

Microbot Medical Inc.
Form 8-K
January 04, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): January 4, 2017

MICROBOT MEDICAL INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

000-19871
(Commission

File Number)
175 Derby Street, 27/1

94-3078125
(I.R.S. Employer

Identification No.)

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Hingham, MA 02043

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (908) 938-5561

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

GENERAL NOTE

On November 28, 2016, C&RD Israel Ltd. (Merger Sub), a wholly-owned subsidiary of Microbot Medical Inc. (then known as StemCells, Inc.; the Company), completed its merger with and into Microbot Medical Ltd. (Microbot Israel), with Microbot Israel surviving as a wholly-owned subsidiary of the Company (the Merger). On November 28, 2016, in connection with the Merger, the Company changed its name from StemCells, Inc. to Microbot Medical Inc. This Current Report on Form 8-K is being filed by the Company to update and describe certain material changes to the business of the Company following and as a result of the Merger.

The financial information, including the operating and financial results and audited financial statements included in this Current Report on Form 8-K are that of Microbot Israel rather than that of our Company prior to the completion of the Merger.

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements. Forward-looking statements are projections in respect of future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as may , should , intends , expects , plans , anticipates , believes , estimates , predicts , continue or the negative of these terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks listed under the section entitled Risk Factors commencing on page 20 of this report, which may cause our or our industry s actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity or performance. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

In this Current Report, unless otherwise specified, all dollar amounts are expressed in United States dollars. Except as otherwise indicated by the context, references in this report to Company , Microbot , we, us and our are reference Microbot Medical Inc., formerly known as StemCells, Inc., including the operating and financial results of Microbot Israel. References to Microbot Israel refer to such company prior to the Merger.

Item 8.01 Other Events

DESCRIPTION OF BUSINESS

The Company

Our Company was incorporated on August 2, 1988 in the State of Delaware under the name Cellular Transplants, Inc. The original Certificate of Incorporation was restated on February 14, 1992 to change the name of the Company to Cytotherapeutics, Inc. On May 24, 2000, the Certificate of Incorporation as restated was further amended to change the name of the Company to StemCells, Inc. As of the Merger, on November 28, 2016, the Company changed its name from StemCells, Inc. to Microbot Medical Inc. Pursuant to the terms of the Merger, at the effective time of the Merger, each outstanding share of Microbot Israel capital stock was converted into the right to receive approximately 2.90 shares of our common stock, par value \$0.01 per share (the Common Stock), after giving effect to a one for nine reverse stock split, for an aggregate of 26,644,979 shares of Common Stock issued to former Microbot

Israel shareholders. In addition, all outstanding options to purchase the ordinary shares of Microbot Israel were assumed by the Company and converted into options to purchase shares of the Common Stock. On November 29, 2016, the stock of the Company began trading on the Nasdaq Capital Market under the symbol **MBOT**.

Prior to the Merger, the Company was a biopharmaceutical company that operated in one segment, the research, development, and commercialization of stem cell therapeutics and related technologies. Following the Merger, the Company is now a pre-clinical medical device company specializing in the research, design and development of next generation micro-robotics assisted medical technologies targeting the minimally invasive surgery space. The Company is primarily focused on leveraging its micro-robotic technologies with the goal of improving surgical outcomes for patients.

Microbot is currently developing its first two product candidates: the Self Cleaning Shunt, or SCS, for the treatment of hydrocephalus and Normal Pressure Hydrocephalus, or NPH; and TipCAT, a self-propelling, semi-disposable endoscope that is being developed initially for use in colonoscopy procedures. Microbot's product candidates are being designed to bring greater functionality to conventional medical devices and to reduce the known risks associated with such devices. Microbot is currently aiming to complete pre-clinical or clinical data collection for both product candidates within the next 24 months and is targeting approval or clearance for SCS by late 2018.

Microbot currently holds an intellectual property portfolio that comprises nine patent families, which include eight patents granted in the United States, eleven patents granted outside the United States, and 17 patent applications pending worldwide, with other patent applications under development, as well as an exclusive license to key components of its technology.

Industry Overview

Shunt Systems

Hydrocephalus is a medical condition in which there is an abnormal accumulation of cerebrospinal fluid, or CSF, in the brain that can cause increased intracranial pressure. It is estimated that one in every 500 babies are born with hydrocephalus, and over 1,000,000 people in the United States currently live with hydrocephalus.

Symptoms of hydrocephalus vary with age, disease progression and individual tolerance to the condition, but they can include convulsion, tunnel vision, mental disability or dementia-like symptoms and even death. Normal Pressure Hydrocephalus (NPH) is a type of hydrocephalus that usually occurs in older adults. NPH is generally treated as distinct from other types of hydrocephalus because it develops slowly over time. In NPH, the drainage of CSF is blocked gradually and the excess fluid builds up slowly. This slow accumulation means that the fluid pressure may not be as high as in other types of hydrocephalus. It is estimated that more than 700,000 Americans have NPH, but less than 20% receive an appropriate diagnosis.

Hydrocephalus is most often treated by the surgical insertion of a shunt system. The shunt system diverts the flow of CSF from the brain's ventricles (or the lumbar subarachnoid space) to another part of the body where the fluid can be more readily absorbed. Hydrocephalus shunt designs have changed little since their introduction in the 1950s. A shunt system typically consists of three parts: the distal tubing or shunt (a flexible and sturdy plastic tube), the ventricular catheter (the proximal catheter), and a valve. The end of the shunt system with the proximal catheter is placed in the ventricles (within the CSF) and the distal catheter is placed in the site of the body where the CSF can be drained. A valve is located along the shunt to maintain and regulate the rate of CSF flow. Current systems can be created from separate components or bought as complete units.

The treatment of hydrocephalus with existing shunt systems often includes complications as well. For example, approximately 50% of shunts used in the pediatric population fail within two years of placement and repeated neurosurgical operations are often required. Ventricular catheter blockage, or occlusions, is by far the most frequent event that results in shunt failure. Shunt occlusion occurs when there is a partial or complete blockage of the shunt that causes it to function intermittently or not at all. Such a shunt blockage can be caused by the accumulation of blood cells, tissue, or bacteria in any part of the shunt system. In the event of shunt occlusion, CSF begins to accumulate in the brain or lumbar region again and the symptoms of untreated hydrocephalus can reappear until a shunt replacement surgery is performed.

