# Titan Medical Reports 2018 Financial Results

TORONTO--(BUSINESS WIRE)-- Titan Medical Inc. (TSX:TMD) (Nasdaq:TMDI) ("Titan" or the "Company"), a medical device company focused on the design and development of a robotic surgical system for application in minimally invasive surgery ("MIS"), announces financial results for the year ended December 31, 2018.

All financial results are prepared under Canadian GAAP and are reported in U.S. dollars, unless otherwise stated. The audited financial statements and management's discussion and analysis for the year ended December 31, 2018 may be viewed on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>.

David McNally, President and CEO, said, "2018 was an exceptionally busy and productive year for Titan Medical as we achieved all milestones related to the development of our SPORT single-port robotic surgery system. I want to congratulate the Titan Medical team and our business partners for their dedication as we continue our important work toward commercialization. By our internal estimates, we believe there is an opportunity for us to access an unaddressed U.S. market that potentially may include more than \$12 billion in capital equipment revenue and more than \$3 billion in associated annual recurring revenue, including smaller hospitals and the underserved ambulatory surgery center market segment.

"During the fourth quarter we completed the system engineering confidence build for our next-generation SPORT Surgical System, including a new camera system and design enhancements to the surgeon workstation and the patient cart, the two primary components of the system. The enhancements reflect our preclinical experience with expert robotic surgeons. We ended the year gaining clarity from the U.S. Food and Drug Administration on the regulatory pathway for the SPORT system. During the second quarter, we expect to begin conducting the requisite animal studies that precede human studies. During the second half of 2019 we plan to complete the required human confirmatory studies under an Investigational Device Exemption, or IDE, in support of a 510(k) filing by the end of the year. We also expect to file for the CE mark by year-end 2019."

Mr. McNally continued, "In parallel with the development of the SPORT Surgical System in 2018, we continued our efforts toward achieving future commercial success. During the year, we filed several new U.S. and international patent applications, and received nine patent grants on various aspects of single-port robotic surgery. Surgeons presented results from the preclinical studies performed during the past two years at important medical conferences, and published a peer-reviewed manuscript with the goal of gaining awareness and support among the key opinion leaders who will be important to our success. To date, 12 experienced robotic surgeons from three continents have successfully performed 43 live animal studies and two human cadaver studies across a broad array of procedures.

"We completed two financings during the year, one where we welcomed new U.S. investors in conjunction with the cross-listing of our common stock on the Nasdag Capital Market.

During the year we effected a 1-for-30 reverse stock split in preparation for the cross-listing and U.S./Canadian financing. Additional funds will be required to see the SPORT system to commercialization, and we are currently evaluating financing alternatives while the exercise of warrants from our most recent financing continues to extend our cash runway," Mr. McNally concluded.

