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 14, 2019

MICROBOT MEDICAL INC.
(Exact name of registrant as specified in its charter)

Delaware	**000-19871**	**94-3078125**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

25 Recreation Park Drive, Unit 108
Hingham, Massachusetts 02043
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (781) 875-3605

(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:

[ ] 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Item 8.01. Other Events.

On December 28, 2018, Microbot Medical Inc. ("Microbot," the "Company," "we," "our" or "us") filed with the Securities and Exchange Commission (the "SEC") a Registration Statement on Form S-1 (file number: 333-228285), as amended, first filed with the SEC on November 8, 2018 (the "Registration Statement"). The Registration Statement contains (i) an updated summary description of the Company's business in the section entitled "Prospectus Summary," and (ii) revised and additional risk factors in the section entitled "Risk Factors" that are not otherwise included in the Company's reports filed with the SEC under the Exchange Act of 1934, as amended. These disclosures, together with certain previously announced updates regarding the Company's in-vitro study and patent portfolio, are attached hereto as Exhibit 99.1 and incorporated herein by reference.

This Current Report on Form 8-K, including the exhibits hereto, shall not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company, which is being made only by means of a written prospectus meeting the requirements of Section 10 of the Securities Act, nor shall there be any sale of the Company's securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Updated Disclosure

SIGNATURES

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

MICROBOT MEDICAL INC.

By: */s/ Harel Gadot*
Name: Harel Gadot
Title: Chairman, President and Chief Executive Officer

Date: January 14, 2019

INDEX TO EXHIBITS

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Exhibit 99.1

Overview

Our Company

Microbot is a pre-clinical medical device company specializing in the research, design and development of next generation robotic endoluminal surgery devices targeting the minimally invasive surgery space. Microbot is primarily focused on leveraging its micro-robotic technologies with the goal of improving surgical outcomes for patients.

Microbot's current technological platforms, ViRob™, CardioSert™ and TipCAT™, are comprised of proprietary innovative technologies. Using the ViRob platform, Microbot is currently developing its first product candidate: the Self Cleaning Shunt, or SCS™, for the treatment of hydrocephalus and Normal Pressure Hydrocephalus, or NPH. Although the SCS utilizes one of our platforms, we are focused on the development of a Multi Generation Pipeline Portfolio utilizing all three of our proprietary technologies.

Microbot has a patent portfolio of 30 issued/allowed patents and 18 patent applications pending worldwide.

Technological Platforms

ViRob

The ViRob is an autonomous crawling micro-robot which can be controlled remotely or within the body. Its miniature dimensions are expected to allow it to navigate and crawl in different natural spaces within the human body, including blood vessels, the digestive tract and the respiratory system as well as artificial spaces such as shunts, catheters, ports, etc. Its unique structure is expected to give it the ability to move in tight spaces and curved passages as well as the ability to remain within the human body for prolonged time. The SCS product was developed using the ViRob technology.

CardioSert

On May 25, 2018, Microbot acquired a patent-protected technology from CardioSert Ltd., a privately-held medical device company based in Israel. The CardioSert technology contemplates a combination of a guidewire and microcatheter, technologies that are broadly used for surgery within a tubular organ or structure such as a blood vessel or duct. The CardioSert technology features a unique guidewire delivery system with steering and stiffness control capabilities which when developed is expected to give the physician the ability to control the tip curvature, to adjust tip load to varying degrees of stiffness in a gradually continuous manner. The CardioSert technology was originally developed to support interventional cardiologists in crossing chronic total occlusions (CTO) during percutaneous coronary intervention (PCI) procedures and has the potential to be used in other spaces and applications, such as peripheral intervention, and neurosurgery. CardioSert was part of a technological incubator supported by the Israel Innovation Authorities (formerly known as the Office of the Chief Scientist, or OCS), and a device based on the technology has successfully completed pre-clinical testing.

