceeded to perform human factors evaluation (“**HFE**”) studies, which included verification of production system operation with clinical experts under simulated robotic manipulation exercises. However, during the GLP and HFE studies, the Company identified opportunities to improve the performance of instruments, camera systems and sterile interfaces before proceeding further, which may require repeating those studies with enhanced designs.

During the third quarter of 2021, the Company completed additional pre-clinical GLP studies. The pre-clinical studies involved utilizing the Enos System to perform hysterectomies in porcine subjects. The subjects successfully completed the survival period in the study. Further tests on the subjects were run post-surgery and pathology results are expected in the first quarter of 2022. The COVID-19 pandemic has impacted the processing time at laboratories, resulting in a longer than expected turnaround time for results. With the completion of these studies, surgeons have now performed over 70 pre-clinical procedures representing multiple subspecialties with Titan’s Enos System.

During the third quarter of 2019, the Company’s European Notified Body also completed audits of the Company’s quality system procedures and related documentation for ISO 13485 Certification, which was ultimately received in January 2020. In September 2021, a surveillance audit of the Company’s quality system was successfully completed by the Company’s Notified Body.

### Development Plan

For the purposes of this section, the description and milestone chart with respect to the Company’s development plan should be read in conjunction with the risk factors associated with the Company as found in the “Risk Factors” section of the AIF, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and filed as an exhibit to the Form 40-F, available on EDGAR at [www.sec.gov](http://www.sec.gov), as well as additional risk factors set forth in this MD&A.

The Company is focused on the development and commercialization of the Enos System. The following chart and narrative are provided to outline the significant development and regulatory milestones required to achieve the overall goal of commercializing the Enos System in the United States.



While the milestone chart is based on information currently available to the Company, there is no assurance that the development, regulatory and commercialization milestones set forth above will be completed within the timeframes forecasted, if at all, and are based upon the following key assumptions:

1. The Company will complete each milestone within the projected timeframe and at the estimated cost.
2. The Company will receive on a timely basis all applicable regulatory approvals or clearances including without limitation the planned IDE application and the planned De Novo application to the FDA.
3. There will be no significant changes to the regulatory authorization process in the United States.
4. The Company will be able to secure a sufficient number of hospital sites, surgeons and patients as part of the IDE clinical study.
5. The costs of materials and components required by the Company, availability of sufficiently qualified personnel and the wages and salaries of such personnel and the costs and timing of engaging third parties in respect of the Company's clinical study and the manufacturing of its Enos System will remain stable.
6. Despite global supply chain challenges, the Company and the manufacturing firms it engages will be able to secure components and subsystems for the Enos System on a timely basis, and no unforeseen shortages or shipping delays will arise.
7. The Company will be able to raise required financing on a timely basis to support its development program, manufacturing, human clinical study and operations.
8. The design of the Enos System and related platforms and equipment will not be required to materially change for any reasons (including without limitation due to results of safety and verification testing, market demands, intellectual property or regulatory issues).
9. The Company will be able to engage, retain and recruit, as necessary, technical personnel, contractors and third parties (such as development firms and manufacturers) with the type of specialized skill and knowledge required to develop, manufacture and test the Enos System.

The foregoing list of assumptions is not exhaustive. Although the Company has attempted to identify on a reasonable basis the key assumptions related to forward-looking statements in the development milestone table above, there can be no assurance that the forward-looking statements will prove to be accurate, as events or circumstances or other factors could cause

actual results to differ materially from those estimated or projected and expressed in, or implied by, these forward-looking statements.

Based on recent discussions with the FDA, discussions with the OEM manufacturer regarding manufacturing transfer, supply chain of components, and product and software testing, the Company has determined that additional time and work will be required prior to an IDE submission. The Company plans to file the IDE application for the Enos System with the FDA in the first quarter of 2023 and anticipates receiving a response on the IDE from the FDA in the first half of 2023. Subsequent milestones have been updated accordingly as set forth below.

- *Completion of Product Development* – Additional time is required to complete product development to accommodate the transfer of the Enos System to manufacturing, including the areas of supply chain management, product assembly and testing, and implementation of software updates related to safety controls. Accordingly, completion of product development is anticipated to be delayed by approximately six months to mid-2022. The Company relies on its employees as well as engagements with consultants, development firms and manufacturers to complete product development. Any delays in the engagement of the forgoing or from their anticipated timing or from other interruptions related thereto, such as supply chain interruptions, will impact the Company's ability to complete product development.
- *Manufactured Units Safety and Verification Testing* – Upon completion of product development and the delivery of manufactured units of the Enos patient cart and surgeon workstation, the Company anticipates completing system verification and validation and safety testing in support of the planned IDE submission.
- *IDE Application, FDA Review, IDE Study* – Upon successful completion of safety and verification testing of the Enos patient cart and surgeon workstation as well as the biocompatibility testing of instruments, cameras and accessories, the Company expects it will have the requisite information necessary to submit a complete IDE application to the FDA in the first quarter of 2023. The Company had previously disclosed that it expected submitting an IDE application to the FDA in the first quarter of 2022. Based on information currently available to the Company, the Company anticipates receiving a response from the FDA in the first half of 2023. Upon receiving approval of the IDE application by the FDA, the Company plans to commence human clinical studies to validate the safety and effectiveness of the Enos System.

