

November 11, 2021

TITAN MEDICAL

Titan Medical Reports Third Quarter 2021 Financial Results

Expanded Surgeon Advisory Board

Completed GLP Studies

Enos System Commercial Launch Timeline Update

TORONTO--(BUSINESS WIRE)-- Titan Medical Inc. (Nasdaq: TMDI; TSX: TMD), a medical technology company focused on the development and commercialization of its innovative surgical technologies for robotic-assisted surgery that requires a single patient access point, today announced financial results for the three and nine months ended September 30, 2021.

During the third quarter of 2021 and in recent weeks, Titan made significant advancements including commencing the transfer of the design documentation dossier for the Enos™ robotic single access surgical system to an OEM manufacturer to support builds of the Enos™ system workstation and patient cart for use in an Investigational Device Exemption ("IDE") human clinical study. The company also demonstrated system functionality in its preclinical good laboratory practice ("GLP") studies and is awaiting the final pathology results. Additionally, and in support of an IDE study, Titan further expanded its development center in Chapel Hill, North Carolina, establishing in-house manufacturing capability for instruments and cameras.

The company continues its discussions with the U.S. Food and Drug Administration ("FDA") regarding a process for regulatory clearance, which provided more clarity on additional information that will be required to complete an IDE application. Using the Q-Submission Program, ongoing dialogue with the FDA clarifies requirements and has indicated a De Novo pathway to marketing authorization for the Enos system. 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 are required prior to an IDE submission. The company plans to file the IDE application 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. Following IDE approval, Titan expects that the IDE clinical study will proceed and be completed in time for submittal of a De Novo application in 2024. Commercial launch of the Enos system will begin upon receipt of marketing authorization from the FDA, currently forecasted in early 2025.

"We are working closely with a leading OEM manufacturer on securing components, mitigating supply chain constraints and developing test plans. Titan intends to use the OEM manufacturer for manufacturing Enos system patient carts and surgeon workstations. It is exciting to observe the expansion and depth of our knowledge base as we build-out our in-house manufacturing in Chapel Hill to produce innovative and proprietary cameras and instruments. Our position as an innovation leader in single access robotic-assisted surgery continues with over 190 patents and applications, in addition to an expanding base of knowledge and know-how. We remain committed to providing an innovative single access

robotic surgery system in an underserved market that meets the needs of patients, surgeons and hospitals and will continue to work diligently to accomplish our goal,” stated David McNally, President and Chief Executive Officer of Titan.

“As we look toward year end, we are focused on the completion of the final milestone associated with the Medtronic development and license agreement. We are also working to transfer design specifications for the surgeon workstation and patient cart to enable manufacturing of systems for safety testing and human factors evaluation in mid-2022, and for use in the IDE study. Acknowledging that robotic assisted surgery systems are highly regulated and complex devices, our interactions with the FDA have been collaborative in identifying the least burdensome pathway to market. In order to drive an efficient and effective IDE approval process, we are investing more time and effort up front. Safety testing, system verification, and human factors testing are all expected in the second half of 2022. Additionally, we will continue to interact with the FDA, where possible, to clarify requirements for the IDE clinical study,” McNally added.

Recent Company Progress and Anticipated Future Activities

- *Advanced the Enos system toward IDE clinical study*
 - Core software development and performance testing completed, safety and user interface enhancements are ongoing
 - Performed preliminary biocompatibility testing of instruments, camera systems and accessories
 - Conducted preliminary electromagnetic compatibility and electromagnetic interference tests at independent lab for surgeon workstations and patient cart
 - Preliminary tests will be repeated in 2022 with manufactured IDE systems
- *Completed preclinical studies*
 - Procedures completed in accordance with FDA’s GLP on schedule
 - Pathology results on post-surgery tests expected in the first quarter of 2022
- *Strengthened intellectual property position*
 - Comprehensive robotic surgery intellectual property portfolio includes over 190 patents and applications with coverage in the United States, Europe, Canada, China, Japan, Korea and Australia
- *Expanded Surgeon Advisory Board*
 - Includes additions of industry leaders in single access and robotic-assisted surgery from multiple health systems and practices across the United States
 - Scientific and clinical luminaries to provide insight and guidance as Titan prepares for human clinical study
- *Continued buildout of Chapel Hill facilities to meet anticipated manufacturing capacity*
 - Buildout of recently increased footprint in Chapel Hill to be completed by year-end 2021 to support in-house manufacturing and lifecycle testing of proprietary cameras and instruments
- *Successfully completed ISO 13485:2016 Quality Management System Audit at Chapel Hill facility*

- *Engaged in productive ongoing discussions with the FDA*
 - IDE clinical study anticipated to include total laparoscopic hysterectomies performed on 30 to 40 patients at 3 to 4 clinical sites
 - IDE study, follow-up and data reporting expected to be completed in early 2024
 - Communications with the FDA indicate De Novo pathway for the Enos system, with the De Novo application expected to be submitted and a response received from the FDA in 2024
- *Continued current process of institutional review board site preparation for the selected clinical sites*
- *David McNally presented and participated in investor meetings at several investor conferences in September*
 - Cantor Virtual Global Healthcare Conference
 - Oppenheimer Virtual Fall Healthcare Life Sciences & MedTech Summit
 - H.C. Wainwright 23rd Annual Global Investment Conference
- *David McNally and Titan Medical featured in interview with Dr. Moira Gunn on National Public Radio's Tech Nation on November 4th*
 - Podcast available at <https://titanmedicalinc.com/media/>

Financial Highlights

As of September 30, 2021, Titan had cash and cash equivalents of \$44.7 million, compared to \$25.5 million at December 31, 2020 and \$55.0 million at June 30, 2021.