TipCAT

The TipCAT is a disposable self-propelled locomotive device that is specially designed to advance in tubular anatomies. The TipCAT is a mechanism comprising a series of interconnected balloons at the device's tip that provides the TipCAT with its forward locomotion capability. The device can self-propel within natural tubular lumens such as the blood vessels, respiratory and the urinary and GI tracts. A single channel of air/fluid supply sequentially inflates and deflates a series of balloons creating an inchworm like forward motion. The TipCAT maintains a standard working channel for treatments. Unlike standard access devices such as guidewires, catheters for vascular access and endoscopes, the TipCAT does not need to be pushed 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. The TipCAT thus offers functionality features equivalent to modern tubular access devices, along with advantages associated with its physiologically adapted self-propelling mechanism, flexibility, and design.

Industry Overview

CSF Management

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. 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. 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 occlusion, 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 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 that can prevent functional failures 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.

An alternative, short-term solution to hydrocephalus is the implantation of an External Ventricular Drainage, or EVD, an implanted device used in neurosurgery for the short-term treatment and monitoring of elevated intracranial pressure when the normal flow of CSF inside the brain is obstructed. If after using an EVD, the underlying hydrocephalus does not eventually resolve, the EVD may then be converted to a cerebral shunt, a fully internalized, long-term treatment for hydrocephalus.

EVDs are also used in other instances when the normal flow of CSF inside the brain is obstructed, such as a result of head trauma, intracerebral hemorrhage, brain tumors and infection. The EVD serves to divert excess fluids from the brain and allows for the monitoring of intracranial pressure. An EVD must be placed in a center with full neurosurgical capabilities because immediate neurosurgical intervention may be needed if a complication of EVD placement, such as bleeding, is encountered. EVD is one of the most commonly used and most important life-saving procedures in the neurologic ICU, with more than 200,000 neuro-intensive patients requiring EVD insertions annually.

Similar to shunts, EVDs are also prone to occlusion, mostly due to cellular debris, such as blood clots and/or tissue fragments. Studies have shown that approximately 1-7% of EVDs require replacement secondary to occlusion. Current solutions for EVD occlusion include irrigation and replacement, which we believe may be ineffective (in the case of irrigation) or costly (in the case of replacement) and in either case, put the patient at risk of unintended side effects. Microbot believes that with its portfolio of technologies, and its initial pre-clinical results, it is well-positioned to explore and expand its offerings as an alternative solution for EVD occlusion.

Minimally Invasive Endovascular Neurosurgery

Minimally Invasive Surgery, or MIS, refers to surgical procedures performed through tiny incisions instead of a single large opening. Because the incisions are small, patients tend to have quicker recovery times and experience less trauma than with conventional surgery. The global MIS market is expected to exceed $50 billion by 2019, with a CAGR of over 20% through 2023. MIS involves three major category of devices: surgical, monitoring and visualization, and endoscopy. The market for surgical devices, including ablation, electrosurgery and medical robotic systems, accounts for the largest share of revenue and is also expected to show the highest rate of growth.

As a subset of MIS, endovascular neurosurgery refers to surgeries performed by using devices that pass through the blood vessels to diagnose and treat neurological diseases and conditions such as stroke, arteriovenous malformations, aneurysms and atherosclerosis, rather than using open surgery.

The global neurovascular device market was valued at $1.62 billion in 2015 and is expected to reach a value of $2.92 billion by 2024, growing at a CAGR of 6.5%. Increases in the geriatric population and a rise in the number of patients suffering from neurovascular disorders, implementation of advanced technological platforms, and favorable reimbursement policies across established markets are expected to drive this market's growth. On the other hand, the high cost of the endovascular devices and scarcity of neurovascular surgeons may impede such growth.

Stroke is a devastating condition, affecting 33 million people worldwide every year. In the United States alone, there are nearly 800,000 instances of stroke yearly, with about three in four being first-time strokes. This number is expected to increase to one million annually in 2021. Stroke is the fifth leading cause of death in the United States and is a leading cause of long-term disability, with related care costs estimated at $70 billion annually.