With the recent feedback from the FDA, it is anticipated that the IDE clinical study will include total laparoscopic hysterectomies performed on 30 to 40 patients at 3 to 4 clinical sites. The Company has already begun IRB site preparation for the selected clinical sites. Based on the expected timing of filing the IDE application and the FDA review and approval process, the Company anticipates that the surgical procedures associated with the IDE, and the associated follow-up, can be completed in early 2024. Prior to the feedback from the FDA and the additional activities required as set forth above, the Company had previously disclosed anticipating completing IDE clinical studies by the end of 2022.

- *De Novo Application and FDA Review* – Assuming the successful completion of the IDE study, including follow-up data, the Company expects to submit its De Novo application to the FDA and receive the FDA's response in 2024.

- *Commercialization* – The Company had previously anticipated commencing commercialization sometime in 2024, given the additional information available to the Company and the work it continues to perform in an effort to transition to manufacturing, the Company anticipates a commercial launch of the Enos System in early 2025 upon receipt of marketing authorization from the FDA. Commercial manufacturing of the Enos System is expected to be an extremely detailed and complex process with the potential for delays, interruptions (including supply chain interruptions) or cost overruns.

### Risks related to the Development Program

Significant risks with respect to the Company's development program are set forth in detail in the "Risk Factors" section of the AIF, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and filed as an exhibit to the Form 40-F, available on EDGAR at [www.sec.gov](http://www.sec.gov).

The Company anticipates that its cash balance of \$44.7 million at September 30, 2021, the \$11.0 million license fee the Company would expect to receive upon completion of Medtronic Milestone 4 under the Development Agreement and the ability to raise additional capital that is available under the Aspire Agreement will be sufficient to fund the development of its Enos System and operational expenses through 2022, including any costs pursuant to the activities under the Development Agreement. However, unexpected increases in costs and expenses due to operational decisions made by the Company and/or factors beyond the Company's control, such as COVID-19 or any variants, or any delays related to sourcing of parts and materials or higher than expected inflation rates impacting pricing of parts and materials could cause a material impact on working capital resources of the Company.

Due to the nature of technology development and the related medical device regulatory pathway in the United States, there is no assurance that the development, regulatory and commercialization milestones set forth above will be completed within the timeframes forecasted, if at all, and there can be no assurance with respect to the resources that may be required to achieve these milestones, including both internal resources with respect to the availability to the Company of qualified technical personnel and third party development and manufacturing firms. Furthermore, additional required development or regulatory tasks could be identified in the course of the development, manufacturing and testing of the Enos System which may elongate the forecast timeline. The review times for IDE applications as well as De Novo applications with the FDA can vary greatly, and there can be no assurance as to the time it will take for the Company to receive FDA marketing clearance for the Enos System, or whether such clearance will be obtained at all.

### *Challenging Global Political and Economic Conditions; Supply Chain*

The general economic and business conditions around the world affect the Company's business prospects and the demand for its products in Canada, the United States, Europe and elsewhere in the world. Such conditions include short and long-term interest rates, inflation, fluctuations in international trade agreements or laws, fluctuations in securities prices and capital markets, exchange rates, debt crisis periodically affecting certain countries, volatility in the financial markets throughout the world, the tightening of liquidity in selected financial markets, and the strength of the regional and international economies.

All of these factors affect the business and economic conditions in a given geographic region and, consequently, may affect the availability of materials, components and services from third party contractors and suppliers required by the Company to carry out its development plan and the

pricing, terms and conditions upon which they may be available to the Company; these factors may also impact the demand for the products being developed by the Company. Currency rate movements and trade relationships in the United States and other countries where the Company seeks to purchase materials, components and services or to market or distribute its products may significantly impact the Company's business prospects and future costs and earnings. The monetary policies of the Bank of Canada, the US Federal Reserve and the European monetary authorities as well as other interventionist measures in capital markets by public organizations are impacting economic conditions and therefore have consequences on the Company's business prospects. Ultimately, these factors may cause delays in the projected timelines and escalations of the projected expenses of the Company's development milestones.

