Titan Medical Shareholder Letter

Dear Stockholders

2015 was a significant year of progress for Titan in which we completed the build of an initial SPORT™ robotic surgical system, including both the workstation and patient cart. We believe that SPORT, a highly versatile, single incision advanced robotic surgical system, will significantly expand the addressable market for single and multi-quadrant abdominal surgical procedures performed with a robotic platform.

In March, we made our first public unveiling and demonstration of the SPORT system to a strong turnout from the surgical community at the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) annual meeting in Boston, one of the prominent, well-attended surgical meetings in the US. Over the course of three exhibit days, more than 800 surgeons viewed the technology and attended live demonstrations of the SPORT system. The overwhelming feedback from those who saw SPORT in action was that it could enable a new era of clinically capable, operationally efficient and ROI friendly robotic surgery.

According to Wintergreen Research, the robotic surgery market is estimated to grow to $20 billion annually by 2021, which is only five years away. The addressable market for SPORT includes over 10,000 system

placement opportunities in the US which, based on our current pricing model, represents an estimated $10 billion in potential capital revenue.

In addition to the capital revenue opportunity, we estimate an additional $4 billion recurring revenue opportunity. SPORT's unique design elements with multi-articulated instruments and single arm patient cart make it well positioned as an attractive per-procedure cost system compared to current robotic platforms.

Today, it is estimated that only five percent of the general surgery market has been penetrated by robotic procedures, leaving 95 percent of the opportunity unmet. In fact, of the four million abdominal surgeries performed each year, only 650,000 are performed using robotic technologies. The currently available robotic technology does not meet the needs of the general surgery market clinically, financially or operationally.

As robotic surgery continues to gain acceptance in many surgical specialties, thousands of hospitals are expressing interest in the next generation of robotic surgical platforms that will address the financial challenges and operational inefficiencies being experienced with the current robotic platforms.

As compared to these existing robotics platforms, SPORT is well positioned on a cost-per-procedure basis when you factor in the following:

- The SPORT system will be priced at $950,000 compared to $1.8 million for existing robotic systems – representing a $950,000 savings

- When you amortize that cost over 150 cases per year, which is less than one procedure per day using 250 work days per year, the system savings compared to existing robotic systems is $809 per procedure

- We estimate the instrument cost per case for SPORT to be $1,075. By comparison, this is $760 less per case than the current market leader's instrument and accessory costs per case. In today's healthcare environment, SPORT is 'reimbursement friendly'

- Lastly, the annual service agreement for SPORT will be $95,000, which is significantly less than existing robotic service agreements and represents a savings of $566 per procedure.

- When you add these all together they add up to a total cost savings of over $2,100 per procedure when compared to today's existing robotic offerings.

As hospitals continue to focus on reimbursement and return on investment, the anticipated cost savings associated with SPORT creates a significant opportunity for Titan Medical in this large and growing market.

As we move into 2016, we continue to make significant progress. We are excited to have announced in the first quarter that we signed a manufacturing and supply agreement with a third party contract manufacturer, one that manufactures in the US and is globally renowned. Their clients include both very large medical device companies and smaller, early stage companies. In fact, they are the largest OEM for one of the largest US medical device companies. We are excited to partner with them because it will ensure the highest quality for Titan products and it validates the prospects for SPORT. In addition to providing manufacturing expertise, their design and development arm will now be contributing significantly in the final stages of development of the SPORT Surgical System, and the addition of their capabilities will help expedite and enhance its development.

Our new partner will be integral in not only completing the design and build of the two main capital components, the patient cart and the workstation, but also the testing of various aspects of SPORT including software development and validation, to which they bring substantial experience. One of the critical elements of this partnership is the initiation of the manufacturing hand-off process, which will enable a smooth transition to manufacturing product once we receive approval from the FDA.

During the first quarter, we also completed the build of the initial enhanced engineering verification units of the SPORT surgical system, which will be used in the upcoming optimization and cadaver studies. In May, we announced that we initiated usability studies for SPORT to comply with updated FDA guidelines published in April under the title “Applying Human

Factors and Usability Engineering to Medical Devices." Our current usability studies are formative evaluations we have undertaken to inform final design and involve critical task identification, cognitive walk-through testing and simulated use testing. The outcomes from these studies include identification of system use-related issues that will be addressed through further engineering to eliminate or reduce use-related hazards.