## **Key operational highlights for 2018 include:**

- On February 6, 2018, the Company reported the successful completion of a single-port prostatectomy procedure using the SPORT Surgical System in a preclinical setting.
- On March 29, 2018, the Company announced, in conjunction with Mimic Technologies, a market leader in robotic simulation, the collaboration and successful demonstration of a first set of simulation modules for use with Titan's SPORT Surgical System surgeon workstation.
- On April 16, 2018, the Company announced the presentation of an abstract highlighting the early physician experience with the SPORT Surgical System at the Society of American Gastrointestinal and Endoscopic Surgeons Annual Meeting.
- On June 18, 2018, David McNally presented the SPORT Surgical System in the plenary session at the Society of Robotic Surgery 2018 Annual Meeting.
- On June 20, 2018, the Company announced that Jasminder Brar, Titan's Director of Strategic Development and Intellectual Property, was recognized by Intellectual Asset Management as a global IP strategy leader.
- On June 27, 2018, the Company's common stock commenced trading on the Nasdaq Capital Market under the symbol TMDI.
- On June 28, 2018, the Company announced the appointment of medical device veteran Domenic Serafino to its board of directors.
- On August 2, 2018, the Company announced an expanded advisory role for Arnold Advincula, M.D., a world-renowned expert in robotic gynecologic surgery.
- On September 5, 2018, an abstract of a pilot study featuring the SPORT Surgical System in partial nephrectomy and heminephrectomy procedures was presented at the European Association of Urology Robotic Urology Section Annual Meeting.
- On September 18, 2018, the Company, in conjunction with Mimic Technologies, announced the successful completion of the core surgical skills simulation modules for use with the SPORT Surgical System surgeon workstation.
- On November 14, 2018, an abstract titled "Reverse Objective Structured Assessment of Technical Skills (Reverse-OSATS) as a means of measuring the capability of the Titan Medical SPORT Surgical System on core surgical principles" was presented at the American Association of Gynecologic Laparoscopists 2018 Global Congress.
- On January 3, 2019, the Company announced that it had completed the system engineering confidence build for all components of the SPORT Surgical System.
- Throughout 2018, the Company enhanced its intellectual property position with the receipt of important global patents and the continued filing of patents. It currently has 29 issued patents and 76 pending patent applications including in the U.S., Europe,

Canada and China.

### Financial highlights for 2018 include:

- Research and development expenses for 2018 were \$32,858,339, compared with \$12,900,855 in 2017.
- Net and comprehensive loss for 2018 was \$22,639,272, compared with \$33,586,984 in 2017. The 2018 net loss includes adjustment for warrant liability gain on the change in fair value of warrants of \$17,095,220.
- The Company raised gross proceeds of \$28,424,732 through two separate public offerings of common stock and warrants.
- Cash, cash equivalents and deposits with product development service providers as of December 31, 2018 were \$20,012,873, compared with \$28,668,927 as of December 31, 2017.
- As of February 8, 2019, a total of 619,606 warrants issued as part of the August 2018 offering were exercised at the conversion price of \$3.20 per warrant, for proceeds to date of \$1,982,739.

#### **Expectations for 2019**

Titan Medical anticipates the completion of verification and validation testing, followed by design freeze and the initiation of animal and cadaver studies, in support of planned regulatory filings, during the first half of 2019. It also expects to submit an IDE study application to the FDA during the first half of 2019, to perform the IDE study at multiple hospitals during the fourth quarter of 2019, and to file a 510(k) premarket notification and submit its technical file to a European Notified body for CE mark by the end of the year.

Mr. McNally reiterated, "We remain confident in our highly experienced team to meet our aggressive timeline, just as they have been doing for the past two years."

#### **Conference Call and Webcast**

Titan Medical plans to hold a conference call and webcast to discuss its plans for 2019 by the end of March. A press release will be issued prior to the call with additional information.

#### **About Titan Medical Inc.**

Titan Medical Inc. is focused on computer-assisted robotic surgical technologies for application in minimally invasive surgery. The Company is developing the SPORT Surgical System, a single-port robotic surgical system comprised of a surgeon-controlled patient cart that includes a 3D high-definition vision system and multi-articulating instruments for performing MIS procedures, and a surgeon workstation that provides an advanced ergonomic interface to the patient cart and a 3D endoscopic view inside the patient's body. Titan intends initially to pursue focused surgical indications for the SPORT Surgical System, which may include one or more of gynecologic, urologic, colorectal or general abdominal procedures.

For more information, please visit the Company's website at <a href="https://www.titanmedicalinc.com">www.titanmedicalinc.com</a>.

### **Forward-Looking Statements**

This news release contains "forward-looking statements" which reflect the current expectations of management of the Company's future growth, results of operations, performance and business prospects and opportunities. Wherever possible, words such as "may", "would", "could", "will", "anticipate", "believe", "plan", "expect", "intend", "estimate", "potential for" 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 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 dated March 31, 2018 (which may be viewed at www.sedar.com). 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.

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