Mechanical thrombectomy has only been approved as a first-line treatment for ischemic stroke since 2016. Prior to such approval, chemical thrombolysis using tissue plasminogen activators was the only first-line treatment available, limiting the therapeutic window for ischemic stroke patients to as little as 3-4 hours from the onset of symptoms. With mechanical thrombectomy, treatment can be started within 6-24 hours of the time the patient was last known to be well. The US mechanical thrombectomy market is projected to grow at a CAGR of 23.9% between 2014-2020, to reach a value over $350 million.

According to the Brain Aneurysm Foundation, an estimated 6 million people in the United States have an unruptured brain aneurysm, or 1 in 50 people. The annual rate of rupture is approximately 8 – 10 per 100,000 people, or about 30,000 people in the United States annually. Embolic coiling is the established gold-standard treatment for aneurysms, and the most established product line in the neurovascular market – it is a strong but relatively stagnant market, projected to grow at a CAGR of 1.7% between 2014-2020, to reach a value of over $800 million. New devices that improve treatment of complex aneurysms, such as embolization-enabling stents, bifurcations stents, flow-diversion stents, liquid embolics and intrasaccular devices, are expected to boost market growth.

The major companies in the field of neurovascular devices include Stryker Corporation, Medtronic Plc., Cerenovus (Johnson & Johnson), Terumo Corporation and Penumbra, Inc. Neurovascular access devices are the means for delivering neurovascular treatment tools and devices from an opening in the femoral or radial arteries into the brain vasculature. Such access devices include sheaths, guidewires and microcatheters. Wires and catheters account for 18.6% of the overall neurovascular market.

Navigating and placing access devices through tortuous and highly delicate brain arteries is a complex procedure that requires high-level surgical skills with specialist training. In many procedures, surgeons exchange numerous access devices before reaching the target and applying the therapeutic agent or device, increasing the risk of adverse events and the exposure of both patient and physician to radiation. Adverse events, such as perforation of brain arteries or the release of embolies from a thrombus or atherosclerotic lesion can have devastating or even fatal results.

Microbot believes that with its portfolio of technologies specifically CardioSert and TipCAT, it is well-positioned to explore and develop such technologies as neurovascular access devices, with a focus on improving the ease and access and enhancing the safety of endovascular neurosurgery.

Our Product Pipeline

Self-Cleaning Shunt

The 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 be able to 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. In May 2018, Microbot announced the results of two pre-clinical studies assessing the SCS, an *in-vitro* study and a small animal study. The in-vitro study, which was performed at Wayne State University by Dr. Carolyn Harris, supports the SCS's potential as a viable technology for preventing occlusion in shunts used to treat hydrocephalus. The animal study designed to assess the safety profile of the SCS, which was performed by James Patterson McAllister, PhD, a Professor of Neurosurgery at Washington University School of Medicine in St. Louis, met the primary goal to determine the safety of the SCS device that aims to prevent obstruction in CSF catheters. Since the completion of these initial studies, Microbot has commenced a follow-up study to further evaluate the safety and to investigate the efficacy of the SCS. The follow-up study is also being conducted by leading hydrocephalus experts at Washington University and Wayne State University. The study will include a larger sample size compared to the initial studies and the primary and secondary endpoints will seek to validate the safety and efficacy of the SCS that will be activated in both *in-vitro* (lab) and *in-vivo* (animal) models. Microbot plans to use the findings for initial regulatory submissions in the United States, Europe and other jurisdictions, although 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.