With detailed attention to these new guidelines, and to measure our progress going forward, we provided a revised development timeline and milestones for achieving our goal of submitting our 510(k) application to the FDA. The remaining milestones and timeline for submitting that application is a well-defined process during which we must not only complete the development of the technology, but also complete the testing that will provide the results that demonstrate substantial equivalence between SPORT and our predicate device.

At this time, we have worked with the FDA to agree on the predicate devices to which we must demonstrate substantial equivalence. That is very important because it provides a clear understanding of what we must demonstrate. We developed these milestones based on several considerations, including but not limited to recent events in our market segment, recent publications of guidelines from the FDA on human factors and usability engineering, and an updated, detailed analysis of the remaining work to develop our technology.

- The first milestones relate to usability and human factors testing. From the beginning of the development of SPORT, Titan has focused on the

human interface. We believe that the FDA has increased the requirements for usability and human factors testing. In February, the FDA released a new set of guidelines for usability and human factors for medical devices. We have a major focus on these new guidelines, and through these trials we will optimize any final designs affecting usability. This includes a focus not only on the ergonomics of the workstation for the surgeon, a key differentiator for SPORT, but also the usability of the system by everyone interacting with the technology. In part because of this recent release of the FDA guidelines, we have this month initiated more formal usability testing that will be ongoing for six months. The information generated by these usability studies will be critical for both finalizing various design features as well as documenting our development process to the FDA.

- Following the usability trials, we will initiate Optimization Trials. These trials will include more procedure-based trials, and in most cases, these trials will involve cadaver studies. Throughout the time of the usability and optimization trials, the device will also be undergoing bench testing and third party testing to measure compliance with both design specifications and regulatory requirements, including testing for factors affecting patient safety and usability.

- The next milestone is Design Freeze, which would follow later in the first half of 2017. At this time, we will lock in the final design of SPORT.

- The next milestone will be to Build Design Verification Units. These units must be production equivalent. This means that these units must

be equivalent to units that will be manufactured for sale in the future. They will be used to complete the test data that will demonstrate compliance with all the requirements to the FDA. In other words, the data generated from testing these units will be used for the 510(k) application and any other regulatory review, such as CE Mark audits. These units will be completed in the second half of 2017.

- The next milestone will be to Complete Design Verification and Validation. This is the testing that will be submitted to the regulatory bodies. This will be completed in second half of 2017.

- With completion of design verification and validation, we will have everything we need to Submit 510(k) Application to the FDA, which is our next milestone. We expect to complete this in the second half of 2017.

- Several other events will occur in parallel with this timeline. We expect the first Audit for CE Mark Approval to commence during design verification in first half of 2017. That audit will review our quality management system and various documents containing design and test data up to that date. The Final CE Mark Audit would be completed very soon after the completion of Design Verification in second half of 2017. This will allow the company to achieve the CE mark for the product for commercialization in the EU.

Several factors have significantly influenced the refinement of our milestones and the cost associated with achieving them. Recent events in

our market segment highlight the importance of attention to detail in preparing and supporting a 510(k) application. Additionally, the FDA has increased its attention to usability and human factors. For both of those reasons, we have increased the amount of testing and documentation that we will do in these areas. The goal of this additional work is to clearly demonstrate substantial equivalence to our predicate.

Our timeline incorporates our current and best broad-based thinking, as well as input from a variety of sources, to reflect recent developments in our industry.

While we are bringing substantial resources to the development of the SPORT technology, we remain focused on generating return to shareholders. We continue to operate on a very lean budget when compared to other robotic development programs that we're aware of. We are focused on maximizing our chances for success, and that means doing as thorough a job as we possibly can in developing the data and developing our application so that we maximize our chances to begin generating returns from the enormous opportunity that we are pursuing.

I am most grateful to our employees and shareholders for their continued support. We look forward to updating your further on our progress.

Sincerely,

John Hargrove
Chief Executive Officer and Chairman