Research and development ("R&D") expenses increased to \$10.6 million in the quarter compared to \$2.3 million in the third quarter of 2020. R&D is focused on the development of the Enos system and development activities under the development and license agreement with Medtronic. In the comparative period, the company initiated the establishment of in-house development capabilities in Chapel Hill, North Carolina. Prior to establishing in-house development, R&D activities was temporarily suspended. For the nine-months ended September 30, 2021, R&D expenses were \$27.2 million compared to \$2.4 million in the comparative period.

General and administrative ("G&A") expenses were \$3.4 million in the quarter compared to \$2.2 million in the comparative period. The company adjusts G&A for non-cash and one-time items such as stock-based compensation ("SBC") and severance. Adjusted G&A was \$2.1 million for the quarter compared to \$1.9 million in the three-month period ending September 30, 2020. For the nine-months ended September 30, 2021, Adjusted G&A expenses were \$7.0 million compared to \$5.6 million in the comparative period. The increase is primarily related to the expansion of the leadership team to support the development of the Enos system, advancement of the company's strategic initiatives, marketing and investor outreach.

The company's interim financial statements and MD&A are available at www.sedar.com and/or at www.sec.gov.

Investor Audio Webcast Information

Titan Medical will host an investor audio webcast at 8:30 a.m. ET today (November 11, 2021) to discuss the company's financial results for the third quarter ended September 30, 2021, and recent business highlights. The webcast can be accessed via the Investor Relations section of the company's website www.titanmedicalinc.com.

Non-IFRS Measures

The company discloses non-IFRS measures (such as adjusted G&A) 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 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 to exclude SBC expense and severance costs. Management believes adjusted G&A are useful supplemental measures 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.

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
	\$	\$	\$	\$
G&A	3,375	2,219	10,442	6,277
Stock-based compensation	(1,301)	(286)	(3,252)	(721)
Severance provision	-	-	(171)	-
Adjusted G&A	2,074	1,933	7,019	5,556

About Titan Medical

Titan Medical Inc. (Nasdaq: TMDI; TSX: TMD), a medical technology company headquartered in Toronto, Ontario and with R&D facilities in Chapel Hill, North Carolina, is focused on enhancing robotic assisted surgery using innovative technology through a single access point. The Enos™ robotic single access surgical system is being developed with an ergonomic focus to provide a surgical experience that imitates real-life movements that surgeons demand and includes multi-articulating instruments designed to allow surgeons an increased range of motion in a confined space, with dexterity and the ability to exert the forces necessary to complete common surgical tasks. With the Enos system, Titan intends to initially pursue gynecologic surgical indications.

Certain aspects of Titan's robotic assisted surgical technologies and related intellectual property have been licensed to Medtronic plc, while retaining world-wide rights to commercialize the technologies for use with the Enos system.

Enos™ is a trademark of Titan Medical Inc.

For more information, visit www.titanmedicalinc.com.

Forward-Looking Statements

This news release contains “forward-looking statements” within the meaning of applicable Canadian and U.S. securities laws, which reflect the current expectations of management of the company’s future growth, results of operations, performance, and business prospects and opportunities. Forward-looking statements are frequently, but not always, identified by words such as “may”, “would”, “could”, “will”, “anticipate”, “believe”, “plan”, “expect”, “intend”, “estimate”, “potential for” and similar expressions, although these words may not be present in all forward-looking statements. Forward-looking statements that appear in this release may include, without limitation, references to: the company’s focus on the development and commercialization of its innovative surgical technologies for robotic single access surgery; the company’s expectation for receiving pathology results from the preclinical studies; the company’s plans and estimation of completing product and software development, testing and verification of the Enos system; the company’s planned communications with the FDA and plans with respect to regulatory submissions, including for an IDE and De Novo application; the company’s plans for manufacturing including in-house expansion and transferring of the Enos system to manufacturing; the company’s plans for clinical studies; the company’s expectations with respect to timing for the commercial launch of the Enos system; the company’s expectations to use the OEM manufacturer for manufacturing Enos system patient carts and surgeon workstations; the company’s work under the development and license agreement with Medtronic and the anticipated completion of the final milestone under the agreement; the company’s vision of providing an innovative single access robotic surgery system in an underserved market that meets the needs of patients, surgeons and hospitals; the company’s intention to host an upcoming investor audio webcast; the company’s focus on enhancing robotic assisted surgery using innovative technology through a single access point; the Enos robotic single access surgical system being developed with an ergonomic focus to provide a surgical experience that imitates real-life movements that surgeons demand; and that Titan intends to initially pursue gynecologic surgical indications. These statements reflect management’s current beliefs and are based on information currently available to management. Forward-looking statements involve significant risks, uncertainties, and assumptions. Many factors could cause the company’s actual results, performance, or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements, including, without limitation, those listed in the “Risk Factors” section of the company’s Annual Information Form and Form 40-F for the fiscal year ended December 31, 2020 (which may be viewed at www.sedar.com and/or at www.sec.gov). Should one or more of these risks or uncertainties materialize, or should assumptions underlying the forward-looking statements prove incorrect, actual results, performance, or achievements may vary materially from those expressed or implied by the forward-looking statements contained in this news release. These factors should be considered carefully, and prospective investors should not place undue reliance on the forward-looking statements. Although the forward-looking statements contained in the news release are based upon what management currently believes to be reasonable assumptions, the company cannot assure prospective investors that actual results, performance or achievements will be consistent with these forward-looking statements. Except as required by law, the company expressly disclaims any

intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

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