Although several companies are active in the field of hydrocephalus treatment and the manufacturing of shunt systems and shunt components, Microbot believes that the majority of those companies are focusing on the development of valves. The development of a smart shunt—a shunt that could provide for weaning from shunt dependency or increase personalized control through advanced control algorithms, that could provide data to the physician on patient conditions and shunt function with sensor based controls, or correct the high failure rate of existing shunt systems—is for the most part at an academic and conceptual level only. Reports of smart shunt technologies are typically focused on a subset of components with remaining factors left unspecified, such as hardware, control algorithms or power management. Microbot does not believe that a smart shunt has been developed to date. Because of the limited innovation in this area, Microbot believes an opportunity exists to provide patients suffering from hydrocephalus or NPH with a more effective instrument for treating their condition.

Endoscopic Equipment

Endoscopes are medical devices used to look inside a body cavity or organ with minimally invasive surgery. The North American flexible endoscopes market was valued at \$1.27 billion in 2013, and is expected to reach \$1.91 billion by 2018, at a CAGR of 8.5% during the period 2013 to 2018.

Colonoscopy is a procedure that allows a physician to examine the colon using an endoscope. It is a commonly performed procedure for the diagnosis and treatment of a range of conditions, including for the screening and surveillance of colorectal neoplasia, or colorectal cancer. Annually, between 15 and 20 million endoscopy procedures are conducted in the United States with reusable endoscope devices to screen various sections of a patient's gastrointestinal, or GI, tract. However, according to data from the American Cancer Society, it is estimated that over 49,000 Americans will die from colorectal cancer and 95,000 new cases of colon cancer will be diagnosed in 2016. It is the third leading cause of cancer deaths in spite of being highly preventable with early identification and removal of colorectal adenomas, or polyps. Colonoscopy with removal of colorectal polyps has been shown to be the most effective way of preventing colorectal cancer. And colonoscopy is generally considered the gold standard for the detection and treatment of adenomas. However, using current colonoscopic technology, approximately 30% of polyps are missed. In addition, the technique remains underutilized—less than 50% of eligible Americans, based on guidelines established by organizations including the American Cancer Society, United States Preventive Services Task Force, and U.S. Multi-Society Task Force on Colorectal Cancer, have undergone screening, with more than 45% of colon cancers being diagnosed at a time when the cancer has become incurable. This reluctance can be linked to patients' general discomfort associated with the colonoscopy screening procedure, due to the use of mechanical force to insert the endoscope into the colon. The procedure is widely perceived to be uncomfortable, and it also can sometimes damage or perforate the bowel wall.

Colonoscopy techniques that improve the Adenoma Detection Rate, or ADR, and reduce patient discomfort could optimize the potential of colonoscopy for the prevention of colorectal cancer. Microbot believes that it has the potential to develop a robotic endoscope product that addresses this issue of patient

discomfort, which it believes will improve patients' willingness to get this important screening test with the additional benefit of providing a new tool to health care practitioners for use in the identification and treatment of colorectal polyps.

Microbot's Product Pipeline

Self-Cleaning Shunt (SCS)

The Self-Cleaning Shunt, or SCS, device is designed to act as the ventricular catheter portion of a CSF shunt system that is used to relieve hydrocephalus and NPH. It is designed to work as an alternative to any ventricular catheter options currently on the market and to connect to all existing shunt system valves currently on the market; therefore, the successful commercialization of the SCS is not dependent on any single shunt system. Initially, Microbot expects the SCS device to be an aftermarket purchase that would be deployed to modify existing products by the end user. Microbot believes that the use of its SCS device will reduce, and potentially eliminate, shunt occlusions, and by doing so Microbot believes its SCS has the potential to become the gold-standard ventricular shunt in the treatment of Hydrocephalus and NPH.

The SCS device embeds an internal robotic cleaning mechanism in the lumen, or inside space, of the ventricular catheter which prevents cell accumulation and tissue ingrowth into the catheter. The SCS device consists of a silicone tube with a perforated titanium tip, which connects to a standard shunt valve at its distal end. The internal cleaning mechanism is embedded in the lumen of the titanium tip. Once activated, the cleaning mechanism keeps tissue from entering the catheter perforations while maintaining the CSF flow in the ventricular catheter.

The internal cleaning mechanism of the SCS device is activated by means of an induced magnetic field, which is currently designed to be externally generated by the patient through a user-friendly headset that transmits the magnetic field at a pre-determined frequency and operating sequence protocol. The magnetic field that is created by the headset is then captured by a flexible coil and circuit board that is placed just under the patient's scalp in the location where the valve is located. The circuit board assembly converts the magnetic field into the power necessary to activate the cleaning mechanism within the proximal part of the ventricular catheter.

Microbot has completed the development of an SCS prototype and is currently completing the safety testing, general proof of concept testing and performance testing for the device, which Microbot began in mid-2013. Microbot had a pre-submission meeting with the FDA in early 2014, and has been working closely with Washington University in St. Louis to develop the protocol for and to execute the necessary animal study. Microbot expects the animal study to start in the first quarter of 2017. Upon the completion of animal studies, Microbot may conduct clinical trials if they are requested by the FDA or if Microbot decides that the data from such trials would improve the marketability of the product candidate. Microbot believes that the first generation of its SCS device should receive regulatory approval or clearance from FDA by late 2018. The proposed indication for use of the SCS device would be for the treatment of hydrocephalus as a component of a shunt system when draining or shunting of CSF is indicated.

Microbot may also conduct clinical trials for the SCS in other countries where such trials are necessary for Microbot to sell its SCS device in such country's market, although it has no current plans to do so.

TipCAT

The TipCAT is a semi-disposable, flexible, self-propelled endoscope. A mechanism comprising a series of interconnected balloons at the device's tip provides the TipCAT with its forward locomotion capability. The device has the capability to self-propel within natural tubular lumens such as the colon, blood vessels, and the urinary tract. The TipCAT is designed to be fully-equipped with a contemporary endoscope, including a high-quality camera, steering capability and a standard working channel for treatments. The TipCAT thus offers functionality and visualization features equivalent to modern endoscopes, along with unique advantages associated with its physiologically adapted self-propelling mechanism, flexibility, and design.

The TipCAT consists of two parts:

A disposable self-propulsion module, which is a series of interconnected, sequentially inflatable balloons constructed on an inner tube (i.e., the working channel); and

A re-usable module isolated from contact with the tissue/body fluids, containing a camera, LED lighting and a steering system.

