

Microbot Medical Inc.
Form S-1/A
December 31, 2018

As filed with the Securities and Exchange Commission on December 28 , 2018

Registration No. 333-228285

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

Amendment No. 3

to

FORM S-1

**REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

MICROBOT MEDICAL INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

2836

94-3078125

(State or Other Jurisdiction of
Incorporation or Organization)

(Primary Standard Industrial
Classification Code Number)

(I.R.S. Employer
Identification Number)

**25 Recreation Park Drive, Unit 108
Hingham, MA 02043**

(781) 875-3605

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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Estimated solely for purposes of computing the amount of the registration fee pursuant to Rule 457(o) under the
(1) Securities Act of 1933, as amended (the "Securities Act"). Includes securities subject to the underwriter's option to purchase additional securities.

Pursuant to Rule 416 under the Securities Act, the shares of common stock registered hereby also include an
(2) indeterminate number of additional shares of common stock as may, from time to time, become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.

The proposed maximum aggregate offering price of the units proposed to be sold in the offering will be reduced
(3) on a dollar-for-dollar basis based on the offering price of any pre-funded units offered and sold in the offering, and as such the proposed maximum aggregate offering price of the units and pre-funded units (including the common stock issuable upon exercise of the pre-funded warrants included in the pre-funded units), if any, is \$11,500,000.

(4) No additional registration fee is payable pursuant to Rule 457(i) under the Securities Act.

(5) No additional registration fee is payable pursuant to Rule 457(g) under the Securities Act.

Represents warrants to purchase a number of shares of common stock equal to 5.0% of the number of shares of common stock (i) included within the units and (ii) issuable upon the exercise of the pre-funded warrants included
(6) within the pre-funded units placed in this offering at an exercise price equal to 125% of the offering price per unit (excluding any shares of common stock underlying the common warrants included in the units and the pre-funded units sold in this offering).

A filing fee of \$2,961.83 was previously paid with respect to shares of the Registrant's common stock to be registered pursuant to a Registration Statement on Form S-1 (Registration No. 333-228285) initially filed with the
(7) SEC on November 8, 2018 as amended by Amendment No. 1 filed with the SEC on November 19, 2018 and Amendment No. 2 filed with the SEC on December 17, 2018. Accordingly, the Registrant has paid the balance of \$2,700.48 in connection with the filing of Amendment No. 3 to Form S-1.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED DECEMBER 28, 2018

Up to 6,024,096 Units (each Unit contains one Share of Common Stock and one Common Warrant to purchase one Share of Common Stock)

Up to 6,024,096 Pre-funded Units (each Pre-funded Unit contains one Pre-funded Warrant to purchase one Share of Common Stock and one Common Warrant to purchase one Share of Common Stock)

6,024,096 Shares of Common Stock Underlying the Pre-funded Warrants and

6,024,096 Shares of Common Stock Underlying the Common Warrants

We are offering up to 6,024,096 units (each unit consisting of one share of our common stock and one common warrant to purchase one share of our common stock). Each common warrant contained in a unit will have an assumed exercise price of \$1.66 per share (representing 100% of the assumed public offering price per unit to be sold in this offering) (which may be adjusted as set forth in this prospectus). The common warrants contained in the units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the units.

We are also offering to each purchaser whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock) in lieu of units that

would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding common stock (or at the election of the purchaser, 9.99%). Each pre-funded warrant contained in a pre-funded unit will be exercisable for one share of our common stock. The purchase price of each pre-funded unit will equal the price per unit being sold to the public in this offering minus \$0.01, and the exercise price of each pre-funded warrant included in the pre-funded unit will be \$0.01 per share. The pre-funded warrants contained in the pre-funded units will be exercisable immediately and may be exercised at any time until the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants contained in the pre-funded units sold in this offering. Each common warrant contained in a pre-funded unit will have an assumed exercise price of \$1.66 per share (representing 100% of the assumed public offering price per unit to be sold in this offering) (which may be adjusted as set forth in this prospectus). The common warrants contained in the pre-funded units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the pre-funded units.

For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. Units and the pre-funded units will not be issued or certificated. The shares of common stock or pre-funded warrants, as the case may be, and the common warrants can only be purchased together in this offering but the securities contained in the units or pre-funded units will be issued separately.

