# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of July, 2019.

Commission File Number: 001-38524

## **Titan Medical Inc.**

(Exact Name of Registrant as Specified in Charter)

#### 170 University Avenue, Suite 1000 Toronto, Ontario M5H 3B3 Canada (Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F. Form 20-F  $\square$  Form 40-F  $\blacksquare$  Form 40-F  $\blacksquare$ 

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \_X

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

**Note:** Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

### SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TITAN MEDICAL INC. (Registrant)

Date: July 23, 2019

By: /s/ Stephen Randall Name: Stephen Randall Title: Chief Financial Officer

<u>99.1</u> <u>News Release dated July 23, 2019.</u>

## Titan Medical a Letter to the Shareholders from the President and CEO

TORONTO--(BUSINESS WIRE)--July 23, 2019--Dear Titan Medical Shareholders,

It is my pleasure to provide this mid-year update on Titan Medical's progress and to share with you our outlook for the remainder of the year.

The first half of 2019 has been very busy and productive. Our dedicated management team, consultants and product development partners have been relentlessly executing on our path toward U.S. Food and Drug Administration (FDA) 510(k) submission for our single-port robotic surgical system by year-end.

As noted in our most recent press release, in June we achieved the most significant of our second quarter milestones by commencing animal and human cadaver studies under Good Laboratory Practice (GLP) guidelines. These studies are required for our Investigational Device Exemption (IDE) submission to the FDA, and we remain focused on the timely completion of these studies and the preparation of documentation to facilitate the planned IDE submission during the third quarter.

Also last month Titan Medical had a prominent presence at the 2019 Annual Meeting of the Society of Robotic Surgery (SRS) in Orlando, Florida. In addition to participating in two panel discussions, we were delighted to present in a plenary session alongside executives from companies recognized for current and promising technology platforms in robotic surgery. It was exciting to hear opinion-leading surgeons and industry analysts at the meeting include moving to single-port surgery among their predictions for the future of robotic surgery. We strongly believe our single-port robotic surgical system will be well positioned to participate in this evolution.

Our confidence in the future is supported by surgeon experience with our system, as this year saw the publication of the first peer-reviewed manuscript on the preclinical performance and potential applications for our single-port robotic surgical system in *Surgical Endoscopy*, a highly-regarded medical journal. The multinational collaboration of experienced minimally invasive surgery specialists and robotic surgeons that contributed to the manuscript validates the broad application potential for our system.

During the first and second quarters of 2019, we announced important accomplishments to prepare for the commencement of the GLP studies. In January we unveiled our latest version of the system and the engineering team proceeded to design freeze and system verification. We are excited about our system's many unique features that were designed with surgeon input from the ground up and are intended to deliver a seamless, uncompromised world-class robotic surgery experience through a single incision. We remain committed to our vision of delivering both patient and physician satisfaction through reduced trauma and virtually scar-free surgery.

With focus on clinically inspired innovation, we have continued the global expansion of our intellectual property portfolio, which now stands at 42 issued U.S. and international patents, and 82 patent applications pending. We believe that a meaningful intellectual property portfolio can contribute significantly to supporting and defending the value of our system and our company.

We also believe that building a strong brand is vital to establishing and communicating a clear vision for our strategy, our product and our company, and that our brand must distinguish us from present and future robotic surgery competitors. During the fourth quarter of 2018, we undertook a product rebranding research initiative that featured numerous external and internal interviews and provided guidance for our new brand strategy, which we expect to launch later this year. Brand development has been ongoing throughout the first half of 2019, and our branding development partner is now producing the materials for product labeling, collateral materials and a refreshed website.

During the first half of 2019 we continued to build our team at the board and executive levels with professionals who bring substantial surgical robotics industry knowledge. In May we were proud to welcome Charles Federico as our new chairman of the board. Charles was a key contributor to creating value at Mako Surgical, which was acquired by Stryker.

Just last week we named Chad Zaring as our chief commercial officer, a new position. Chad led strategy and market adoption of Mazor Robotics' MazorX<sup>TM</sup> robotic system under a strategic marketing agreement that led to that company's acquisition by Medtronic. Regarding his move, Chad said, "I joined Titan Medical because I believe it represents an opportunity to disrupt robotic surgery by targeting a potential new market in single-port surgery aimed at delivering higher clinical value to the patient while overcoming the limitations of traditional options. In observing the GLP studies, both the vision system and multi-articulating instruments performed well as expected, and our objective is to deliver the devices through a single point of access, in order to substantially benefit the patient. Based on feedback from surgeons and administrators, there's strong interest in new options that will propel the robotic surgery market forward, and I'm excited to develop a commercial launch strategy to be executed upon receipt of regulatory approvals."