In conjunction with initiating this follow-up study, Microbot also contracted with Envigo CRS Israel, a leading provider of non-clinical contract research services, to conduct an *in-vitro* study designed to evaluate the operational performance of the SCS. The Envigo study used human brain glioblastoma cells in order to assess the performance of the SCS in a test system with accelerated cell growth, accumulation, and obstruction rates. The performance of a constantly activated (always-on) SCS to prevent shunt occlusion in the laboratory study was compared with a non-operating SCS after 30 days, and the results were captured with photographs shared by Microbot in a press release issued on January 14, 2019. While significant cell growth and accumulation was seen in the cell cultures with a non-operating SCS, the shunt openings within the cells seeded with a constantly operating SCS remained clear, with little to no cell attachment on the robotic brush (ViRob) and on the opening where the robotic brush (ViRob) operates after 30 days of cell culturing and growth. We believe this experiment validates the operational effectiveness of the SCS to prevent shunt occlusion and provides additional data to support the device's proof of concept. We believe the *in-vitro* laboratory study further confirms that the SCS has the ability to operate after cells have accumulated on the catheter holes and the robotic brush (ViRob) and to potentially disintegrate existing occlusions formed on the robotic brush (ViRob) and on the opening where the robotic brush (ViRob) operates, based on the results from a third test group in which cells were allowed to grow for 4 weeks and then exposed to an activated SCS device. The images captured by Envigo and Microbot demonstrate that the cleaning mechanism of the SCS is powerful enough to clear accumulated cells at blocked pores, as significant improvements were observed in the degree of shunt obstruction after only a short period of time following activation of the SCS.

Microbot believes that the animal study results of its first generation SCS device should be available during the second half of 2019 and we expect to submit that data to the FDA as part of a pre-submission meeting request. 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. It continues to be possible that the FDA could require us to conduct a human clinical study to support the safety and efficacy of the SCS and that such clinical data would need to be part of the future regulatory submission to authorize marketing of the medical device in the U.S.

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

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 no longer pursuing the development of the TipCAT as a colonoscopy tool but is currently exploring the use of the TipCAT for minimally invasive endovascular neurosurgical applications.

Risk Factors

Microbot's business depends heavily on the success of its lead product candidate, the SCS. If Microbot is unable to commercialize the SCS or experiences significant delays in doing so, Microbot's business will be materially harmed.

On January 27, 2017, Microbot entered into a research agreement with Washington University in St. Louis to develop the protocol for and to execute the necessary animal study to determine the effectiveness of the Microbot's SCS prototype. The initial research was completed in 2017 with a comprehensive study expected to be completed in 2019. 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. After all necessary clinical and performance data supporting the safety and effectiveness of SCS are collected, Microbot must still obtain FDA clearance or approval to market the device and those regulatory processes can take several months to several years to be completed. Therefore, Microbot's ability to generate product revenues will not occur for at least the next few years, if at all, and will depend heavily on the successful commercialization of SCS in the treatment of hydrocephalus. The success of commercializing SCS will depend on a number of factors, including the following:

- our ability to obtain additional capital;
- successful completion of animal studies and, if necessary, human clinical trials and the collection of sufficient data to demonstrate that the device is safe and effective for its intended use;
- receipt of marketing approvals or clearances from the FDA and other applicable regulatory authorities;
- establishing commercial manufacturing arrangements with one or more third parties;
- obtaining and maintaining patent and trade secret protections;
- protecting Microbot's rights in its intellectual property portfolio;
- establishing sales, marketing and distribution capabilities;
- generating commercial sales of SCS, if and when approved, whether alone or in collaboration with other entities;
- acceptance of SCS, if and when commercially launched, by the medical community, patients and third-party payors;
- effectively competing with existing shunt and endoscope products on the market and any new competing products that may enter the market; and
- maintaining quality and an acceptable safety profile of SCS following clearance or approval.

If Microbot does not achieve one or more of these factors in a timely manner or at all, it could experience significant delays or an inability to successfully commercialize SCS, which would materially harm its business.

Microbot's ability to expand our technology platforms for other uses, including endovascular neurosurgery other than for the treatment of hydrocephalus, may be limited.

