

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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

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

For the transition period from ____ to ____

Commission file number: 000-19871

MICROBOT MEDICAL INC.

(Exact name of registrant as specified in its charter)

Delaware

*(State or Other Jurisdiction
of Incorporation or Organization)*

94-3078125

*(I.R.S. Employer
Identification No.)*

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

(Address including zip code of registrant's Principal Executive Offices)

(781) 875-3605

(Registrant's Telephone Number, Including Area Code)

Securities registered under Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par value \$0.01	MBOT	NASDAQ Capital Market

Securities registered under Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data file required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

Accelerated filer

Smaller reporting company

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.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently

completed second fiscal quarter: approximately \$46,050,375.

Common stock outstanding as of March 29, 2021: 7,108,133 shares

INFORMATION CONCERNING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements. Forward-looking statements are projections in respect of future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as “may”, “should”, “intends”, “expects”, “will”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, or “continue” or the negative of these terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks listed under the section entitled “Risk Factors” commencing on page 22 of this report, which may cause our or our industry’s actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements.

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NOTE REGARDING REFERENCES TO OUR COMPANY

Throughout this Form 10-K, the words “we,” “us,” “our,” the “Company” and “Microbot” refer to Microbot Medical Inc., including our directly and indirectly wholly-owned subsidiaries and, unless the context otherwise requires, the historical business, financial statements and operations of Microbot are of Microbot Medical Ltd., an Israeli corporation (“Microbot Israel”) which became a wholly-owned subsidiary of the Company on November 28, 2016.

Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, operations, and financial results. A more thorough discussion of these and other risks are listed under the section entitled “Risk Factors” commencing on page 22.

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

- Microbot has had no revenue and has incurred significant operating losses since inception and is expected to continue to incur significant operating losses for the foreseeable future. The Company may never become profitable or, if achieved, be able to sustain profitability.
- Microbot has a limited operating history, which may make it difficult to evaluate the prospects for the Company’s future viability.
- Microbot may need additional funding. If Microbot is unable to raise capital when needed, it could be forced to delay, reduce or eliminate its product development programs or commercialization efforts.
- An epidemic of the coronavirus disease is ongoing and may result in significant disruptions to our clinical trials or other business operations, which could have a material adverse effect on our business.

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

- Unsuccessful animal studies, clinical trials or procedures relating to product candidates under development could have a material adverse effect on Microbot’s prospects.
- Microbot’s business depends heavily on the success of its lead product candidates, the LIBERTY™ and SCS. If Microbot is unable to commercialize the LIBERTY or SCS, or experiences significant delays in doing so, Microbot’s business will be materially harmed.
- Microbot’s ability to expand its technology platforms for other uses, including endovascular neurosurgery other than for the treatment of hydrocephalus, may be limited.
- 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.
- The FDA may disagree with Microbot’s determination that the SCS is a Class II device or that the chosen predicate device (or any predicate device) is appropriate for a substantial equivalence comparison to the SCS.
- Microbot’s CardioSert technology is subject to a buy-back clause which, if triggered, could cause us to lose rights to the technology and delay or curtail the development of our products.
- If the commercial opportunity for SCS, LIBERTY and any other commercial products that may be developed by Microbot is smaller than Microbot anticipates, Microbot’s future revenue from SCS, LIBERTY and such other products will be adversely affected and Microbot’s business will suffer.
- Customers will be unlikely to buy the SCS, LIBERTY or any other product candidates unless Microbot can demonstrate that they can be produced for sale to consumers at attractive prices.
- Microbot will rely on third party design houses for the redesign of the CardioSert guidewire to other specific indications.
- Microbot has relied on, and intends to continue to rely on, third-party manufacturers to produce its product candidates.
- If Microbot’s product candidates are not considered to be a safe and effective alternative to existing technologies, Microbot will not be commercially successful.
- Microbot may be subject to penalties and may be precluded from marketing its product candidates if Microbot fails to comply with extensive governmental regulations.
- If Microbot is not able to both obtain and maintain adequate levels of third-party reimbursement for procedures involving its product candidates after they are approved for marketing and launched commercially, it would have a material adverse effect on Microbot’s business.
- Clinical outcome studies for the SCS may not provide sufficient data to make Microbot’s product candidates the standard of care.
- Microbot products may in the future be subject to mandatory product recalls that could harm its reputation, business and financial results.
- If Microbot’s future commercialized products cause or contribute to a death or a serious injury, Microbot will be subject to Medical Device Reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.
- Microbot could be exposed to significant liability claims if Microbot is unable to obtain insurance at acceptable costs and adequate levels or otherwise protect itself against potential product liability claims.
- The results of Microbot’s research and development efforts are uncertain and there can be no assurance of the commercial success of Microbot’s product candidates.
- If Microbot fails to retain certain of its key personnel and attract and retain additional qualified personnel, Microbot might not be able to pursue its growth strategy effectively.