The Company has no control over changes in inflation and interest rates, foreign currency exchange rates and controls or other economic factors affecting its business or the possibility of political unrest, legal and regulatory changes in jurisdictions in which the Company operates or intends to market its products.

Credit and liquidity problems may make it difficult for some businesses to access credit markets and obtain financing and may cause some businesses slowdowns and liquidity needs. In the future if and when the Company's products are made available in the market place, the Company's exposure to bad debt losses could increase if customers are unable to pay for products previously ordered and delivered. Global economic conditions may have adverse effects on the Company's business. The Company's global market may include governmental entities or other entities that rely on government healthcare systems or government funding. If government funding for healthcare becomes limited, the Company's future customers may be unable to pay their obligations on a timely basis or to make payment in full and it may become necessary to increase reserves.

Additionally, the Company's development plans may be impacted by global supply chain challenges including extended delivery times, increases in pricing and constraints on the availability of materials and components required by the Company and the development and manufacturing firms it has engaged including severe constraints in the semiconductor market. Prices of numerous materials and components have increased and they may continue to increase due increased demand and supply constraints. If supply constraints and pricing increases continue, the Company could fail to complete its milestones within the timelines forecast or at all and such failure could have a material adverse impact on the Company's business, financial condition, results of operations, or cash flows.

### *IDE Clinical Study*

Upon obtaining the IDE from the FDA, the performance of human surgeries as part of the proposed IDE clinical study with the Enos System will require an engagement of a sufficient number of hospital sites, surgeons, and the recruitment of a sufficient number of patients to complete the study. The Company has not entered into agreements with any hospital sites or with a Contract Research Organization. In addition, pandemics, including the reoccurrence of the COVID-19 pandemic or its variants, may slow or otherwise prevent the Company from installing equipment and training users on the equipment, may slow or prevent recruiting patients as part of the study, or may cause clinical study sites to limit, delay or otherwise cancel clinical studies of the Enos System. Subjects who participate in the study could be lost to treatment or follow ups, including as a result of the COVID-19 pandemic or other medical conditions, resulting in the need to replace those subjects and delay the study completion. Clinical study sites may also face staffing challenges that may also limit, delay or cancel clinical studies of the Enos System. The

inability to visit clinical study sites to monitor, audit, or source data may limit or slow the closure of the clinical study. Furthermore, any adverse events during the clinical study may impact the Company's ability to continue recruitment and complete the study. Any such limitations, delays or cancellations may cause the Company to delay or fail to complete its IDE clinical studies, and such delay or failure could have a material adverse impact on the Company's business, financial condition, results of operations, or cash flows.

## INTELLECTUAL PROPERTY AND LICENSING

The Company's patent portfolio has expanded from 12 issued patents at December 31, 2016, to 100 issued patents and 96 patent applications as of September 30, 2021. The Company anticipates further expanding its patent portfolio by filing additional patent applications as it progresses in the development of robotic surgical technologies and, potentially, by licensing suitable technologies.

Pursuant to the License Agreement (see "*Significant Transactions - Development Agreement & License Agreement with Medtronic*"), the Company exclusively licensed to Medtronic a portion of its portfolio related to certain aspects of instruments and cameras, while retaining the world-wide rights to commercialize the licensed technologies for the Company's own business in single access robotic assisted surgery. Furthermore, pursuant to the Development Agreement with Medtronic, the Company is developing certain robotic assisted surgery technologies, that if completed, will be exclusively licensed by Medtronic for license payments of up to \$31 million, of which \$20 million has already been received by the Company in respect of the completion of Medtronic Milestone 1 and 3, and a further \$11 million will be eligible for receipt upon completion of Medtronic Milestone 4. The Company will retain the world-wide rights to commercialize any developed technology in its own business (see "*Significant Transactions - Development Agreement & License Agreement with Medtronic*").

### IP Exclusivity and Independence

Under each of the Medtronic Agreements, while Titan has granted an exclusive license to Medtronic, Titan retains world-wide ownership rights to independently commercialize the licensed technologies in single access robotic assisted surgery, including with the Enos System and enhancements thereof. Under each of the Medtronic Agreements Titan may assign its intellectual property rights thereunder in connection with the sale of all or substantially all of the assets of Titan or in connection with a "change of control" (as such term is defined therein).