In the self-propulsion module, the air to inflate the balloons is supplied from a single channel. The sequential inflating and deflating of the balloons creates an inchworm-like forward motion. Therefore, unlike standard endoscopes, the TipCAT does not need to be mechanically forced into the patient's lumen using external pressure; rather, it will gently advance itself through the organ's anatomy. As a result, the TipCAT is designed to be able to reach every part of the lumen under examination regardless of the topography, be less operator dependent, and greatly reduce the likelihood of damage to lumen structure.

Furthermore, Microbot believes that use of the TipCAT will improve ADR by straightening the intestinal topography, smoothing colon topography and improving tissue visualization. In addition, by incorporating the TipCAT in therapeutic procedures, Microbot believes that the inflated balloons will provide the additional benefits of assisting the physician in centralizing endoscope optics and allowing for the colonoscope to be secured in each treatment position throughout the procedure, resulting in more efficient and effective procedures.

The TipCAT is also designed such that only disposable parts are in direct contact with the lumen tissue, which should eliminate the risk of cross contamination between patients and the need for post-use reprocessing. Reducing dependence on reprocessing procedures is important from a regulatory perspective because safety issues related to the reprocessing of reusable medical devices are a growing concern for regulatory authorities.

A TipCAT prototype was shown to self-propel and self-navigate in curved plastic pipes and curved ex-vivo colon. In addition, in its first feasibility study, the prototype device was tested in a live animal experiment and successfully self-propelled through segments of the animal's colon, with no post-procedural damage. All tests were conducted at AMIT (Alfred Mann Institute of Technology at the Technion), prior to the licensing of TipCAT by Microbot. Microbot is currently reviewing the design and general proof of concept of the TipCAT and working closely with experts in the field to define the optimal design. Microbot expects animal studies for this device to begin in 2017. Upon the completion of animal studies, Microbot may conduct clinical trials if they are requested by the FDA or if Microbot decides that the data from such trials would improve the marketability of the product candidate. Regulatory approval or clearance for marketing the TipCAT colonoscope in the United States is targeted to occur soon after the applicable animal or clinical trials are completed, depending on when the applicable premarket submission is finalized and filed with FDA, and Microbot's ability to raise money and conduct the necessary trials for approval.

Microbot also plans to further develop the TipCAT for application for other diagnostic and therapeutic endoscopic procedures outside of colonoscopy, such as Chronic Total Occlusion, or CTO, urethroscopy and catheterization.

Microbot may conduct clinical trials for the TipCAT in other countries where such trials are necessary for Microbot to sell its TipCAT device in such country's market, although it has no current plans to do so.

Strategy

Microbot's goal is to generate sales of its products, once they have received regulatory approval, by establishing SCS and TipCAT devices as the standard-of-care in the eyes of doctors, surgeons, patients and medical facilities, as well as getting the support of payors and insurance companies. Microbot believes that it can achieve this objective by working with hospitals to demonstrate the key benefits of its products. Microbot's strategy includes the following key elements:

Continue to refine existing product candidates and develop additional micro-robotic solutions. As Microbot prepares to bring its initial product candidates through pre-clinical and clinical trials, if necessary, and eventually to market, it continues to focus on improving its product candidates to respond to clinical data and patient and physician feedback. Microbot also expects to continue to innovate in the micro-robotics field by continuing to find ways of using its technology to solve unmet needs, with the overarching goal of providing a safer, more effective and more efficient surgical environment for patients and physicians.

Establish and leverage relationships with key institutions and leading clinicians. Microbot intends to develop relationships with a relatively small number of hospitals and clinics through its clinical stage. Microbot's objective will be to maintain clinical focus with such hospitals and clinics so as to establish the SCS and TipCAT as the standard of care in such institutions for their respective procedures. Microbot also expects to identify key clinicians in the hydrocephalus and colonoscopy specialties with the expectation that such clinical focus will accelerate the adoption of its candidate products.

Invest in research and development. Microbot's most significant expense has historically been research and development, and Microbot expects that this will continue in the foreseeable future, including expenses it expects to incur to improve on its prototype products in order to respond to clinical data, to develop additional applications using its technologies and to develop future product candidates.

Explore partnerships for the introduction of Microbot's products. Microbot intends to focus its marketing and sales efforts initially on pursuing collaborations with global medical device companies that have established sales and distribution networks. Microbot will seek to enter collaborations and partnerships with strategic players that offer synergies with Microbot's product candidates and expertise.

Seek additional IP and technologies to complement and strengthen Microbot's current IP portfolio. Microbot intends to continue exploring new technologies, IP and know-how to add to its current portfolio and to allow Microbot to enter new spaces and strengthen its overall product portfolio.

SCS Opportunities

The SCS is designed to prevent shunt occlusions in hydrocephalus and NPH patients who have undergone or are undergoing the surgical insertion of a shunt system. For purposes of its marketing strategy, Microbot has split the market for shunt systems into two sub-markets:

Primary shunt placement; and

Shunt replacement.

Microbot's SCS device is universal (meaning that it is designed to be attachable to any valve on the market); therefore, Microbot's initial go-to-market strategy is the development of strategic partnerships with leading global medical device companies with ready sales and distribution channels. Outside of a strategic partnership, it is most likely that Microbot's SCS product will be initially used in shunt replacement surgeries to replace occluded ventricular catheters. Accordingly, Microbot intends to establish key hospital and clinic relationships that will allow it to diffuse the technology among experts and other stakeholders. Microbot is also planning to apply for the SCS device to be covered under the current reimbursement codes in the United States for use in hydrocephalus and NPH shunt procedures.

TipCAT Opportunities

Microbot expects that its initial go-to-market strategy for the TipCAT will be to establish key hospital and clinic relationships in the field of colonoscopy that will allow Microbot to introduce and then diffuse the technology among colonoscopy experts and other stakeholders. Generally, Microbot expects the hospitals and clinics selected for the TipCAT clinical trials to also start using the product commercially, which will help to promote and support market uptake of the TipCAT product. Because Microbot expects the use of the TipCAT to increase the number of colonoscopy procedures that can be performed at any such facility, Microbot will seek to promote the technology among the doctors and experts involved in the distribution and buying groups within such selected partner hospitals.

Competition

SCS Competitive Landscape

Several academic research groups, such as at the New Jersey Institute of Technology, are currently researching sensing and obstruction-resistant catheter designs, and the Smart Sensors and Integrated Microsystems (SSIM) Program at Wayne State University has publicized that it is engaging in smart shunt development activity. However, based on its knowledge of the patented technologies, Microbot believes that these technologies are still early in the research and development cycle. The SCS also faces non-direct competition from Aqueduct Neurosciences, Inc., which is developing a non-shunt, electro-mechanical technology platform to control the draining of cerebrospinal fluid.