Risks Relating to Microbot's Intellectual Property

- Microbot's right to develop and commercialize the SCS and TipCAT product candidates are subject to the terms and condition of a license granted to Microbot by Technion Research and Development Foundation Ltd. and termination of the license with respect to one or both of the technology platforms underlying the product candidates would result in Microbot ceasing its development efforts for the applicable product candidate(s).
- Microbot may not meet its product candidates' development and commercialization objectives in a timely manner or at all.
- Intellectual property litigation and infringement claims could cause Microbot to incur significant expenses or prevent Microbot from selling certain of its product candidates.
- If Microbot or TRDF are unable to protect the patents or other proprietary rights relating to Microbot's product candidates, or if Microbot infringes on the patents or other proprietary rights of others, Microbot's competitiveness and business prospects may be materially damaged.
- Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may result in Microbot's payment of significant monetary damages or impact offerings in its product portfolios.

Risks Relating to Operations in Israel

- Microbot has facilities located in Israel, and therefore, political conditions in Israel may affect Microbot's operations and results.
- Political relations could limit Microbot's ability to sell or buy internationally.
- Israel's economy may become unstable.
- Exchange rate fluctuations between the U.S. dollar and the NIS currencies may negatively affect Microbot's operating costs.
- Funding and other benefits provided by Israeli government programs may be terminated or reduced in the future and the terms of such funding may have a significant impact on future corporate decisions.
- Some of Microbot's employees and officers are obligated to perform military reserve duty in Israel.
- It may be difficult to enforce a non-Israeli judgment against Microbot or its officers and directors.

Risks Relating to Microbot's Securities, Governance and Other Matters

- If we fail to comply with the continued listing requirements of The Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.
- We do not expect to pay cash dividends on our common stock.
- Anti-takeover provisions in the Company's charter and bylaws under Delaware law may prevent or frustrate attempts by stockholders to change the board of directors or current management and could make a third-party acquisition of the Company difficult.
- We are subject to litigation, which may divert management's attention and have a material adverse effect on our business, financial condition and results of operations.

PART I

Item 1. Description of Business.

The 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 redefining surgical robotics while improving surgical outcomes for patients.

Microbot's current technological platforms, ViRob™, TipCAT™, LIBERTY™ and certain CardioSert assets, are comprised of proprietary innovative technologies. Using the ViRob platform, Microbot is currently developing the Self Cleaning Shunt, or SCS™, for the treatment of hydrocephalus and Normal Pressure Hydrocephalus, or NPH. Utilizing the LIBERTY and CardioSert platforms, Microbot is developing the first ever fully disposable robot for various endovascular interventional procedures. In addition, the Company is focused on the development of a Multi Generation Pipeline Portfolio utilizing all of its proprietary technologies.

Microbot has a patent portfolio of 42 issued/allowed patents and 23 patent applications pending worldwide.

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.

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.

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.

CardioSert Technology

On April 8, 2018, Microbot acquired a patent-protected technology from CardioSert Ltd., a privately-held medical device company based in Israel that was part of a technological incubator supported by the Israel Innovation Authorities. 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.