## RESULTS OF OPERATIONS

	Three Months Ended		Nine Months Ended	
	September 30		September 30,	
	2021	2020	2021	2020
	\$	\$	\$	\$
Revenue	-	-	10,093	10,000
Expenses				
Research and development	10,586	2,266	27,150	2,434
General and administrative	3,375	2,219	10,442	6,277
Depreciation and amortization	168	39	403	89
	14,129	4,524	37,995	8,880
Net (loss) income from operations	(14,129)	(4,524)	(27,902)	1,200
Finance income	(20)	(11)	(53)	(18)
(Gain) loss on fair value of warrant derivative	(5,554)	(2,872)	(3,560)	4,794
Warrant derivative liability issue cost	-	-	-	1,816
Gain on settlement	-	-	-	(1,840)
	(5,574)	(2,883)	(3,613)	4,752
Net and comprehensive loss	(8,555)	(1,641)	(24,289)	(3,552)
Basic and diluted loss per share	(0.08)	(0.02)	(0.23)	(0.06)

### Revenue

Revenue was \$nil and \$10.1 million for the three and nine months ended September 30, 2021, respectively compared to \$nil and \$10.0 million for the three and nine months ended September 30, 2020. Revenue is entirely related to license payments earned from Medtronic. The Company earns license revenue from achieving defined milestones in the Development Agreement. To date the Company has earned \$30 million of the maximum amount of \$41 million that could be payable by Medtronic under the Development Agreement and the License Agreement if all of the Medtronic Milestones are completed. The Company's entitlement to receive the balance of up to \$11 million pursuant to the Development Agreement is conditional upon the completion of Medtronic Milestone 4 set forth in the Development Agreement. There is no assurance that the Company will receive further payments from Medtronic pursuant to the Development Agreement. See "*Significant Transactions - Development Agreement & License Agreement with Medtronic*".

### Research and Development

R&D expenses were \$10.6 million for the three months ended September 30, 2021 compared to \$2.3 million for the three months ended September 30, 2020. R&D expenses were \$27.2 million for the nine months ended September 30, 2021 compared to \$2.4 million for the nine months ended June 30, 2020.

R&D expenses are related to the development of the Enos System and the development work required to achieve the milestones under the Development Agreement with Medtronic. The Company continues to establish its team in Chapel Hill that has grown from 5 employees at September 30, 2020 to over 35 employees at September 30, 2021, comprised of engineers, quality and regulatory staff focused on the development of the Enos System. In the comparative period, following execution of the Medtronic Agreements in June 2020, the Company made the strategic decision to move a significant portion of its R&D in-house at its new R&D center in

Chapel Hill, North Carolina to advance both the development of the Enos System and complete the development work required to achieve the Medtronic Milestones. See “*Significant Transactions - Development Agreement & License Agreement with Medtronic*”.

### General and Administrative

	Three Months Ended		Nine Months Ended	
	September 30		September 30,	
	2021	2020	2021	2020
	\$	\$	\$	\$
General and administrative expense	3,375	2,219	10,442	6,277
Less:				
Stock-based compensation expense	1,301	286	3,252	721
Severance provision	-	-	171	-
Adjusted general and administrative expense	2,074	1,933	7,019	5,556

G&A expenses were \$3.4 million for the three months ended September 30, 2021 compared to \$2.2 million for the three months ended September 30, 2020. The increase in G&A expenses in the quarter is primarily related to an increase in stock-based compensation of \$1.0 million. Adjusted G&A expenses were \$2.1 million for the three months ended September 30, 2021 compared to \$1.9 million for the three months ended September 30, 2020.

G&A expenses were \$10.4 million for the nine months ended September 30, 2021 compared to \$6.3 million for the nine months ended September 30, 2020. The increase in G&A expenses is related to an increase in the compensation costs noted above, as well as professional fees related to market research, an increase in stock-based compensation of \$2.5 million and \$0.2 million in severance costs. Adjusted G&A expenses were \$7.0 million for the nine months ended September 30, 2021 compared to \$5.6 million for the nine months ended September 30, 2020.

### Depreciation and Amortization

Depreciation and amortization expenses consists of depreciation of right of use (“**ROU**”) assets, property plant and equipment and amortization of patent rights.

Depreciation and amortization expenses were \$168,000 and \$403,000 for the three and nine months ended September 30, 2021 compared to \$39,000 and \$89,000 for the three and nine month ended September 30, 2020. The increase in expense was due to expansion of leased premises at its R&D facility in Chapel Hill, equipment purchased to support R&D and manufacturing, and amortization of the Company’s patents.

### Net (Loss) Income from Operations

Net loss from operations was \$14.1 million and \$27.9 million for the three and nine months ended September 30, 2021 compared to a net loss from operations of \$4.5 million and net income from operations of \$1.2 million for the three and nine months ended September 30, 2020.