Microbot does not expect its SCS device to directly compete against shunt systems currently available in the market. The SCS device is designed to replace a component of existing shunt systems and is expected to be an aftermarket purchase that would be used to modify existing products by the end user. However, there can be no assurance that Microbot's product candidate will be accepted by the shunt market as an alternative component.

TipCAT Competitive Landscape

The market for endoscopy products is highly competitive with several players operating both at a global and regional level. The leading players in the colonoscopy space are Pentax, Fuji and Olympus,

which dominate the U.S. market for reusable colonoscopes. However, Microbot believes that the most relevant competitors to TipCAT are smaller companies such as GI View and SMART Medical Systems, which produce disposable, self-propelled colonoscopes.

GI View produces a colonoscope with 360° omni-directional visualization and offers self-propelled intubation created using balloons and low pressure CO₂ gas. In addition, the GI View product is single use and disposable.

SMART Medical Systems' product, which, according to publicly available information is being commercialized by Pentax, is introduced by a physician through a standard colonoscope's tool channel and uses its balloon technology to anchor the bowel, which enables the colonoscope to be maneuvered beyond challenging lumen sections.

Microbot believes the TipCAT can successfully compete against its relevant competitors in that it offers all of the following attributes:

the ability to have varied dimensions during insertion and any subsequent point of a procedure, so as to accommodate the particular diameters of the organ at any moment, allows for the straightening of an organ's topography and improved visualization;

disposability, which protects against cross-contamination;

a working channel for therapeutic interventions (and additional visualization capabilities);

lower cost; and

a self-propelling mechanism, allowing for passage through challenging anatomical structures while eliminating tissue trauma.

Some of Microbot's competitors currently have significantly greater resources than Microbot does; have established relationships with healthcare professionals, customers and third-party payors; and have long-term contracts with group purchasing organizations in the United States. In addition, many of Microbot's competitors have established distributor networks, greater resources for product development, sales and marketing, additional lines of products and the ability to offer financial incentives such as rebates, bundled products or discounts on other product lines that Microbot cannot provide.

Microbot's products could also be rendered obsolete or uneconomical by technological advances developed in the future by existing or new competitors.

Intellectual Property

General

Microbot is currently developing its first two product candidates, the SCS and TipCAT based on technological platforms licensed from TRDF, as further discussed below, and Microbot plans to develop other micro-robotic solutions through internal research and development to strengthen its intellectual property position, and continue exploring strategic collaborations and accretive acquisition opportunities. Microbot currently holds an intellectual

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property portfolio that includes 9 patent families, which include 8 patents granted in the US, 11 patents granted outside the US, and 17 patent applications pending worldwide, with other patent applications under development.

Microbot relies on intellectual property licensed or developed, including patents, trade secrets, technical innovations, laws of unfair competition and various licensing agreements to provide its future growth and to build its competitive position. As Microbot continues to expand its intellectual property portfolio, it is critical for Microbot to continue to invest in filing patent applications to protect its technology, inventions, and improvements.

Microbot relies on a combination of patents, trade secret, copyright and other intellectual property rights and measures to aggressively protect its intellectual property. It also relies on other forms of intellectual property, including trade secrets and know-how, to maintain its competitive position. Microbot requires its employees and consultants to execute confidentiality agreements in connection with their employment or consulting relationships with Microbot. Microbot also requires its employees and consultants who work on its product candidates to agree to disclose and assign to Microbot all inventions conceived during the term of their service, while using Microbot property, or which relates to Microbot's business.

Patent applications in the United States and in foreign countries are maintained in secrecy for a period of time after filing, which results in a delay between the actual discoveries and the filing of related patent applications and the time when discoveries are published in scientific and patent literature. Patents issued and patent applications filed relating to medical devices are numerous, and there can be no assurance that current and potential competitors and other third parties have not filed or in the future will not file applications for, or have not received or in the future will not receive, patents or obtain additional proprietary rights relating to product candidates, products, devices or processes used or proposed to be used by Microbot. Microbot believes that the technologies it employs in its products and systems do not infringe the valid claims of any third party patents. There can be no assurance, however, that third parties will not seek to assert that Microbot devices and systems infringe their patents or seek to expand their patent claims to cover aspects of Microbot's products and systems.

The medical device industry in general has been characterized by substantial litigation regarding patents and other intellectual property rights. Any such claims, regardless of their merit, could be time-consuming and expensive to respond to and could divert Microbot's technical and management personnel. Microbot may be involved in litigation to defend against claims of infringement by other patent holders, to enforce patents issued to Microbot, or to protect Microbot's trade secrets. If any relevant claims of third-party patents are upheld as valid and enforceable in any litigation or administrative proceeding, Microbot could be prevented from practicing the subject matter claimed in such patents, or would be required to obtain licenses from the patent owners of each such patent, or to redesign Microbot's products, devices or processes to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be available on terms acceptable to Microbot or Microbot would be successful in any attempt to redesign products or processes to avoid infringement. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent Microbot from manufacturing and selling its products.

Issued U.S. patents which cover Microbot's product candidates will expire between 2026 and 2031, excluding any patent term extensions that might be available following the grant of marketing authorization. Issued patents outside of the United States directed to Microbot's product candidates will expire between 2026 and 2032.

License Agreement with the Technion

In June 2012, Microbot entered into a license agreement with Technion Research and Development Foundation Ltd., or TRDF, the technology transfer subsidiary of the Technion Institute of Technology, pursuant to which it obtained an exclusive, worldwide, royalty-bearing, sub-licensable

license to certain patents and inventions relating to the SCS and TipCAT technology platforms and invented by Professor Moshe Shoham, a director of the Company, and in certain circumstances other TRDF-related persons. Pursuant to the terms of the license agreement, in order to maintain the license with respect to each platform, Microbot must use commercially reasonable efforts to develop products covered by the license, including meeting certain agreed upon development milestones. The milestones for SCS include commencing initial studies in humans by December 2018 and commencing a full clinical trial, if necessary, by December 2019. The milestones for TipCAT include commencing initial studies in humans by December 2018 and commencing a full clinical trial, if necessary, by December 2020. Failure to meet any development milestone will give TRDF the right to terminate the license with respect to the technology underlying the missed milestone. Although Microbot expects to meet the milestone requirements, TRDF has demonstrated flexibility with respect to amending the terms of the license to extend the milestone dates.