LIBERTY

On January 13, 2020, Microbot unveiled what it believes is the world's first fully disposable robotic system for use in Endovascular Interventional procedures, such as cardiovascular, peripheral and neurovascular. The LIBERTY robotic system features a unique compact design with the capability to be operated remotely, reduce radiation exposure and physical strain to the physician, reduce the risk of cross contamination, as well as the potential to eliminate the use of multiple consumables when used with its "One & Done" capabilities, which would be based in part on the CardioSert platform or possibly other guidewire/microcatheter technologies.

LIBERTY is designed to maneuver guidewires and over-the-wire devices (such as microcatheters) within the body's vasculature. It eliminates the need for extensive capital equipment requiring dedicated Cath-lab rooms as well as dedicated staff. In addition, when combined with CardioSert technology or possibly other guidewire/microcatheter technologies, it is being designed to streamline Cath-lab procedures with our proprietary "One & Done" tool that combines guidewire and microcatheter into a single device. With control over tip curvature and stiffness for maneuverability and access – and without the need for constant tool exchanges – the "One & Done" feature, when integrated into the LIBERTY device, may drastically reduce procedure time and costs while enhancing the operator experience.

On August 17, 2020, Microbot announced the successful conclusion of its feasibility animal study using the LIBERTY robotic system. The study met all of its end points with no intraoperative adverse events, which supports Microbot's objectives to allow physicians to conduct a catheter-based procedure from outside the catheterization laboratory (cath-lab), avoiding radiation exposure, physical strain and the risk of cross contamination. The study was performed by two leading physicians in the neuro vascular and peripheral vascular intervention spaces, and the results demonstrated robust navigation capabilities, intuitive usability and accurate deployment of embolic agents, most of which was conducted remotely from the cath-lab's control room.

We are continuously exploring and evaluating additional innovative guidewire/microcatheter technologies to be integrated and combined with the LIBERTY robotic platform.

Recent Developments

On January 14, 2021, Microbot announced the successful completion of an additional feasibility animal study using the LIBERTY robotic system. The study end points included navigating to a clot, crossing the clot, deploying a stent retriever, and manually retrieving an arterial clot in a live pig. All the end points were met with no intraoperative adverse events. This and earlier animal feasibility studies support Microbot's assertion that LIBERTY will potentially allow physicians to safely and easily conduct catheter-based peripheral and neurovascular procedures remotely, avoiding radiation exposure, physical strain and the risk of cross contamination.

On January 21, 2021, Microbot announced the continued enhancement of its thought leadership capabilities with the addition of several new Scientific Advisory Board members:

- Stephen B. Solomon, MD, a board-certified radiologist with clinical expertise in Interventional Radiology with a focus in Tumor Ablation;
- Ajay K. Wakhloo, MD PhD FAHA, an internationally recognized expert in acute stroke therapy and the isolation of intracranial aneurysms and arteriovenous malformations;
- Gal Yaniv, MD, PhD, an endovascular neurosurgeon and leading authority on Artificial Intelligence;
- Dmitry J. Rabkin, MD, PhD, FSIR, a vascular and Interventional Radiology Specialist; and
- Ziv Neeman, MD, a vascular and interventional radiology clinician and researcher with a wide array of expertise, particularly in the field of navigation systems for minimally invasive image-guided interventional procedures.

On January 27, 2021, Microbot announced the completion of successful discussions with the U.S. Food and Drug Administration, or FDA, for the SCS™. After review of Microbot's existing pre-clinical data, the FDA's feedback will allow Microbot to apply for a limited clinical investigation known as an Early Feasibility Study, or EFS. Microbot expects to continue to work with the FDA towards finalizing the SCS™ design, and to incorporate their feedback prior to submitting the Investigational Device Exemption, or IDE, to seek authorization to begin the EFS clinical trial. While there can be no assurance that the FDA will approve the EFS study, the agency's recent feedback indicates that the agency will be receptive to allowing a first-in-human study to proceed based on existing data. After completing the EFS, Microbot would then seek FDA input on the device design as finalized through the EFS process in a subsequent IDE filing for approval of a clinical study proposal. Consequently, the timeline for the First-in-Human clinical trial under the EFS is expected to commence following IDE approval, estimated in the third quarter of 2022.