After spending time working with experts in the field, Microbot has recently decided to no longer pursue the use of TipCAT in colonoscopy and has instead committed to focus on expanding all of its technology platforms for use in segments of the endovascular neurosurgery market, including traumatic brain injury, to capitalize on its existing competencies in hydrocephalus and the market's needs. Microbot's ability to expand its technology platforms for use in the endovascular neurosurgery market will be limited by its ability to develop and/or refine the necessary technology, obtain the necessary regulatory approvals for their use on humans, and the marketing of its products and otherwise obtaining market acceptance of its product in the United States and in other countries.

Microbot operates in a competitive industry and if its competitors have products that are marketed more effectively or develop products, treatments or procedures that are similar, more advanced, safer or more effective, its commercial opportunities will be reduced or eliminated, which would materially harm its business.

Our competitors that have developed or are developing endoluminal robotics surgical systems include Corindus Vascular Robotics, Inc., Hansen Medical, Inc. Auris Health, Inc., Stereotaxis, Inc., Medrobotics Corporation and others. Our competitors may develop products, treatments or procedures that directly compete with our products and potential products and which are similar, more advanced, safer or more effective than ours. The medical device industry is very competitive and subject to significant technological and practice changes. Microbot expects to face competition from many different sources with respect to the SCS and products that it is seeking to develop or commercialize with respect to its other product candidates in the future.

Competing against large established competitors with significant resources may make establishing a market for any products that it develops difficult which would have a material adverse effect on Microbot's business. Microbot's commercial opportunities could also be reduced or eliminated if its competitors develop and commercialize products, treatments or procedures quicker, that are safer, more effective, are more convenient or are less expensive than the SCS or any product that Microbot may develop. Many of Microbot's potential competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than Microbot may have. Mergers and acquisitions in the medical device industry market may result in even more resources being concentrated among a smaller number of Microbot's potential competitors.

At this time, Microbot does not know whether the FDA will require it to submit clinical data in support of its future marketing applications for its SCS product candidate, particularly in light of recent initiatives by the FDA to enhance and modernize its approach to medical device safety and innovation, which creates uncertainty for Microbot as well as the possibility of increased product development costs and time to market.

Microbot anticipates that its lead product candidate, the SCS, will be classified by the FDA as Class II and thus be eligible for marketing pursuant to a cleared 510(k) notification. However, there is no guarantee that the FDA will agree with the Company's determination or that the FDA would accept the predicate device that Microbot intends to submit in its 510(k) notification in order to establish that its new device product is substantially equivalent to one or more predicate devices. The FDA also may request additional data in response to a 510(k) notification, or require Microbot to conduct further testing or compile more data in support of its 510(k) submission. Such additional data could include clinical data that must be derived from human clinical studies that are designed appropriately to address the potential questions from the FDA regarding a proposed product's safety or effectiveness. It is unclear at this time whether and how various activities recently initiated or announced by the FDA to modernize the U.S. medical device regulatory system could affect the marketing pathway or timeline for our product candidate, given the timing and the undeveloped nature of some of the FDA's new medical device safety and innovation initiatives. One of the recent initiatives was announced in April 2018, when the FDA Commissioner issued a statement with the release of a Medical Device Safety Action Plan. Among other key areas of the Medical Device Safety Action Plan, the Commissioner stated that the FDA is "exploring what further actions we can take to spur innovation towards technologies that can make devices and their use safer. For instance, our Breakthrough Device Program that helps address unmet medical needs can be used to facilitate patient access to innovative new devices that have important improvements to patient safety. We're considering developing a similar program to support the development of safer devices that do not otherwise meet the Breakthrough Program criteria, but are clearly intended to be safer than currently available technologies." This type of program may negatively affect our existing development plan for the SCS product candidate or it may benefit Microbot, but at this time those potential impacts from recent FDA medical device initiatives are unknown and uncertain. Similarly, the FDA Commissioner announced various agency goals under a Medical Innovation Access Plan in 2017.