As partial consideration for the grant of the licenses under the agreement, Microbot issued a number of shares to TRDF equal to 3% of its issued and outstanding shares at such time on a fully diluted basis. Such shares were initially subject to antidilution protections but are no longer subject to adjustment. In addition, as partial consideration for the licenses granted, Microbot agreed to pay TRDF royalties of between 1.5% and 3.0% of net sales of products covered by the licenses, subject to certain reductions, and certain percentages of amounts received by Microbot in the event of sublicensing.

In the case of termination of the license by Microbot without cause or by TRDF for cause, TRDF has the right to receive a non-exclusive license from Microbot with respect to improvements to the licensed technologies made by Microbot. In such cases, TRDF would pay a royalty of 10% of the income received by TRDF in connection its sublicensing of such patent right and related intellectual property. If the license from TRDF were to be terminated with respect with either of the technology platforms underlying the SCS or the TipCAT, Microbot would no longer be able to continue its development of the related product candidate. However, Microbot believes that its current intellectual property portfolio, and its ongoing efforts to expand into other micro-robotic surgical technologies, will give it the flexibility to shift its resources towards developing and commercializing related products.

Research and Development

Microbot's research and development programs are generally pursued by engineers and scientists employed by Microbot in its offices in Israel on a full-time basis or as consultants, or through partnerships with industry leaders in manufacturing and design and researchers in academia. Microbot is also working with subcontractors in developing specific components of its technologies.

The primary objectives of Microbot's research and development efforts are to continue to introduce incremental enhancements to the capabilities of its candidate products and to advance the development of proposed products.

Microbot has received funds from the Office of the Chief Scientist in Israel, or OCS, for research and development activities. Microbot received a grant from the OCS in 2012, which grant reimbursed Microbot for 50% of its research and development expenses, up to \$764,466. This first grant from the OCS ended in 2014. After the expiration of the first grant, Microbot received approval for an additional grant from the OCS which reimbursed Microbot for 50% of its research and development expenses for the period from May 1, 2014 through September 30, 2015, up to \$924,166. After the expiration of the second grant, Microbot received an approval for a third grant from the Chief Scientist of Israel which reimbursed Microbot for 50% of its research and development expenses for the period from May 1, 2016 through April 30, 2017, up to \$1,026,050. Microbot expects to continue to access government funding in the future.

For the fiscal year ended December 31, 2015, Microbot incurred research and development expenses of \$822,759 compared to research and development expenses of \$836,698 for the fiscal year ended December 31, 2014.

Microbot has already made plans to develop a second version of its SCS device that will have an embedded controller and battery. This alternative design will allow the cleaning mechanism to be automatically activated, without the need for the patient's involvement in the activation process.

Manufacturing

Microbot does not have any manufacturing facilities or manufacturing personnel. Microbot currently relies, and expects to continue to rely, on third parties for the manufacturing of its product candidates for preclinical and clinical testing, as well as for commercial manufacturing if its product candidates receive marketing approval.

Commercialization

Microbot has not yet established a sales, marketing or product distribution infrastructure for its product candidates, which are still in development stages. Microbot plans to access the U.S. markets for hydrocephalus, NPH, and colonoscopy with its initial device offerings through strategic partnerships but may develop its own focused, specialized sales force or distribution channels once it has several commercialized products in its portfolio. Microbot has not yet developed a commercial strategy outside of the United States.

Government Regulation

General

Microbot's medical technology products and operations are subject to extensive regulation in the United States and other countries. Most notably, if Microbot seeks to sell its products in the United States, its products will be subject to the Federal Food, Drug, and Cosmetic Act (FDCA) as implemented and enforced by the U.S. Food and Drug Administration (FDA). The FDA regulates the development, bench and clinical testing, manufacturing, labeling, storage, record-keeping, promotion, marketing, sales, distribution and post-market support and reporting of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. Regulatory policy affecting its products can change at any time.

Advertising and promotion of medical devices in the United States, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

Foreign countries where Microbot wishes to sell its products may require similar or more onerous approvals to manufacture or market its products. Government agencies in those countries also enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and market surveillance of medical device products. These regulatory requirements can change rapidly with relatively short notice.

Other regulations Microbot encounters in the United States and in other jurisdictions are the regulations that are common to all businesses, such as employment legislation, implied warranty laws, and environmental, health and safety standards, to the extent applicable. In the future, Microbot will also encounter industry-specific government regulations that would govern its products, if and when they are developed for commercial use.

U.S. Regulation

The FDA governs the following activities that Microbot performs, will perform, upon the clearance or approval of its product candidates, or that are performed on its behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

product design, and development;

product safety, testing, labeling and storage;

record keeping procedures; and

product marketing.

There are numerous FDA regulatory requirements governing the approval or clearance and subsequent commercial marketing of Microbot's products. These include:

the timely submission of product listing and establishment registration information, along with associated establishment user fees;

continued compliance with the Quality System Regulation, or QSR, which require specification developers and manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;

clearance or approval of product modifications that could significantly affect the safety or effectiveness of the device or that would constitute a major change in intended use;

Medical Device Reporting regulations (MDR), which require that manufacturers keep detailed records of investigations or complaints against their devices and to report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;

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adequate use of the Corrective and Preventive Actions process to identify and correct or prevent significant systemic failures of products or processes or in trends which suggest same;

post-approval restrictions or conditions, including post-approval study commitments;

post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and

notices of correction or removal and recall regulations.

Unless an exemption applies, before Microbot can commercially distribute medical devices in the United States, Microbot must obtain, depending on the classification of the device, either prior 510(k) clearance, 510(k) de-novo clearance or premarket approval (PMA), from the FDA. The FDA classifies medical devices into one of three classes based on the degree of risk associated with each medical device and the extent of regulatory controls needed to ensure the device's safety and effectiveness:

Class I devices, which are low risk and subject to only general controls (e.g., registration and listing, medical device labeling compliance, MDRs, Quality System Regulations, and prohibitions against adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements;

Class II devices, which are moderate risk and generally require 510(k) or 510(k) de-novo premarket clearance before they may be commercially marketed in the United States as well as general controls and potentially special controls like performance standards or specific labeling requirements; and

Class III devices, which are devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device.

Class III devices generally require the submission and approval of a PMA supported by clinical trial data.

Microbot expects the medical products in its pipeline currently to be classified as Class II. Class II devices are those for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and there is sufficient information to establish special controls. Special controls can include performance standards, post-market surveillance, patient histories and FDA guidance documents. Premarket review and clearance by the FDA for these devices is generally accomplished through the 510(k) or 510(k) de-novo premarket notification process. As part of the 510(k) or 510(k) de-novo notification process, FDA may require the following:

Development of comprehensive product description and indications for use.