The increase in net loss from operations in the quarter is primarily related to R&D costs to advance the development of the Enos System and the costs incurred related to the Medtronic Development Agreement and an increase in stock based compensation. In the comparative period, the Company started to incur R&D expenses related to the strategic decision to move a significant portion of its R&D in-house at its new R&D center in Chapel Hill, North Carolina to advance both

the development of the Enos System and complete the development work required to achieve the Medtronic Milestones.

For the nine months ended September 30, 2021, the increase in net loss is related to R&D costs to advance the development of the Enos System and the costs incurred related to the Medtronic Development Agreement and an increase in G&A expenses including stock based compensation, partially offset by the revenue from the Medtronic Development Agreement. In the comparative period, net income from operations was related to \$10 million in license revenue from the License Agreement with Medtronic, partially offset by G&A expenses and limited R&D expenses as the Company temporarily suspended R&D activities in the first half of 2020.

#### Finance Income

Finance income was \$20,000 and \$53,000 for the three and nine months ended September 30, 2021 compared to \$11,000 and \$18,000 for the three and nine months ended September 30, 2020. The increase is related to interest income earned on the Company's cash balances that were significantly higher in the current period versus the comparative period.

#### (Gain) Loss on Fair Value of Warrant Derivative

For the three months ended September 30, 2021, the gain on fair value of warrant derivative was \$5.6 million compared to \$2.9 million for the three months ended September 30, 2020. For the nine months ended September 30, 2021, the gain on fair value of warrant derivative was \$3.6 million compared to a loss of \$4.8 million for the nine months ended September 30, 2020.

The warrant derivative is marked to market at each reporting period and the gain or loss represents the change in valuation of the warrant derivative liability and can fluctuate significantly based on the market price of the Company's Common Shares.

#### Warrant Derivative Liability Issue Cost

Warrant derivative liability issue cost was \$nil for both the three and nine months ended September 30, 2021 compared to \$nil and \$1.8 million for the three and nine months ended September 30, 2020. The warrant derivative liability issue cost is related to the proportional amount of issuance costs associated with the purchase warrants pursuant to the June 2020 equity offering.

#### Gain on Settlement

Gain on settlement was \$nil for both the three and nine months ended September 30, 2021 compared to \$nil and \$1.8 million for the three and nine months ended September 30, 2020. In the second quarter of 2020, the Company settled a legal claim with a supplier for a payment to the supplier of \$1.1 million and in exchange the supplier returned certain personal property and related electronic data to the Company.

#### Net and Comprehensive Loss

Net and comprehensive loss was \$8.6 million for the three months ended September 30, 2021 compared to a net and comprehensive loss of \$1.6 million for the three months ended September 30, 2020. The increase in net loss in the quarter versus the comparative period was due to a \$9.6 million increase in loss from operations related to the development of the Enos System and an

increase in stock based compensation, partially offset by the \$2.7 million difference in the fair value of the warrant derivative.

Net and comprehensive loss was \$24.3 million for the nine months ended September 30, 2021 compared to a net and comprehensive loss of \$3.6 million for the nine months ended September 30, 2020. The increase in net and comprehensive loss was related to an increase in loss from operations primarily related to the development of the Enos System and an increase in G&A expenses, partially offset by the \$8.4 million difference in the fair value of the warrant derivative.

## LIQUIDITY AND CAPITAL RESOURCES

	Three Months ended September 30		Nine Months ended September 30	
	2021	2020	2021	2020
	\$	\$	\$	\$
Cash used in operating activities	(10,274)	(4,580)	(24,322)	(841)
Cash provided by financing activities	212	717	44,131	24,956
Cash used in investing activities	(266)	(152)	(601)	(254)
Net change in cash during the period	(10,328)	(4,015)	19,208	23,861
Cash, beginning of period	55,005	28,690	25,469	814
<b>Cash, end of period</b>	<b>44,677</b>	<b>24,675</b>	<b>44,677</b>	<b>24,675</b>

The Company had cash of \$44.7 million at September 30, 2021 as compared to \$24.7 million at December 31, 2020, representing an increase of \$19.2 million.

### Operating Activities

Cash used in operating activities was \$10.3 million and \$24.3 million for the three and nine months ended September 30, 2021 compared to cash used in operating activities of \$4.6 million and \$0.8 million for the three and nine months ended September 30, 2020.

Cash used in operating activities during the current three and nine month periods was primarily related to the costs associated with the development of the Enos System and the development work under the Development Agreement with Medtronic.

In the comparative period, cash used in operating activities was significantly lower as the Company temporarily suspended R&D activities in the first half of 2020 and then following execution of the Medtronic Agreements in June 2020, made the strategic decision to move a significant portion of its R&D in-house at its new R&D center in Chapel Hill, North Carolina to advance both the development of the Enos System and complete the development work required to achieve the Medtronic Milestones. See “*Significant Transactions - Development Agreement & License Agreement with Medtronic*”.

