

# Titan Medical Reports Financial Results for the Second Quarter 2022

## New CEO Appointed, Manufacturing Progress Noted

TORONTO, Aug. 11, 2022 (GLOBE NEWSWIRE) -- 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 six months ended June 30, 2022.

"I am thrilled to lead Titan Medical as President and CEO and have been committed to the company's mission to improve surgical outcomes as a director of the company since September 2020. We continue to make progress on impacting the future of minimally invasive robotic surgery and the operating room ecosystem. Our technical partnerships, our relationships with surgeons and the dedication of our employees support our efforts in submitting an IDE application, designing forthcoming clinical trials and planning our commercialization strategy for the U.S. market," stated Cary G. Vance, Titan's President and CEO. "Setting Titan apart is our innovative, ergonomic platform design derived from extensive surgeon input. We believe this will set the stage for the next generation of single access RAS to advance patient care. The capability of the Enos system to operate robust, small-scale, and dexterous instruments through a minimal incision should improve patient outcomes and change the paradigm for surgeons and patients," concluded Mr. Vance.

The company plans to pursue a De Novo regulatory process for marketing authorization with the U.S. Food and Drug Administration (FDA). Utilizing the Q-Submission program, the company has engaged in ongoing dialogue with the FDA to clarify requirements in an effort to mitigate against timeline risks. The company plans to file the IDE application with the FDA mid-year 2023 for its initial target indication for benign gynecologic surgical procedures. Titan anticipates receiving a response on the IDE application from the FDA in the second half of 2023. Following IDE approval, Titan expects to proceed with and complete a clinical study in time for submission of a De Novo classification request with the FDA in 2024. Commercial launch of the Enos™ single access RAS system is scheduled to begin upon receipt of marketing authorization from the FDA, anticipated in early 2025.

## Recent Company Activities and Progress

- *Announced appointment of Cary G. Vance as President and Chief Executive Officer*
  - Previously served as CEO at Xcath Incorporated, a privately held neurovascular robotics company, and held similar positions at Optiscan Biomedical, and Myoscience. Served as President and CEO at Hansen Medical, a publicly held intravascular robotics company acquired by Auris Health in 2016, which was subsequently acquired by Johnson & Johnson in 2019. Prior to Hansen, served in various global executive leadership roles at Teleflex, Covidien (now part of Medtronic) and GE Healthcare.

- *Granted 180-day extension by Nasdaq to regain compliance with minimum bid price rule*
  - In addition to reviewing its options, the company continues to try to regain compliance with Nasdaq Rule 5550(a)(2) prior to the December 26, 2022 deadline.
- *Continued communications with the FDA via Q-submission process*
  - The company submitted an additional Q-submission with the FDA, as part of its ongoing communications plan to obtain additional guidance from the FDA.
- *Participated at the Society of Robotic Surgery Annual Meeting held June 30 - July 3, 2022*
  - Chris Seibert, Titan's VP, Upstream Marketing participated in a panel discussion featuring executives from companies recognized for promising technology platforms in robotic surgery and delivered a presentation on Titan during the plenary session.
- *Announced agreement with Nissha Medical Technologies for the manufacture of surgical consumables*
  - Manufactured single use surgical components will be used for verification and validation testing and in pre-clinical and clinical studies of Titan's Enos system.
- *Held an Annual and Special Meeting of Shareholders*
  - All nominees for election were elected as directors of the company by shareholders. The shareholders approved the renewal and amendment of the company's share unit plan and deferred share unit plan and adoption of an employee share purchase plan.
- *Bill Fahey appointed Vice President, Manufacturing and Operations*
  - Previously SVP of Engineering at Precision Spine/Spinal USA and was with Orthofix/Blackstone Medical Inc as Sr. Director of Engineering. Bringing development, manufacturing and commercialization experience to Titan, is responsible for both in-house and contract manufacturing relationships, working closely with product development and the quality and regulatory affairs teams.
- *Finalizing product design transfer to manufacturing*
  - Manufactured units of the Enos system expected later this year.
- *Presented at the H.C. Wainwright Global Investment Conference in Miami on May 25, 2022 and participated in investor meetings*

## **Financial Highlights Summary**

As of June 30, 2022, Titan had cash and cash equivalents of \$20.2 million, compared to \$32.3 million at December 31, 2021.

For the three months ended June 30, 2022, R&D expenses increased to \$9.5 million compared to \$8.4 million for the for the three months ended June 30, 2021. R&D expenses were \$19.1 million for the six months ended June 30, 2022 compared to \$17.6 million for the

six months ended June 30, 2021. R&D expenses for the three and six-month period ending June 30, 2022 were related to the development of the Enos system and an increase in labor costs as the company continues to add the required resources to its engineering, regulatory and quality teams to advance the Enos system. During this period, the company's focus was on completing product development and transferring key components on the Enos system to our external manufacturing partner. During the quarter, the Company transferred substantially all of the components to its manufacturing partner.

G&A expenses decreased to \$3.1 million for the three months ended June 30, 2022 compared to \$3.6 million for the three months ended June 30, 2021. The decrease in G&A expenses in the three-month period is related to a decrease in stock-based compensation of \$1.1 million, partially offset by an increase in severance costs and public company costs.

For the six-month period ended June 30, 2022, G&A expenses were \$5.7 million compared to \$6.2 million in the comparative period. The decrease in G&A expenses in the six-month period is primarily related to a decrease in stock-based compensation of \$1.4 million and a decrease in professional and consulting fees partially offset by an increase in severance costs, public company costs and recruitment fees related to filling open roles on the senior leadership team.

The company's interim financial statements and MD&A are available at [www.sedar.com](http://www.sedar.com) and 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 (August 11, 2022) to discuss the company's financial results for the three months ended June 30, 2022, 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/titanmedical).