On February 4, 2021, Microbot announced that it has received official notification from the Japan Patent Office (JPO) that it intends to grant Microbot a patent for its 'One & Done' guidewire technology for use with endoluminal interventions. Japan is the second jurisdiction to grant a patent for the 'One & Done' guidewire technology and further protects the novel technology Microbot is currently developing.

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 replaced with 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 Robot-Assisted Endovascular Interventions

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 surgery is expected to grow from \$24 billion in 2020 to \$42 billion in 2026, representing a CAGR of 9.85%. MIS involves three major categories 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. According to the Society of Robotic Surgery, the US market growth in endoluminal robotic surgery is projected to be 15-25% by 2025.

Vascular disease is the most common precursor to ischemic heart disease and stroke, which are two of the leading causes of death worldwide. Advances in endovascular intervention in recent years have transformed patient survival rates and post-surgical quality of life. It is estimated that more than three million percutaneous coronary interventions (PCI) and over two million of peripheral vascular interventions are performed annually worldwide. The incidence of stroke in the US alone is estimated at 900,000 cases annually. Compared to open surgery, it has the advantages of faster recovery, reduced need for general anesthesia, reduced blood loss and significantly lower mortality. However, the current practice of endovascular procedures, which virtually has remained unchanged since the introduction of Intervention four decades ago, is limited by a number of factors, including physical strain and exposure to X-Ray radiation of the operator, and involves complex maneuvering of intervention tools, such as guidewires and catheters, to reach target areas in the vasculature. Despite recent advancements in technology and devices, manual procedures are still highly dependent on the technical skills and training of the operator, what makes the access to expert medical centers and advanced emergent treatments, such as endovascular thrombectomy for acute ischemic stroke, geographically limited. In addition, we believe that demand for physicians continues to grow faster than supply.

Endovascular robotic systems are aimed to increase the stability and precision of guidewires and catheters, protecting the physicians from ionizing radiation and physical strain by removing them from the radiation source, helping in closing shortages of skilled physicians and skill gaps and enable tele-interventions (e.g. the Hub & Spoke hospital model).

Today, there are only few commercially available robotic systems for endovascular interventions. We believe these systems have major drawbacks, such as limited maneuverability, the requirement to exchange and use multiple expensive surgical tools, being cumbersome to set-up and operate, and requiring significant capital expenditures.

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 CardioSert and LIBERTY technologies, 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 interventions.

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 treat 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 continuing 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 first stage 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. Following the completion of the first stage initial studies, Microbot commenced a follow-up study to further evaluate the safety of the SCS. The follow-up study was also conducted by leading hydrocephalus experts at Washington University. The study, included a larger sample size compared to the initial studies and the primary and secondary endpoints were to validate the safety of the activated SCS in-vivo (animal) models. In that in-vivo study the major finding was that the SCS system is as safe to use as currently marketed devices. The study also mentions, that in the animal model, contact of the shunt with the choroid plexus is impossible to avoid and that it may lead to shunt obstruction due to hemorrhage of this highly vascular structure

In parallel with the in-vivo 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. Human brain glioblastoma cells were used in order to assess performance of the SCSTM in a test system with accelerated cell growth, accumulation and obstruction rates. In 2018, Microbot and Envigo conducted an in-vitro trial that its final conclusion was:

While significant cell growth and accumulation were seen in the non-operating SCSTM group after 30 days, the shunt openings remained clear in the constantly operating SCSTM group, with little to no cell attachment on the robotic cleaning mechanism (the ViRobTM system) and on the shunt openings.

The SCSTM was further validated in a broader follow-up in-vitro study which commenced in July 2019 and concluded on August 14, 2019 and clearly demonstrated that the SCSTM prevented shunt occlusions under the parameters of that study. This follow-up study was also conducted by Envigo CRS Israel using Human brain glioblastoma cells Specifically, the study demonstrated:

- Significant cell growth and accumulation in a non-operating SCSTM as well as in a standard of care ventricular catheters (control group).
- A significant inhibition in cell growth in daily (5-10 minutes) or weekly (up to 2 hours over the week) operating regimes of the SCSTM, with little cell attachment on the ViRob mechanism.
- The effectiveness of the SCSTM device in preventing cells blockage as compare to standard of care surgical ventricular catheters.