### Financing Activities

Cash provided by financing activities was \$0.2 million and \$44.1 million for the three and nine months ended September 30, 2021 compared to cash provided by financing activities of \$0.7 million and \$25.0 million for the three and nine months ended September 30, 2020.

During the three months ended September 30, 2021, the Company raised \$0.3 million from the issuance of Common Shares under the common share purchase agreement with Aspire (see “*Significant Transactions – Aspire Common Share Purchase Agreement*”). In the comparative period, the Company raised \$0.7 million from the issuance of equity.

During the nine months ended September 30, 2021, the Company raised \$31.3 million from the issuance of Common Shares and warrants in two separate financings (see “*Significant Transactions – February 2021 Equity Offering and January 2021 Equity Offering*”). In addition, the Company received proceeds of \$10.0 million related to the exercise of warrants and \$2.5 million from the issuance of Common Shares to Aspire. In the comparative period, the Company raised \$22.7 million from three separate financings (see “*Significant Transactions – June 2020 Financing, May 2020 Financing and March 2020 Financing*”) and received a \$1.5 million note from Medtronic (see “*Significant Transactions – Senior Secure Loan from Medtronic*”).

### Investing Activities

Cash used in investing activities was \$266,000 and \$601,000 for the three and nine months ended September 30, 2021 compared to \$151,000 and \$254,000 for the three and nine months ended September 30, 2020. Cash used in investing activities relates to the purchase of equipment for the development of the Enos System and patent costs.

### Working Capital

The Company defines working capital as current assets less current liabilities. Working capital was \$22.8 million at September 30, 2021. Working capital includes the non-cash warrant derivative liability of \$17.0 million, excluding the impact of the non-cash warrant derivative liability, working capital would have been \$39.8 million. The Company anticipates that its working capital and the \$11 million milestone from the Medtronic Development Agreement will be sufficient to continue to fund the development of its Enos System and operational expenses through 2022, including any costs pursuant to the development program pursuant to the Medtronic Development Agreement.

However, unexpected increases in costs and expenses due to operational decisions made by the Company and/or factors beyond the Company’s control, such as COVID-19 or any variants, could cause a material impact on working capital resources of the Company.

## SELECTED QUARTERLY INFORMATION

The following is selected financial data for each of the eight most recently completed quarters, derived from the Company’s financial statements, and calculated in accordance with IFRS. Net and comprehensive (loss) / income figures include the non-cash effects of adjustments in the valuation of outstanding warrant liability.

	Revenue	Net and comprehensive (loss) income	Basic and diluted (loss) earnings per share
	\$	\$	\$
September 30, 2021	-	(8,555)	(0.08)
June 30, 2021	10,043	(940)	(0.01)
March 31, 2021	50	(14,794)	(0.15)
December 31, 2020	10,000	(20,633)	(0.25)
September 30, 2020	-	(1,641)	(0.02)
June 30, 2020	10,000	(1,143)	(0.02)
March 31, 2020	-	(768)	(0.02)
December 31, 2019	-	2,413	0.07

Significant changes in key financial data from the three and nine months ended September 30, 2020, through the three and nine months ended September 30, 2021 reflect (i) the revenue recognition of the payment under the Medtronic License Agreement, the resumption of product development following receipt of license fees earned pursuant to the Medtronic License Agreement and Development Agreement, as well as equity capital raises in the capital markets, all since the first quarter of 2020, (ii) the Company established in-house R&D capabilities in Q3 2020 that increased staffing costs, and (iii) the ongoing non-cash impact associated with the requirement to revalue the Company's warrant derivative liability at fair value, with subsequent changes recorded through net and comprehensive loss for the period.

Historically, operating results have fluctuated on a quarterly basis and the Company expects that quarterly results will continue to fluctuate in the future. Operating results for interim periods should not be relied upon as an indication of the results to be expected or achieved in any future period or any fiscal year as a whole. Risk factors affecting revenue and results are identified in this MD&A.

## CONTRACTUAL OBLIGATIONS

Contractual obligations relating to accounts payable and accrued liabilities, long-term debt, and lease liabilities and purchase order commitments as at September 30, 2021, are as follows:

	Total	Less than 1 year	2 – 3 years	4 – 5 years	Greater than 5 years
	\$	\$	\$	\$	\$
Accounts payable and accrued liabilities	4,062	4,062	-	-	-
Lease liabilities	1,406	335	776	295	-
Notes payable <sup>1</sup>	2,134	2,134	-	-	-
Purchase order commitments <sup>2</sup>	7,282	7,282	-	-	-
<b>TOTAL</b>	<b>14,884</b>	<b>13,813</b>	<b>776</b>	<b>295</b>	<b>-</b>

Note:

- On April 28, 2020, the Company issued the Note to an affiliate of Medtronic for the Medtronic Loan and executed and delivered the Security Agreement. The Note is in the principal amount of \$1,500 plus Legal Expenses and accrued interest, presently equaling \$635. See "Significant Transactions – Senior Secured Loan from Medtronic".