Completion of extensive preclinical tests and preclinical animal studies, performed in accordance with the FDA's Good Laboratory Practice (GLP) regulations.

Comprehensive review of predicate devices and development of data supporting the new product's substantial equivalence to one or more predicate devices.

If appropriate and required, certain types of clinical trials (IDE submission and approval may be required for conducting a clinical trial in the US).

Clinical trials involve use of the medical device on human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices (GCPs), including the requirement that all research subjects provide informed consent for their participation in the clinical study. A written protocol with predefined end points, an appropriate sample size and pre-determined patient inclusion and exclusion criteria, is required before initiating and conducting a clinical trial. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's Investigational device Exemption, or IDE, regulations that among other things, govern investigational device labeling, prohibit promotion of the investigational device, and specify

recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a significant risk, as defined by the FDA, the agency requires the device sponsor to submit an IDE application, which must become effective prior to commencing human clinical trials. The

IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA denies the application or notifies the company that the investigation is on hold and may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE that requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but it must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

Assuming successful completion of all required testing, a detailed 510(k) premarket notification or 510(k) de-novo is submitted to the FDA requesting clearance to market the product. The notification includes all relevant data from pertinent preclinical and clinical trials, together with detailed information relating to the product's manufacturing controls and proposed labeling, and other relevant documentation.

A 510(k) clearance letter from the FDA will authorize commercial marketing of the device for one or more specific indications for use.

After 510(k) clearance, Microbot will be required to comply with a number of post-clearance requirements, including, but not limited to, Medical Device Reporting and complaint handling, and, if applicable, reporting of corrective actions. Also, quality control and manufacturing procedures must continue to conform to QSRs. The FDA periodically inspects manufacturing facilities to assess compliance with QSRs, which impose extensive procedural, substantive, and record keeping requirements on medical device manufacturers. In addition, changes to the manufacturing process are strictly regulated, and, depending on the change, validation activities may need to be performed. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with QSRs and other types of regulatory controls.

After a device receives 510(k) clearance from FDA, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use or technological characteristics, requires a new 510(k) clearance or could require a PMA. The FDA requires each manufacturer to make the determination of whether a modification requires a new 510(k) notification or PMA in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA for a particular change, the FDA may retroactively require the manufacturer to seek 510(k) clearance or PMA. The FDA can also require the manufacturer to cease U.S. marketing and/or recall the modified device until additional 510(k) clearance or PMA approval is obtained.

The FDA and the Federal Trade Commission, or FTC, will also regulate the advertising claims of Microbot's products to ensure that the claims Microbot makes are consistent with its regulatory clearances, that there is scientific data to substantiate the claims and that product advertising is neither false nor misleading.

To obtain 510(k) clearance, Microbot must submit a notification to the FDA demonstrating that its proposed device is substantially equivalent to a predicate device (i.e., a device that was in commercial distribution before May 28, 1976, a device that has been reclassified from Class III to Class I or Class II, or a 510(k)-cleared device). The FDA's 510(k) clearance process generally takes from three to 12 months from the date the application is submitted but also can take significantly longer. If the FDA determines that the device or its intended use is not substantially equivalent to a predicate device, the device is automatically placed into Class III, requiring the submission of a PMA.

There is no guarantee that the FDA will grant Microbot 510(k) clearance for its pipeline medical device products, and failure to obtain the necessary clearances for its products would adversely affect Microbot's ability to grow its business. Delays in receipt or failure to receive the necessary clearances, or the failure to comply with existing or future regulatory requirements, could reduce its business prospects.

Devices that cannot be cleared through the 510(k) process due to lack of a predicate device but would be considered low or moderate risk may be eligible for the 510(k) de-novo process. In 1997, the Food and Drug Administration Modernization Act, or FDAMA added the de novo classification pathway now codified in section 513(f)(2) of the FD&C Act. This law established an alternate pathway to classify new devices into Class I or II that had automatically been placed in Class III after receiving a Not Substantially Equivalent, or NSE, determination in response to a 510(k) submission. Through this regulatory process, a sponsor who receives an NSE determination may, within 30 days of receipt, request FDA to make a risk-based classification of the device through what is called a de novo request. In 2012, section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA), in order to provide a second option for de novo classification. Under this second pathway, a sponsor who determines that there is no legally marketed device upon which to base a determination of substantial equivalence can submit a de novo request to FDA without first submitting a 510(k).

In the event that Microbot receives a Not Substantially Equivalent determination for either of its device candidates in response to a 510(k) submission, the Microbot device may still be eligible for the 510(k) de-novo classification process.

Devices that cannot be cleared through the 510(k) or 510(k) de-novo classification process require the submission of a PMA. The PMA process is much more time consuming and demanding than the 510(k) notification process. A PMA must be supported by extensive data, including but not limited to data obtained from preclinical and/or clinical studies and data relating to manufacturing and labeling, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. After a PMA application is submitted, the FDA's in-depth review of the information generally takes between one and three years and may take significantly longer. If the FDA does not grant 510(k) clearance to its products, there is no guarantee that Microbot will submit a PMA or that if Microbot does, that the FDA would grant a PMA approval of Microbot's products, either of which would adversely affect Microbot's business.

Foreign Regulation

In addition to regulations in the United States, Microbot will be subject to a variety of foreign regulations governing clinical trials, marketing authorization and commercial sales and distribution of its products in foreign countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval or clearance. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

International sales of medical devices are subject to foreign governmental regulations which vary substantially from country to country. Whether or not Microbot obtains FDA approval or clearance for its products, Microbot will be required to make new regulatory submissions to the comparable regulatory authorities of foreign countries before Microbot can commence clinical trials or marketing of the product in such countries. The time required to obtain certification or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. Below are

summaries of the regulatory systems for medical devices in Europe and Israel, where Microbot currently anticipates marketing its products. However, its products may also be marketed in other countries that have different systems or minimal requirements for medical devices.

Europe. The primary regulatory body in Europe is the European Union, or E.U., which consists of 28 member states and has a coordinated system for the authorization of medical devices.

The E.U. has adopted legislation, in the form of directives to be implemented in each member state, concerning the regulation of medical devices within the European Union. The directives include, among others, the Medical Device Directive, or MDD, that establishes certain requirements with which medical devices must comply before they can be commercialized in the European Economic Area, or EEA (which comprises the member states of the E.U. plus Norway, Liechtenstein and Iceland). Under the MDD, medical devices are classified into four Classes, I, IIa, IIb, and III, with Class I being the lowest risk and Class III being the highest risk. However, the E.U. authorities, including the European Commission, do not have direct regulatory over medical device manufacturers under the MDD. Rather, the MDD directs E.U. Member States to implement laws and regulations consistent with the provisions set forth in the directive.