### **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 surgical technologies for single access RAS; the company's plans and expectations with respect to timing for regulatory submissions, including for an IDE application and De Novo application, clinical trials and the commercialization of the Enos system; the company's dialogue with the FDA and utilization of the Q-Submission program to mitigate against timeline risks; the company's plans to regain compliance with Nasdaq Rule 5550(a)(2); the company's intention to host an upcoming investor audio webcast; the Enos system being developed with an ergonomic focus to provide a surgical experience that imitates real-life movements; and the company's intention 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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**Titan Medical Inc.****Interim Consolidated Statements of Financial Position**

(In thousands of US dollars)

	June 30, 2022	December 31, 2021
<b>Assets</b>	<b>\$</b>	<b>\$</b>
<b>CURRENT ASSETS</b>		
Cash	20,179	32,306
Receivables	-	8,280
Prepaid expenses, deposits and receivables	1,517	3,076
<b>TOTAL CURRENT ASSETS</b>	<b>21,696</b>	<b>43,662</b>
<b>NON-CURRENT ASSETS</b>		
Right-of-use assets, net	1,388	1,177
Property and equipment, net	683	464
Patent rights, net	1,991	1,919
<b>TOTAL NON-CURRENT ASSETS</b>	<b>4,062</b>	<b>3,560</b>
<b>Total assets</b>	<b>25,758</b>	<b>47,222</b>
<b>Liabilities</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued liabilities	7,821	5,616
Current portion of lease liabilities	339	346
Warrant derivative liability	263	4,930
<b>TOTAL CURRENT LIABILITIES</b>	<b>8,423</b>	<b>10,892</b>
<b>NON-CURRENT LIABILITIES</b>		
Deferred income tax liabilities	56	56
Long-term lease liabilities	1,202	981
<b>Total Liabilities</b>	<b>9,681</b>	<b>11,929</b>
<b>Shareholders' equity</b>		
Share capital	263,871	263,364
Contributed surplus-Warrant reserve	11,749	11,749
Contributed surplus	14,448	14,067
Deficit	(273,991)	(253,887)
<b>Shareholders' equity</b>	<b>16,077</b>	<b>35,293</b>
<b>Total liabilities and Shareholders' equity</b>	<b>25,758</b>	<b>47,222</b>

**Titan Medical Inc.****Interim Consolidated Statements of Net and Comprehensive Loss**

(In thousands of US dollars, except share and per share amount)

	<b>Three Months Ended June 30</b>		<b>Six Months Ended June 30</b>	
	<b>2022</b>	2021	<b>2022</b>	2021
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
Revenues	-	10,043	-	10,093
Expenses				
Research and development	<b>9,509</b>	8,361	<b>19,109</b>	17,644
General and administrative	<b>3,142</b>	3,630	<b>5,660</b>	6,207
Depreciation	-	-	-	-
Total expenses	<b>12,651</b>	11,991	<b>24,769</b>	23,851
Net loss from operations	<b>(12,651)</b>	(1,948)	<b>(24,769)</b>	(13,758)
Other Expenses (Income)				
Finance income	<b>(21)</b>	(20)	<b>(61)</b>	(33)
Finance expense	<b>17</b>	57	<b>35</b>	-
Foreign exchange (gain) loss	<b>(6)</b>	15	<b>28</b>	59
(Gain) loss on fair value of warrant	<b>(1,758)</b>	(1,060)	<b>(4,667)</b>	1,950
Total other (income) expenses	<b>(1,768)</b>	(1,008)	<b>(4,665)</b>	1,976
<b>Net and comprehensive loss</b>	<b>(10,883)</b>	(940)	<b>(20,104)</b>	(15,734)
<b>Basic and fully diluted loss per share</b>	<b>(0.10)</b>	(0.01)	<b>(0.18)</b>	(0.16)

**Titan Medical Inc.**  
**Interim Consolidated Statements of Cash Flows**  
(In thousands of US dollars)

	Six Months Ended June 30	
	2022	2021
	\$	\$
<b>OPERATING ACTIVITIES</b>		
Net loss and comprehensive loss	(20,104)	(15,734)
Items not involving current cash flows:		
Depreciation and amortization	349	235
Interest expense on lease liabilities	36	33
Share-based compensation expense	888	2,198
(Gain) loss on change in fair value of warrants	(4,667)	1,950
Accrued interest on Note payable	-	76
Warrant liability-foreign exchange adjustment	-	44
Changes in non-cash working capital balances		
Receivables	8,280	-
Prepaid expenses and deposits	1,559	(426)
Accounts payable and accrued liabilities	2,205	(2,424)
Cash used in operating activities	(11,454)	(14,048)
<b>FINANCING ACTIVITIES</b>		
Exercise of Derivative warrants	-	8,000
January 2021 Equity Offering, net of issuance costs	-	10,375
February 2021 Equity Offering, net of issuance costs	-	21,093
Exercise of Equity warrants	-	1,985
Exercise of stock options	-	14
Proceeds from issuance of common shares	-	2,380
Note payable	-	174
Repayment of lease liabilities	(205)	(102)
Cash (used in) provided by financing activities	(205)	43,919
<b>INVESTING ACTIVITIES</b>		
Purchase of property, plant and equipment	(334)	(152)
Purchase of patents	(134)	(183)
Cash used in investing activities	(468)	(335)
(Decrease) increase in cash	(12,127)	29,536
Cash, beginning of the period	32,306	25,469
<b>Cash, end of the period</b>	<b>20,179</b>	<b>55,005</b>

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**TITAN MEDICAL**

Source: Titan Medical Inc.