If the FDA does require clinical data to be submitted as part of the SCS marketing submission, any type of clinical study performed in humans will require the investment of substantial expense, professional resources and time. In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, a company must, among other things, apply for and obtain Institutional Review Board, or IRB, approval of the proposed investigation. In addition, if the clinical study involves a "significant risk" (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an Investigational Device Exemption, or IDE, application. Microbot may not be able to obtain FDA and/or IRB approval to undertake clinical trials in the United States for any new devices Microbot intends to market in the United States in the future. Moreover, the timing of the commencement, continuation and completion of any future clinical trial may be subject to significant delays attributable to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delay in or failure to obtain IRB approval to conduct a clinical trial at a prospective site, and shortages of supply in the investigational device.

Thus, the addition of one or more mandatory clinical trials to the development timeline for the SCS would significantly increase the costs associated with developing and commercializing the product and delay the timing of U.S. regulatory authorization. The current uncertainty regarding near-term medical device regulatory changes by the FDA could further affect our development plans for the SCS, depending on their nature, scope and applicability. Microbot and its business, financial condition and operating results could be materially and adversely affected as a result of any such costs, delays or uncertainty.

We are subject to a lawsuit that could adversely affect our business.

We are named as the defendant in a lawsuit, which we refer to as the Matter, captioned Sabby Healthcare Master Fund Ltd. and Sabby Volatility Warrant Master Fund Ltd., Plaintiffs, against Microbot Medical Inc., Defendant, pending in the Supreme Court of the State of New York, County of New York (the "Court") (Index No. 654581/2017). The complaint alleges, among other things, that we breached multiple representations and warranties contained in the Securities Purchase Agreement (the "SPA") related to our June 8, 2017 equity financing, or the Financing, of which the Plaintiffs participated. The complaint seeks rescission of the SPA and return of the Plaintiffs' $3,375,000 purchase price with respect to the Financing, and damages in an amount to be determined at trial, but alleged to exceed $1 million. On August 3, 2018, both Plaintiffs and Defendant filed motions for summary judgment. On September 27, 2018, the Court heard oral argument on the parties' respective summary judgment motions. After oral argument, the Court denied Plaintiffs' motion in its entirety from the bench. On September 28, 2018, the Court issued a decision granting our motion for summary judgment regarding Plaintiffs' claim for monetary damages and denying our motion for summary judgment on Plaintiffs' claim for rescission, finding that there were material questions of fact that would need to be resolved at trial. A trial date has been set for February 11, 2019. On January 8, 2019, the plaintiffs filed a motion seeking to amend the complaint to also pursue rescission on a material misrepresentation theory.

On April 4, 2018, we entered into a Tolling and Standstill Agreement with Empery Asset Master, Ltd., Empery Tax Efficient LP, Empery Tax Efficient II LP, and Hudson Bay Master Fund, Ltd., the other investors in the Financing, of whom we refer to as the Other Investors. Pursuant to the Tolling Agreement, among other things, (a) the Other Investors agree not to bring any claims against us arising out of the Matter, (b) the parties agree that if we reach an agreement to settle the claims asserted by the Sabby Funds in the above suit, we will provide the same settlement terms on a pro rata basis to the Other Investors, and the Other Investors will either accept same or waive all of their claims and (c) the parties froze in time the rights and privileges of each party as of the effective date of the Tolling Agreement, until (i) an agreement to settle the suit is executed; (ii) a judgment in the suit is obtained; or (iii) the suit is otherwise dismissed with prejudice.

We believe that the claims are without merit and have been and intend to continue to defend the action vigorously. However, management is unable to assess the likelihood of the claim and the amount of potential damages, if any, to be awarded. Accordingly, no assurance can be given that any adverse outcome would not be material to our consolidated financial position. Additionally, in the event the court holds for the Plaintiffs in the Matter and we lose our appeals, we will likely be required to use available cash towards payment of damages to the Plaintiffs and the Other Investors, that we otherwise would have used to build our business and develop our technologies into commercial products. In such event, we would be required to raise additional capital sooner than we otherwise would, of which we can give no assurance of success.