Under the MDD, to demonstrate compliance of a medical device with the essential requirements, manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. An accredited body known as a Notified Body, which is an entity designated by an E.U. Member State (or competent authority) to perform conformity assessments, will typically audit and examine the manufacturer's quality system for the production, quality, design and final inspection of the medical devices and review a Technical File containing technical documents regarding the device, including but limited to, detailed device description, manufacturing information, preclinical and clinical tests, risk analysis, compliance with essential requirements, etc., before issuing a certification demonstrating compliance with the essential requirements. Medical devices that comply with the essential requirements are entitled to bear the Conformité Européene, or CE Mark. Medical devices properly bearing the CE Mark may be commercially distributed throughout the EEA. Under the MDD, notified bodies are also charged with performing periodic inspections to verify that a manufacturer's quality system, particularly the production and quality controls, is adequately executed and maintained.

In addition, the MDD requires all medical device manufacturers to inform the competent authorities of their respective Member States of the address(es) of any business facilities and descriptions of any certified medical device products. The MDD also requires manufacturers to file vigilance reports in the event a device malfunction, deterioration in performance, or inadequate instructions or labeling results in, or could lead to, death or serious harm to a patient.

In September 2012, the European Commission published proposals for the revision of the EU regulatory framework for medical devices. The proposal would replace the MDD with a new regulation, the Medical Devices Regulation, or MDR. Unlike the MDD that must be implemented into national laws, the Medical Devices Regulation would be directly applicable in all EEA member states and so is intended to eliminate current national differences in regulation of medical devices. E.U. lawmakers published a revised draft of the proposed MDR in June 2016, which continues to be discussed within the Council of the European Union.

If finally adopted, the MDR is expected to enter into force in late 2016 and become applicable three years thereafter. The adoption of the MDR may, however, be materially delayed due to disagreements about specific portions of the regulation, as well as the implementation process. In its current form it would, among other things, impose additional reporting requirements on manufacturers of high risk medical devices, impose an obligation on manufacturers to appoint a qualified person

responsible for regulatory compliance, and provide for more strict clinical evidence requirements. These new rules and procedures will likely result in increased regulatory oversight of all medical devices marketed in the E.U., and this may, in turn, increase the costs, time and requirements that need to be met in order to place a medical devices on the EEA market.

Microbot intends to apply for the CE Mark for each of its medical device products. There is no guarantee that Microbot will be granted a CE Mark for all or any of its pipeline products and failure to obtain the CE Mark would adversely affect its ability to grow its business.

Israel. Israel's Medical Devices Law generally requires the registration of all medical products with the Ministry of Health, or MOH, Registrar as a precondition for production and distribution in Israel. Special exemptions may apply under limited circumstances and for purposes such as the provision of essential medical treatment, research and development of the medical device, and personal use, among others.

Registration of medical devices requires the submission of an application to the Ministry of Health Medical Institutions and Devices Licensing Department, or AMAR. An application for the registration of a medical device includes the following:

Name and address of the manufacturer, and of the importer as applicable;

Description of the intended use of the medical device and of its medical indications;

Technical details of the medical device and of its components, and in the event that the device or the components are not new, information should be provided on the date of renovation;

Certificate attesting to the safety of the device, issued by a competent authority of one of the following countries: Australia, Canada, European Community (EC), Member States (MSs), Israel, Japan, or the United States;

Information on any risk which may be associated with the use of the device (including precautionary measures to be taken);

Instructions for use of the device in Hebrew; the MOH may allow the instructions to be in English for certain devices;

Details of the standards to which the device complies;

Description of the technical and maintenance services, including periodic checks and inspections; and

Declaration, as appropriate: of the local manufacturer/importer, and of the foreign manufacturer.

If the application includes a certificate issued by a competent authority of one of the following recognized countries: Australia, Canada, European Community (CE) Member States (MSs), Japan, or the United States, the registration process is generally expedited, but could still take 6-9 months for approval. If such certificate is not available, the registration process will take significantly longer and a license is rarely issued. Furthermore, the MOH will determine what type of testing is needed. In general, in the case of Israeli manufactured devices that are not registered or authorized in any recognized country, the application requires presentation of a risk analysis, a clinical evaluation, a summary of the clinical trials, and expert opinions regarding the device's safety and effectiveness. Additional requirements may apply during the registration period, including follow-up reviews, to improve the quality and safety of the devices.

According to regulations issued by Israel's Minister of Health in June 2013, a decision on a request to register a medical device must be delivered by AMAR within 120 days from the date of the request, although this rarely occurs. The current rules for the registration of medical devices do not provide for an expedited approval process.

Once granted by the MOH, a license (marketing authorization) for a medical device is valid for five years from the date of registration of the device, except for implants with a life-supporting function, for which the validity is for only two years from the date of registration. Furthermore, the holder of the license, the Israeli Registration Holder, or IRH, must do the following to maintain its license:

Reside and maintain a place of business in Israel and serve as the regulatory representative.

Respond to questions from AMAR concerning the registered products.

Report adverse events to AMAR.

Renew the registration on time to keep the market approval active.

Comply with post-marketing requirements, including reporting of adverse and unexpected events occurring in Israel or in other countries where the device is in use.

Getting a device listed on Israel's four major Sick Funds (health insurance entities) is also necessary in order for Israeli hospitals and health care providers to order such products.

Microbot intends to apply for a license from the MOH for each of its medical devices. There is no guarantee that Microbot will be granted licenses for its pipeline products and failure to obtain such licenses would adversely affect its ability to grow its business.

Employees

Microbot's Chief Executive Officer, President and Chairman, Harel Gadot, is based in Microbot's U.S. office located in Hingham, Massachusetts. Additionally, Microbot currently has five full-time employees and one part time employee based in its office located in Yokneam, Israel. These employees oversee day-to-day operations of the Company supporting management and leading engineering, manufacturing, intellectual property and administration functions of the Company. As required, Microbot also engages consultants to provide services to the Company, including regulatory, legal and corporate services. Microbot has no unionized employees.

Microbot currently plans to hire an additional 6-8 full-time employees within the next 12 months subject to the availability of funds, whose principal responsibilities will be the support of its operational, research and development, and clinical development activities.