- Purchase order commitments are obligations that are not reflected on the balance sheet. These are contracts with suppliers not yet fulfilled.

## OFF-BALANCE SHEET ARRANGEMENTS

As of the date of this report, the Company had no off-balance sheet arrangements.

## OUTSTANDING COMMON SHARE DATA

The following table summarizes the outstanding share capital as of November 10, 2021:

Type of Securities	Number of Common Shares issued or issuable upon conversion
Common Shares <sup>1, 2</sup>	111,127,690
Stock options <sup>3</sup>	5,783,290
Restricted share units <sup>4</sup>	2,253,040
Derivative warrant units	18,955,281
Equity warrants <sup>5, 6</sup>	9,912,633

### Notes:

- The Company has entered into an agreement with a consultant under which the Company has certain contractual obligations to grant up to 100,000 restricted Common Shares based on the consultant's achievement of multiple pre-determined performance criteria. To date, the performance criteria have not been achieved and no restricted Common Shares have been granted to the consultant. The agreement expires on May 13, 2022.
- The Company has entered into an agreement with a consultant under which the Company has certain contractual obligations to grant up to 125,000 restricted Common Shares based on the consultant's achievement of multiple pre-determined performance criteria. Subsequent to the quarter, the consultant achieved certain performance criteria and earned 75,000 restricted Common shares to be issued in the fourth quarter. The other performance criteria have not been achieved. The agreement expires on September 21, 2022 unless terminated earlier per the provisions of the agreement.
- The Company has outstanding stock options enabling certain employees, directors, officers and consultants to purchase Common Shares. On March 3, 2021, the Company issued 1,801,262 stock options with an exercise price of \$2.21. On June 10, 2021, the Company issued 821,124 stock options with an exercise price of \$1.87. On August 20, 2021, the Company issued 693,809 stock options with an exercise price of \$1.58.
- Pursuant to the Company's Share Unit Plan, the Company granted 338,059 RSUs to certain directors and officers during the three months ended September 30, 2021 (2,253,040 RSUs were granted to certain directors and officers during the nine months ended September 30, 2021).
- Pursuant to the January 2021 offering, 3,709,677 equity warrants were issued with an exercise price of \$2.00 and exercisable until January 26, 2026 and 518,234 broker warrants with an exercise price of \$1.9375 and exercisable until January 26, 2023. See "*Significant Transactions – January 2021 Equity Offering*".
- Pursuant to the February 2021 offering, 4,792,625 equity warrants were issued with an exercise price of \$3.00 and exercisable until January 26, 2026 and 670,967 broker warrants with an exercise price of \$3.00 and exercisable until February 24, 2023. See "*Significant Transactions – February 2021 Equity Offering*".

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

A description of the Company's significant accounting policies is included in note 2 of the Company's audited consolidated financial statements for the year ended December 31, 2020 and are unchanged as of the date of this MD&A.

The preparation of the Consolidated Financial Statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the Consolidated Financial Statements and the reported amounts of

revenue and expenses during the reporting periods. Management has identified accounting estimates that it believes are most critical to understanding the Consolidated Financial Statements and those that require the application of management's most subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. The Company's actual results could differ from these estimates and such differences could be material.

Financial statement items subject to significant judgement include, (a) incremental borrowing rate used to measure lease liabilities, (b) the fair value estimate of the measurement of lease, warrant derivative liabilities and the note payable, and (c) the assessment of the Company's ability to meet its obligations as they come due. While management believes that the estimates and assumptions are reasonable, actual results may differ.

## RELATED PARTY TRANSACTIONS

During the three and nine months ended September 30, 2021 and September 30, 2020, transactions between the Company and directors, officers and other related parties were related to compensation matters in the normal course of operations and are measured at the fair value, which is the amount of consideration established and agreed to by the related parties.

## FINANCIAL INSTRUMENTS

The Company's financial instruments consist of cash, accounts payable and accrued liabilities and the warrant derivative liability. The fair value of these financial instruments approximates their carrying values, unless otherwise noted, due to the short-term maturities of these instruments, the discount rate applied or in the case of the warrant liability, due to the application of mark-to-market policy.