Our common stock is listed on The Nasdaq Capital Market under the ticker symbol "MBOT". On December 24, 2018, the closing price of our common stock on The Nasdaq Capital Market was \$1.66. We do not intend to apply for listing of the common warrants or pre-funded warrants on any securities exchange or other nationally recognized trading system. There is no established public trading market for the common warrants or pre-funded warrants, and we do not expect a market to develop. Without an active trading market, the liquidity of the common warrants and pre-funded warrants will be limited. We have assumed a public offering price of \$1.66 per unit, the closing price for our common stock as reported on The Nasdaq Capital Market on December 24, 2018, and \$1.65 per pre-funded unit. The actual offering price per unit or pre-funded unit, as the case may be, will be negotiated between us and the underwriter based on the trading of our common stock prior to the offering, among other things, and may be at a discount to the current market price. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final offering price.

Investing in our securities involves a high degree of risk. See the section entitled "Risk Factors" beginning on page 7 of this prospectus and in the documents incorporated by reference into this prospectus for a discussion of risks that should be considered in connection with an investment in our securities.

	Per Unit	Per Pre-Funded Unit	Total
Public offering price	\$	\$	\$
Underwriting discounts and commissions(1)	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

(1) See “Underwriting” beginning on page 21 of this prospectus for a description of compensation and reimbursement of expenses payable to the underwriter.

The offering is being underwritten on a firm commitment basis. We have granted the underwriter an option for a period of 30 days from the date of this prospectus to purchase up to an additional 903,614 shares of our common stock at a purchase price of \$ per share and/or common warrants to purchase up to an aggregate of 903,614 shares of common stock at a purchase price of \$0.01 per common warrant with an exercise price of \$ per share, less the underwriting discounts and commissions . If the underwriter exercises this option in full, the total underwriting discounts and commissions payable by us will be \$, and the total proceeds to us, before expenses, will be \$.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Delivery of the securities to purchasers is expected on or about , 2018, subject to certain customary closing conditions.

Sole Book-Running Manager

H.C. Wainwright & Co.

The date of this prospectus is , 2018

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We have not, and the underwriter has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable, authorized free writing prospectus is current only as of its date, and any information in documents incorporated by reference is current only as of the date of the document incorporated by reference, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriter has not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus or information incorporated by reference into this prospectus from our filings with the Securities and Exchange Commission, or SEC, listed in the section of the prospectus entitled “Incorporation of Certain Information by Reference.” Because it is only a summary, it does not contain all of the information that you should consider before purchasing our securities in this offering and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere or incorporated by reference into this prospectus. You should read the entire prospectus, the registration statement of which this prospectus is a part, and the information incorporated by reference herein in their entirety, including the “Risk Factors” and our financial statements and the related notes incorporated by reference into this prospectus, before purchasing our securities in this offering. Unless the context requires otherwise, references in this prospectus to “Microbot,” “we,” “us” and “our” refer to Microbot Medical Inc. together with its wholly owned subsidiaries.

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. 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 either in a regulatory submission or as part of a pre-submission meeting request, depending on the final results of this ongoing studies. 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 submitted as part of a 510(k) notification 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.

Risks Associated with Our Business and this Offering

Our business and our ability to implement our business strategy are subject to numerous risks, as more fully described in the section of this prospectus entitled “Risk Factors” and under similarly titled headings of the documents incorporated herein by reference. You should read these risks before you invest in our securities. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include:

We will need to raise significant additional capital to support our operations.

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain.

Our product candidates must undergo rigorous clinical testing, such clinical testing may fail to demonstrate safety and efficacy and any of our product candidates could cause undesirable side effects, which would substantially delay or prevent regulatory approval or commercialization.

We are dependent on patents and proprietary technology. If we fail to adequately protect this intellectual property or if we otherwise do not have exclusivity for the marketing of our products, our ability to commercialize products could suffer.

If our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited.

If you purchase our securities in this offering, you will incur immediate and substantial dilution.

We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Corporate and Other Information

We were 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 our name to CytoTherapeutics, Inc. On May 24, 2000, the Certificate of Incorporation as restated was further amended to change our name to StemCells, Inc. On November 28, 2016, C&RD Israel Ltd., a wholly-owned subsidiary of ours, completed its merger with and into Microbot Medical Ltd., or Microbot Israel, an Israeli corporation that then owned our assets and operated our current business, with Microbot Israel surviving as a wholly-owned subsidiary of ours. We refer to this transaction as the Merger. On November 28, 2016, in connection with the Merger, we changed our name from “StemCells, Inc.” to Microbot Medical Inc., and each outstanding share of Microbot Israel capital stock was converted into the right to receive shares of our common stock. In addition, all outstanding options to purchase the ordinary shares of Microbot

Israel were assumed by us and converted into options to purchase shares of the common stock of Microbot Medical Inc. On November 29, 2016, our common stock began trading on the Nasdaq Capital Market under the symbol “MBOT”. Prior to the Merger, we were a biopharmaceutical company that operated in one segment, the research, development, and commercialization of stem cell therapeutics and related technologies. Substantially all of the material assets relating to the stem cell business were sold on November 29, 2016.