On the engineering and operational fronts, we are recruiting experienced individuals to support our senior vice president of research and development, Perry Genova, Ph.D., in managing the transition from product development to manufacturing during the months ahead. We also hired Monique Delorme, CPA, CA as corporate controller. Monique brings to Titan broad accounting and finance experience across many industries and is expected to be instrumental in supporting our cost and product margin goals, along with compliance in financial reporting. All of these additions are joining a talented, experienced and highly committed team that has demonstrated an ability to overcome obstacles to achieve our milestones.

Our accomplishments during the first half of 2019 put us on track to deliver on some of the most important regulatory milestones ahead. As previously stated, during the third quarter we completed the surgeries associated with our GLP studies and will now be focused on compiling the follow-up documentation required for our IDE submission. Once IDE approval is received, we can then submit applications to the Institutional Review Board (IRB) committees of the hospitals where the first human surgeries will be performed under the IDE prior to regulatory marketing clearance. The hand-picked surgeons in the IDE studies are highly-skilled, world-renowned thought leaders in gynecologic surgery, and each is excited about the potential for single-port robotic surgery to improve outcomes for their patients.

The timing of IDE approval by the FDA and subsequent IRB committee approvals cannot be precisely predicted. Currently, we believe it is possible that human surgeries aimed at collecting confirmatory data required for our 510(k) submission can commence and be completed during the fourth quarter of 2019. The schedule for completing patient follow-up and compiling data for the 510(k) submission in December is very tight and not completely within our control; however, our team remains committed to the goal of filing this submission and filing for CE Mark in Europe by year-end. In parallel we are developing and exercising our quality system toward ISO13485 compliance.

Looking forward, we plan to lease a facility in Chapel Hill, North Carolina during the third quarter to house our U.S. operations, including the team that will manage engineering and manufacturing, technical support, quality, customer service, training, clinical support and, ultimately, commercialization. The location is close to our product development partners and has access to the significant talent that resides in this medical technology hub. Importantly, the facility will include a dry lab to host surgeon training following product launch.

Minimizing surgical trauma, reducing post-operative pain and scarring, and hastening healing have been consistent surgical themes for many years. First, manual laparoscopic surgery performed through small incisions replaced open surgery in numerous applications. Although attempts were made by some to perform laparoscopic surgery through a single incision with manual instruments, limitations of the available devices inhibited widespread adoption. Then, multi-port robotic surgery provided improved visualization, dexterity and ergonomics that have proven to be valuable in certain applications. Along with the experts we heard from during the SRS Annual Meeting, we believe the next frontier is single-port robotic surgery, with its ability to overcome the limitations of previous manual single incision approaches, but with the proven benefits of robotic technology.

I am proud of Team Titan, which includes our employees, our expert consultants, development and manufacturing partners, and the surgeons who advise us. It is through their ongoing commitment, endless energy, guidance and teamwork that we have achieved so much. We remain grateful to you, our shareholders, who have provided the capital resources for our growing team to execute on our vision for single-port robotic surgery.

We look forward to reporting our progress during what we expect to be a very productive second half of 2019.

Sincerely,

David McNally President & CEO This letter contains "forward-looking information" and "forward-looking statements," within the meaning of applicable Canadian and United States securities laws, which relate to future events or future performance and reflect the current expectations and assumptions of management of the company's future growth, results of operations, performance and business prospects, opportunities, and illustrations and prototypes of our single-port robotic surgical system. Wherever possible, words such as "may", "would", "could", "will", "anticipate", "believe", "plan", "expect", "intend", "estimate", "project", "predict", "target", "potential", and similar expressions have been used to identify these forward-looking statements. These statements reflect management's current beliefs with respect to future events 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, achievements or technological development and implementation to be materially different from any future results, performance, achievements or technological development and implementation to be materially different from any future results, performance, achievements or technological development and implementation to be materially different from any future results, performance, achievements or technological development and implementation to be materially different from any future results, performance, achievements or technological development from respect of the fiscal year ended December 31, 2018 and other information contained in the "Risk Factors" section of the company's Annual Information Form in respect of the fiscal year ended December 31, 2018 and other information contained in the company's public filings (which may be viewed at www.sedar.com and www.sec.gov). Should one or more of these risks or uncertainties materialize, or should assumptions underlying the forward-looking statements prove incorre

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