

# Titan Medical Reports Operating and Financial Results for the Fourth Quarter and Year End 2021

*Completed Final Milestone with Medtronic  
Selected Benchmark to Manufacture Enos System  
Expanded Patent Portfolio to More Than 200*

TORONTO--(BUSINESS WIRE)-- Titan Medical Inc. (Nasdaq: TMDI; TSX: TMD), a medical device company focused on the development and commercialization of innovative surgical technologies for single access robotic-assisted surgery (RAS), today announced financial results for the three and twelve months ended December 31, 2021.

## Key Accomplishments and Recent Activities

- *Received payment and retired senior secured loan from Medtronic after completion of final milestone under development agreement*
  - Net payment of \$8.3 million received
  - Retired senior secured loan of \$2.3 million
- *Selected Benchmark to manufacture Enos system surgeon workstation and patient cart*
  - Manufactured units will be integrated with proprietary cameras and multi-articulating instruments to be manufactured at Titan's Chapel Hill facility
- *Expanded patent portfolio to more than 200 patents and applications*
  - Continue to evaluate options for geographical expansion and revenue generating opportunities with third parties
  - Comprehensive RAS patent portfolio includes coverage in the United States, Europe, Canada, China, Japan, Korea and Australia
- *Completed buildout of Chapel Hill facilities*
  - Increased footprint to serve as a controlled manufacturing space. Procurement of parts for assembly of cameras and instruments underway, as well as processes for lifecycle testing
- *Announced CEO transition*
  - Paul Cataford named as Interim President and CEO. The company has commenced a process to identify a permanent CEO using a top tier recruiting firm
- *Attended Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) annual meeting, March 16-18, 2022*
  - Deepak Basra, VP Strategy & Business Development and Chris Seibert, VP Upstream Marketing attended SAGES and met with surgeons to discuss innovations in the development of the Enos system, and assessed the potential

for the downstream integration of advanced software, including artificial intelligence and machine learning, to further enhance the patient experience

- *Paul Cataford presented and participated in the H.C. Wainwright & Co. BioConnect 2022 Conference on January 10, 2022 and in Oppenheimer's 32<sup>nd</sup> Annual Investor Conference on March 15, 2022*

The company remains on track with activities to support a De Novo classification request with the U.S. Food and Drug Administration (FDA) in 2024. Utilizing the Q-Submission Program, the company has engaged in ongoing dialogue with the FDA to clarify requirements in an effort to mitigate against risks to the development plan and timeline. 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, the company expects to start the IDE human clinical study in the second half of 2023. Upon completion, the company plans to submit a De Novo application in 2024. Commercial launch of the Enos system will begin upon receipt of marketing authorization from the FDA, anticipated in early 2025.

“Our focus and commitment are on executing against our IDE submission milestone. Design transfer to our capital equipment contract manufacturing partner continues and we are currently on track to begin system verification and validation testing later this year. We have completed the build-out of our in-house manufacturing facility in Chapel Hill to assemble our proprietary RAS cameras and instruments, that will be used in clinical trials,” stated Paul Cataford, Interim President and CEO of Titan. “Our team’s ability to execute is key as we deliver on our mission to bring the innovative Enos system to market to benefit patients, while addressing feedback from surgeons and improving hospital economics. Our interactions with the FDA continue to be collaborative as we finalize our IDE submission package and work on requirements for our clinical trials. With a regulatory authorization process established and the team properly resourced, we are excited about our progress and the opportunity that we have to bring to market an advanced surgical experience for patients and surgeons,” added Mr. Cataford.

### **Financial Highlights**

As of December 31, 2021, Titan had cash and cash equivalents of \$32.3 million, compared to \$25.5 million at December 31, 2020.

For the year ended December 31, 2021, research and development (R&D) expenses were \$37.9 million compared to \$7.9 million in the comparative period. R&D expenses were related to the development of the Enos system and development activities under the development and license agreement with Medtronic. Comparatively, in the first half of 2020, the company temporarily suspended R&D activities and then, following execution of the Medtronic agreements in June, initiated the establishment of in-house development capabilities in Chapel Hill, North Carolina.

For the three months ended December 31, 2021, R&D expenses increased to \$10.8 million compared to \$5.5 million for the for the three months ended December 31, 2020. In the quarter, R&D expenses related to the development of the Enos System and the development work required to achieve the final milestone under the Development Agreement with Medtronic. In the comparative period, the R&D expenses related to the establishing a new facility in Chapel Hill, North Carolina to focus on the development of the Enos System and development work required to complete the milestone under the Development Agreement with Medtronic.

General and administrative (G&A) expenses were \$12.4 million for the year ended December 31, 2021 compared to \$7.6 million in the comparative period. The increase in G&A expenses in 2021 compared to 2020 is related to an increase in stock-based compensation of \$2.6 million, \$0.7 million in severance costs, expansion of the senior leadership team to support the development of the Enos system and professional fees related to market research. Adjusting for non-cash stock-based compensation expenses and one-time severance expenses, G&A expenses for 2021 were \$8.1 million compared to \$6.5 million in 2020, primarily due to expansion of the leadership team to support the development of the Enos system.

G&A expenses increased to \$2.0 million for the three months ended December 31, 2021 compared to \$1.4 million for the three months ended December 31, 2020. The increase in G&A expenses is related to \$0.5 million in severance costs and an increase in stock-based compensation.

With respect to the Nasdaq notification regarding minimum bid price deficiency received on December 30, 2021, the company is evaluating all options to regain compliance with Nasdaq Rule 5550(a)(2) prior to the June 28, 2022 deadline.

The company's audited annual financial statements and MD&A are available at [www.sedar.com](http://www.sedar.com) and/or at [www.sec.gov](http://www.sec.gov).

### **Investor Audio Webcast Information**

Titan Medical will host an investor audio webcast at 8:30 a.m. ET today (March 24, 2022) to discuss the company's financial results for the three and twelve months ended December 31, 2021, and recent business highlights. The webcast can be accessed via the Investor Relations section of the company's website [www.titanmedicalinc.com](http://www.titanmedicalinc.com).

### **About Titan Medical**

Titan Medical Inc. (Nasdaq: TMDI; TSX: TMD), a medical device company headquartered in Toronto, Ontario and with operations 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.

Enos™ is a trademark of Titan Medical Inc.

For more information, visit [www.titanmedicalinc.com](http://www.titanmedicalinc.com) and follow [@TitanMedical](https://twitter.com/TitanMedical) on Twitter and [LinkedIn](https://www.linkedin.com/company/titan-medical).

## 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 single access robotic-assisted surgery; the company’s plans to manufacture and integrate proprietary cameras and multi-articulating instruments with manufactured Enos system units; the company’s plans to evaluate options for geographical expansion and revenue generating opportunities with third parties with respect to its patent portfolio; the company’s plans for manufacturing at its Chapel Hill facilities; the Company’s plans to resolve the Nasdaq minimum bid price deficiency; the process to identify a permanent CEO; the downstream integration of advanced software, including artificial intelligence and machine learning, with the Enos system; the company’s activities to support a De Novo classification request and its discussions with the FDA, including its expectations with respect to timing for filing an IDE application, starting a IDE human clinical study, submission of a De Novo application, and the commercial launch of the Enos system; the company’s progress with its capital equipment contract manufacturing partner including with respect to system verification and validation testing; the company’s belief in bringing to market an advanced surgical experience; the company’s intention to host an upcoming investor audio webcast; 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 Report for the fiscal year ended December 31, 2021 (which may be viewed at [www.sedar.com](http://www.sedar.com) and at [www.sec.gov](http://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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