In May 2016, we effected a 1-for-12 reverse split of our common stock, and in November 2016, we effected a 1-for-9 reverse split of our common stock in connection with the Merger. In September 2018, we effected a 1-for-15 reverse split of our common stock. The share and per share information described in this prospectus that occurred prior to these reverse splits have been adjusted to give retrospective effect to the reverse splits.

Our principal executive offices are located at 25 Recreation Park Drive, Unit 108, Hingham, MA 02043. The telephone number at our principal executive office is (781) 875-3605. Our website address is www.microbotmedical.com. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on our website or any such information in making your decision whether to purchase our securities in this offering.

This prospectus contains references to our trademarks and to trademarks and trade names belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company” as defined in the Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies, including certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The Offering

Units offered by us Up to 6,024,096 units, each consisting of one share of our common stock and one common warrant to purchase one share of our common stock.

Pre-funded units offered by us We are also offering to each purchaser whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock) in lieu of units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding common stock (or, at the election of the purchaser, 9.99%). The purchase price of each pre-funded unit will equal the price at which the units are being sold to the public in this offering, minus \$0.01, and the exercise price of each pre-funded warrant included in each pre-funded unit will be \$0.01 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. Because we will issue a common warrant as part of each unit or pre-funded unit, the number of common warrants sold in this offering will not change as a result of a change in the mix of the units and pre-funded units sold.

Common warrants offered by us Common warrants to purchase an aggregate of 6,024,096 shares of our common stock. Each unit and each pre-funded unit includes a common warrant to purchase one share of our common stock. Each common warrant will have an assumed exercise price of \$1.66 per share (representing 100% of the assumed public offering price per unit to be sold in this offering) (which may be adjusted as set forth in this prospectus), will be immediately separable from the common stock or pre-funded warrant, as the case may be, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.

Option to purchase additional securities The underwriter has the option to purchase up to an additional 903,614 shares of our common stock at a purchase price of \$ per share and/or common warrants to purchase up to an aggregate of 903,614 shares of common stock at a purchase price of \$0.01 per common warrant with an exercise price of \$ per share, less underwriting discounts and commissions. The underwriter can exercise this option at any time within 30 days from the date of this prospectus.

Common stock to be outstanding immediately 9,036,439 shares (assuming no exercise of the underwriter's option to purchase additional securities, assuming no sale of any pre-funded units and assuming none of the common warrants issued in this offering are exercised).

after this offering ⁽¹⁾

Public offering price

The assumed public offering price is \$1.66 per unit and \$1.65 per pre-funded unit, which is based on the closing price for our common stock as reported on The Nasdaq Capital Market on December 24, 2018. The actual offering price per each unit and pre-funded unit will be negotiated between us and the underwriter based on the trading of our common stock prior to the offering, among other things, and may be at a discount to the current market price.

Use of proceeds

We intend to use the net proceeds from this offering for attaining regulatory approvals for our SCS device for the treatment of hydrocephalus and NPH; expanding and developing the applications of our existing ViRob and SCS IP and prototypes into other areas of CSF management, such as EVD, through regulatory submission; developing the CardioSert™ technology, including the potential addition of complementary assets to the CardioSert portfolio either through internal development or acquisition, for neurovascular disorders from proof of concept to pre-clinical studies; and for working capital and other general corporate purposes. See “Use of Proceeds.”

Risk Factors

An investment in our securities involves a high degree of risk. See “Risk Factors” beginning on page 7 of this prospectus and the similarly titled sections in the documents incorporated by reference into this prospectus.

Nasdaq Capital Market trading symbol

Our common stock is listed on The Nasdaq Capital Market under the symbol “MBOT.” We do not intend to apply for listing of the common warrants or pre-funded warrants on any securities exchange or other nationally recognized trading system. There is no established public trading market for the common warrants or pre-funded warrants, and we do not expect a market to develop. Without an active trading market, the liquidity of the common warrants and pre-funded warrants will be limited.