## INTERNAL CONTROL OVER FINANCIAL REPORTING

The Chief Executive Officer and the Chief Financial Officer of the Company (collectively the "**Certifying Officers**") are responsible for establishing and maintaining internal control over financial reporting ("**ICFR**"), as those terms are defined in National Instrument 52-109 Certification of Disclosure in Issuer's Annual and Interim Filings, and in applicable SEC rules and regulations, for the Company.

During the preparation of its financial statements in respect of the fiscal year ended December 31, 2020, the Company identified material weaknesses in its ICFR. Certain adjustments, discussed below, were made to these financial statements prior to their approval by the Company's audit committee and board of directors and prior to their filing or other public disclosure. If the Company fails to maintain effective ICFR, this may adversely affect the accuracy and reliability of its financial statements and it could impact its reputation, business and the price of the Company's Common Shares or other securities, as well as lead to a loss of investor confidence.

The Company concluded that, as of December 31, 2020, the Company's ICFR was not effective due to three identified material weaknesses. The Company experienced significant and rapid change during the 2020 fiscal year as a result of the establishment of a new R&D facility, the

augmentation of its development team, new arrangements with external development firms and the transition arising from the retirement of the Company's former Chief Financial Officer ("CFO") and the appointment of a new CFO in the fall of 2020, as well as changes in the Company's financial accounting and reporting personnel. The Company recently appointed a new CFO in July 2021. The Company's continuous risk assessment process was not effective in responding to the rapid rate of change in personnel and new business developments and the Company did not have sufficient human resources available to adequately assess risk and reinforce or strengthen controls in the requisite timeframe. Prior to presentation of its financial statements for their approval by the Company's audit committee and board of directors, the Company determined that it would adjust its consolidated annual financial statements as at and for the year ended December 31, 2020 with respect to expense recognition to correct errors in the calculation of asset and liability balances and the appropriate IFRS application and disclosure required for an amendment of a contract with an external development firm.

The Company's three identified material weaknesses at December 31, 2020 and the steps the Company has taken to remediate these weaknesses are:

	<b>Material Weakness</b>	<b>Remediation Actions</b>
1	The Company did not have sufficient accounting resources with relevant technical accounting skills to address issues relating to the assessment of IFRS treatment for complex accounting issues, specifically relating to a material amendment to a contract with an external development firm.	<p>The Company has enhanced its finance team to add more in-depth experience to support the growth and complexity of the business.</p> <p>The Company has engaged the services of third party financial experts to assist in the preparation and review of more complex financial transactions.</p>
2	The Company did not have sufficient accounting resources with relevant technical accounting skills to address and review issues relating to the valuation of warrant liabilities.	<p>The Company has enhanced its finance team to add more in-depth experience to support the growth and complexity of the business.</p> <p>The Company has engaged the services of third party financial experts to assist in the preparation and review of more complex financial transactions.</p> <p>The Company has purchased technology that will value the warrant liabilities as well as all equity compensation.</p>
3	The Company did not sufficiently design internal controls to provide an appropriate level of oversight regarding the financial recordkeeping and review of the Company's cut-off procedures as they relate to the accounts payable and valuation of supplier liabilities.	<p>The Company has enhanced its finance team to add more in-depth experience to support the growth and complexity of the business.</p> <p>The Company has engaged the services of third party financial experts to assist in the preparation and review of more complex financial transactions.</p>

	<b>Material Weakness</b>	<b>Remediation Actions</b>
		The Company has designed improved internal controls related to supplier liabilities, procurement and cut-off.

The identified internal control weaknesses were part of the annual control cycle and therefore management will only be able to evaluate these controls as part of the annual reporting process at December 31, 2021. Management believes it has taken the necessary steps to remediate these control weaknesses to ensure there are sufficient controls in place to ensure the reliability of the interim financial statements. However, given management’s inability to evaluate the effect of remediation efforts until the next annual reporting process, management is unable to conclude that ICFR were effective as of September 30, 2021.

ICFR is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the annual financial statements for external reporting purposes in line with IFRS. Management is responsible for establishing and maintaining adequate internal controls over financial reporting appropriate to the nature and size of the Company. However, any system of internal control over financial reporting has inherent limitations and can only provide reasonable assurance with respect to annual financial statement preparation and presentation.

**RISK FACTORS**

For a detailed description of risk factors associated with the Company, refer to the “Risk Factors” section of the AIF, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and filed as an exhibit to the Form 40-F, available on EDGAR at [www.sec.gov](http://www.sec.gov).

An investment in the Company’s securities is speculative and involves a high degree of risk due to the nature of the Company’s business. It is recommended that investors consult with their own professional advisors before investing in the Company’s securities.