Facilities

Microbot's principal executive office is located at 175 Derby St., 27/1, Hingham, MA 02043. Microbot also has facilities in premises of approximately 1,840 square feet at 5 Hamada Street, 2nd Floor, Yokneam, Israel. Microbot plans to relocate to a larger facility in Israel within the next 12-18 months, which will provide the space and

infrastructure necessary to accommodate its development work based on its current operating plan. Microbot does not own any real property.

Legal Matters

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm business.

We are not currently a party in any legal proceeding or governmental regulatory proceeding nor are we currently aware of any pending or potential legal proceeding or governmental regulatory proceeding proposed to be initiated against us that would have a material adverse effect on us or our business.

RISK FACTORS

The risks set forth below are not the only ones facing our Company. Additional risks and uncertainties may exist that could also adversely affect our business, financial condition, prospects and/or operations. If any of the following or other risks actually materialize, our business, financial condition, prospects and/or operations could suffer. In such event, the value of our securities could decline.

Risks Relating to Microbot's Financial Position and Need for Additional Capital

Microbot has had no revenue and has incurred significant operating losses since inception and is expected to continue to incur significant operating losses following the Merger for the foreseeable future. The Company may never become profitable or, if achieved, be able to sustain profitability.

Microbot has incurred significant operating losses since its inception and expects to incur significant losses for the foreseeable future as Microbot continues its preclinical and clinical development programs for its existing product candidates, SCS and TipCAT; its research and development of any other future product candidates; and all other work necessary to obtain regulatory clearances or approvals for its product candidates in the United States and other markets. In the future, Microbot intends to continue conducting micro-robotics research and development; performing necessary animal and clinical testing; working towards medical device regulatory compliance; and, if SCS, TipCAT or other future product candidates are approved or cleared for commercial distribution, engaging in appropriate sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in Microbot incurring further significant losses for the foreseeable future.

Microbot is a development-stage medical device company and currently generates no revenue from product sales, and may never be able to commercialize SCS, TipCAT or other future product candidates. Microbot does not currently have the required approvals or clearances to market or test in humans SCS, TipCAT or any other future product candidates and Microbot may never receive them. Microbot does not anticipate generating significant revenues until the Company can successfully develop, commercialize and sell products derived from its product pipeline, of which Microbot can give no assurance. Even if Microbot or any of its future development partners succeed in commercializing any of Microbot's product candidates, Microbot may never generate revenues significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with its product development pipeline and strategy, Microbot cannot accurately predict when it will achieve profitability, if ever. Failure to become and remain profitable would depress the value of the Company and could impair its ability to raise capital, which may force the Company to curtail or discontinue its research and development programs and/or day-to-day operations. Furthermore, there can be no assurance that profitability, if achieved, can be sustained on an ongoing basis.

Microbot's business depends on the success of the SCS and the TipCAT, both of which are still in pre-clinical development. If Microbot is unable to obtain regulatory approval for or to successfully commercialize these products, its business will be materially harmed.

To date, the primary focus of Microbot's product development has been on SCS, for the treatment of hydrocephalus and normal pressure hydrocephalus, or NPH, and TipCAT, a self-propelling, semi-disposable endoscope being developed initially for use in colonoscopy procedures. Successful continued development and ultimate regulatory approval or clearance of both SCS and TipCAT are critical to the future success of Microbot's business. Microbot has invested, and will continue to invest, a significant portion of its time and financial resources in the development, pre-clinical and clinical testing of and obtaining regulatory authorization for SCS and TipCAT. Microbot will need to raise sufficient funds to successfully complete its development of these products. The future regulatory and commercial success of SCS and TipCAT is subject to a number of risks, including the following:

Microbot may not have sufficient financial and other resources to complete the necessary clinical trials for SCS and TipCAT;

If clinical trials are required for FDA clearance or approval of SCS or TipCAT, Microbot may not be able to obtain adequate evidence from such clinical trials of safety and effectiveness in order to receive the applicable clearance or approval from the FDA; and

Microbot does not know the degree to which SCS or TipCAT will be accepted and adopted by physicians, patients and payors, even if approved or cleared by FDA for commercial marketing.

If Microbot is unable to successfully navigate these risks and achieve commercial success for its products, its business will be significantly harmed and Microbot may never become profitable.

Microbot has a limited operating history, which may make it difficult to evaluate the prospects for the Company's future viability.

Microbot has a limited operating history upon which an evaluation of its business plan or performance and prospects can be made. The business and prospects of Microbot must be considered in the light of the potential problems, delays, uncertainties and complications that may be encountered in connection with a newly established business. The risks include, but are not limited to, the possibility that Microbot will not be able to develop functional and scalable products, or that although functional and scalable, its products will not be economical to market; that its competitors hold proprietary rights that may preclude Microbot from marketing such products; that its competitors market a superior or equivalent product; that Microbot is not able to upgrade and enhance its technologies and products to accommodate new features and expanded service offerings; or the failure to receive necessary regulatory clearances or approvals for its products. To successfully introduce and market its products at a profit, Microbot must establish brand name recognition and competitive advantages for its products. There are no assurances that Microbot can successfully address these challenges. If it is unsuccessful, Microbot and its business, financial condition and operating results could be materially and adversely affected.

Microbot's operations to date have been limited to organizing the company, entering into licensing arrangements to initially obtain rights to its technologies, developing and securing its technologies, raising capital, developing regulatory and reimbursement strategies for its product candidates and preparing for pre-clinical and clinical trials of the SCS and TipCAT. Microbot has not yet demonstrated its ability to successfully complete development of any product candidate, obtain marketing clearance or approval, manufacture a commercial-scale product or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about Microbot's future success or viability may not be as accurate as they could be if Microbot had a longer operating history.

Microbot's independent registered public accounting firm has noted that the continuation of Microbot as a business will be dependent on its ability to receive additional financing.

Based on Microbot's limited operating history and the risks it faces, including uncertainties regarding the development of its product, Microbot's independent registered public accounting firm has included an explanatory paragraph in its report on Microbot's financial statements as of and for the years ended December 31, 2015 and December 31, 2014 elaborating on the business conditions Microbot faces. As Microbot expects to continue to incur significant operating costs and losses in connection with the development of its product and financing its business development operations, as of the date of the financial statements, the continuation of Microbot's activities and its obligations are dependent upon the receipt of financing from its shareholders or new investors.

Microbot will need substantial additional funding. If Microbot is unable to raise capital when needed, it could be forced to delay, reduce or eliminate its product development programs or commercialization efforts.

To date, Microbot Israel has funded its operations primarily through private placement offerings of debt and equity