- (1) The number of shares of our common stock to be outstanding after this offering is based on 3,012,343 shares of common stock outstanding as of December 24, 2018, and excludes, as of December 24, 2018:

422,478 shares of our common stock issuable upon the exercise of outstanding stock options, with exercise prices ranging from \$0 to \$19.35 and having a weighted-average exercise price of \$11.70 per share;

211,239 shares of our common stock reserved for future grant under our 2017 Equity Incentive Plan;

Approximately 7,531 shares of our common stock issuable upon the exercise of outstanding warrants, with exercise prices ranging from approximately \$40.00 to \$2,885 per share and having a weighted-average exercise price of \$1,697 per share;

6,024,096 shares of common stock issuable upon the exercise of common warrants to be issued to investors in this offering at an exercise price of \$ _____ per share; and

301,204 shares (or 346,385 shares if the underwriter’s option to purchase additional securities is exercised in full) of our common stock issuable upon exercise of the warrants being issued to the underwriter in connection with this offering.

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Except as otherwise indicated herein, all information in this prospectus, including the number of shares that will be outstanding after this offering, does not assume or give effect to the exercise of options or warrants outstanding as of December 24, 2018 and assumes no sale of any pre-funded units in this offering.

Unless otherwise indicated, all information contained in this prospectus assumes no exercise by the underwriter of its option to purchase additional securities.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks described below, together with all of the other information included or incorporated by reference in this prospectus, including the risks and uncertainties discussed under “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2018, before deciding whether to purchase our securities in this offering. All of these risk factors are incorporated herein in their entirety. The risks described below and incorporated by reference are material risks currently known, expected or reasonably foreseeable by us. However, the risks described below or that we incorporate by reference are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition. If any of these risks actually materialize, our business, prospects, financial condition, and results of operations could be seriously harmed. This could cause the trading price of our common stock and the value of the warrants to decline, resulting in a loss of all or part of your investment.

Risks Relating to the Development and Commercialization of Microbot’s Product Candidates

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.

Risks Related to this Offering

You will experience immediate and substantial dilution if you purchase securities in this offering.

As of September 30, 2018, our net tangible book value was approximately \$6,566,000 , or \$2.2066 per share. You will not suffer any dilution if you purchase securities in this offering with respect to the net tangible book value of the common stock included in the units or issuable upon the exercise of the common warrants or the pre-funded warrants issued in this offering, based on the assumed public offering price of \$1.66 per unit being sold in this offering (the closing price of our common stock on The Nasdaq Capital Market on December 24, 2018) and our net tangible book value per share as of September 30, 2018. However, upon certain circumstances such as increases in the actual public offering price per share in this offering, you can suffer immediate and substantial dilution per share with respect to the net tangible book value of the common stock included in the units or issuable upon the exercise of the common warrants or the pre-funded warrants issued in this offering. See the section entitled “Dilution” for a more detailed discussion of the dilution, if any, you will incur if you purchase units in this offering. The discussion above assumes (i) no sale of common warrants or the pre-funded warrants, which, if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis until such warrants are exercised and (ii) no exercise by the underwriter of the Underwriter’s Warrants.

There is no public market for the common warrants or the pre-funded warrants being offered in this offering.

There is no established public trading market for the common warrants or the pre-funded warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the common warrants or the pre-funded warrants on any securities exchange or nationally recognized trading system, including The Nasdaq Capital Market. Without an active market, the liquidity of the common warrants and the pre-funded warrants will be limited.

We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management may not apply the net proceeds from this offering in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities or as otherwise provided in our investment policies in effect from time to time. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

We are subject to a lawsuit that could adversely affect our business and our use of proceeds from this offering.

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 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 the proceeds from this offering or 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.

There may be future sales of our securities or other dilution of our equity, which may adversely affect the market price of our common stock.

We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock after this offering or the perception that such sales could occur.

Holders of common warrants and pre-funded warrants purchased in this offering will have no rights as common stockholders until such holders exercise their respective warrants and acquire our common stock.

Until holders of common warrants and pre-funded warrants acquire shares of our common stock upon exercise of their respective warrants, holders of such warrants will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of such warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the applicable exercise date.

Even if this offering is successful, we will need to raise additional capital in the future to continue operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We have had significant recurring losses from operations and we do not generate any cash from operations and must raise additional funds in order to continue operating our business. We expect to continue to fund our operations in the future primarily through equity and debt financings, grants from the Israel Innovation Authority and other sources. If additional capital is not available to us when needed or on acceptable terms, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely. As of September 30, 2018, we had cash and cash equivalents of approximately \$6.7 million. We estimate that we will receive net proceeds of approximately \$8.7 million from the sale of the securities offered by us in this offering, based on the assumed

public offering price of \$1.66 per unit (the closing price of our common stock on The Nasdaq Capital Market on December 24, 2018) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the common warrants and the pre-funded warrants issued pursuant to this offering. In the event of a decrease in the net proceeds to us from this offering as a result of a decrease in the assumed public offering price or the number of units offered by us, if the Plaintiffs succeed in the Matter or if our use of proceeds changes from our plans as described under “Use of Proceeds”, we may need to raise additional capital sooner than we anticipate. In addition, we cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Our ability to raise additional funds will depend, in part, on the success of our product development activities, any clinical trials, regulatory events, our ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic and market conditions, many of which are beyond our control. There can be no assurances that sufficient funds will be available to us when required or on acceptable terms, if at all.

If we are unable to secure additional funds when needed or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of technology or assets, pursue an acquisition of our company by a third party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations. Moreover, if we are unable to obtain additional funds on a timely basis, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and up to a total loss of investment by our stockholders.

The common warrants and the pre-funded warrants in this offering are speculative in nature.

Neither the common warrants nor the pre-funded warrants in this offering confer any rights of common stock ownership on its holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price and, with respect to the common warrants, during a fixed period of time. Specifically, commencing on the date of issuance, holders of the common warrants may exercise their right to acquire the common stock and pay an exercise price of \$ _____ per share, subject to certain adjustments, prior to the expiration of the common warrants on the fifth anniversary of the original issuance date. Commencing on the date of issuance, holders of the pre-funded warrants may exercise their right to acquire the common stock and pay an exercise price of \$0.01 per share, subject to certain adjustments, at any time until the pre-funded warrants are exercised in full. Moreover, following this offering, the market value of the common warrants and the pre-funded warrants, if any, is uncertain and there can be no assurance that the market value of the common warrants or the pre-funded warrants will equal or exceed their imputed offering price. Neither the common warrants nor the pre-funded warrants will be listed or quoted for trading on any market or exchange. There can also be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the common warrants, and consequently, whether it will ever be

profitable for holders of the common warrants to exercise the common warrants.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” in this prospectus or the documents incorporated herein by reference. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

our estimates regarding anticipated operating losses, capital requirements and needs for additional funds;

our ability to raise additional capital when needed and to continue as a going concern;

our ability to manufacture, or otherwise secure the manufacture of, sufficient amounts of our product candidates for our preclinical studies and clinical trials;

our ability to find and develop applications for our technologies for other neurosurgical conditions besides hydrocephalus;

our clinical development and other research and development plans and expectations;

the safety and efficacy of our product candidates;

the anticipated regulatory pathways for our product candidates;

our ability to successfully complete preclinical and clinical development of, and obtain regulatory approval of our product candidates and commercialize any approved products on our expected timeframes or at all;

the content and timing of submissions to and decisions made by the U.S. Food and Drug Administration and other regulatory agencies;

our ability to leverage the experience of our management team;

our ability to attract and keep management and other key personnel;

the capacities and performance of our suppliers, manufacturers and other third parties over whom we have limited control;

the actions of our competitors and success of competing products that are or may become available;

our expectations with respect to future growth and investments in our infrastructure, and our ability to effectively manage any such growth;

the size and potential growth of the markets for any of our product candidates, and our ability to capture share in or impact the size of those markets;

the benefits of our product candidates;

market and industry trends;

the outcome of any litigation in which we or any of our officers or directors may be involved, including with respect to the Matter;

the effects of government regulation and regulatory developments, and our ability and the ability of the third parties with whom we engage to comply with applicable regulatory requirements;

the accuracy of our estimates regarding future expenses, revenues, capital requirements and need for additional financing;

our expectations regarding future planned expenditures;

our ability to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act;

our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of any of our products and product candidates;

our expected use of the net proceeds from this offering; and

our ability to operate our business without infringing the intellectual property rights of others.

In some cases, you can identify these statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions convey uncertainty of future events or outcomes. These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the documents incorporated by reference herein, usually under the heading “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should carefully read this prospectus, the documents that we incorporate by reference into this prospectus and the documents we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different

from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.