To further investigate the efficacy of the SCSTM, Microbot conducted a follow-up in-vitro study at Wayne State University. The study included a larger sample size compared to the initial study and the primary and secondary end points aimed to validate the efficacy of the SCS in comparison to commercially available devices. After careful analysis of the results the final conclusion was that the data from this study did not reveal statistically significant differences between the study's groups.

Microbot used the findings of the second stage of the animal study combined with additional experimental data that was acquired in the past year for initial regulatory FDA pre-submissions.

On January 27, 2021, we announced the completion of successful discussions with the FDA, for the SCSTM. After review of Microbot existing pre-clinical data, the FDA's feedback will allow us to apply for the EFS (Early Feasibility Study) without further animal studies.

We expect to continue to work with the FDA towards finalizing the SCSTM design, and to incorporate their feedback prior to submitting the IDE to seek authorization to begin the EFS clinical trial. While there can be no assurance that the FDA will approve the EFS study, the agency's recent feedback indicates that the agency will be receptive to allowing a first-in-human study to proceed based on existing data. After completing the EFS, we would then seek FDA input on the device design as finalized through the EFS process in a subsequent IDE filing for approval of a clinical study proposal. Consequently, the timeline for the First-in-Human clinical trial under the EFS is expected to commence in the third quarter of 2022.

In spite of the above, there is still a possibility that 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.

The proposed indication for use of the SCS™ device would be for the treatment of hydrocephalus and/or NPH as a component of commercially available shunt systems. 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.

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.

Currently, Microbot is not pursuing the development of the TipCAT as a colonoscopy tool due to its focus on the neurosurgical and endovascular intervention spaces, and as such it is currently exploring the use of the TipCAT for minimally invasive neurosurgical and endovascular applications to complement its other technologies.

LIBERTY

The LIBERTY robotic system features a unique compact design with the capability to be operated remotely, reduce radiation exposure and physical strain to the physician, reduce the risk of cross contamination, as well as the potential to eliminate the use of multiple consumables when used with its "One & Done" capabilities, which would be based in part on the CardioSert platform or possibly other guidewire/microcatheter technologies. LIBERTY is being designed to have the following attributes:

- Compact size - Eliminates the need for large capital equipment in dedicated cath-lab rooms with dedicated staff.
- Fully disposable - To our knowledge, the first and only fully disposable, robotic system for endovascular procedures.
- Streamlines Cath-lab procedures - Compatible with Microbot's unique "One & Done" tool, which would be based in part on the CardioSert platform or possibly other guidewire/microcatheter technologies, that combines guidewire and microcatheter into a single device. The "One & Done" tool, when integrated into the system, is expected to provide full control over tip curvature and stiffness for maneuverability and access without the need for constant tool exchanges, while enhancing the operator experience.
- State of the art maneuverability - Provides linear, rotational and tip control of its "One & Done" tool when integrated into the system, as well as linear motion for an additional "over the wire" device.
- Enhanced operator safety and comfort - Reduces exposure to ionizing radiation and the need for heavy lead vests otherwise to be worn during procedures.
- Ease of use - LIBERTY's intuitive remote controls simplify advanced procedures while shortening the physician's learning curve.
- Telemedicine compatible - Capable of tele-catheterization, carried out remotely by highly trained specialists.

We are continuing our feasibility animal trials with respect to the LIBERTY device, with a planned pre-submission to the FDA as early as the fourth quarter of 2021, with submission to the FDA planned in the fourth quarter of 2022.

Strategy

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

- **Continue to refine existing product candidates and develop additional micro-robotic solutions.** As Microbot prepares to bring its initial product candidates through pre-clinical and clinical trials, if necessary, and eventually to market, it continues to focus on improving its product candidates to respond to clinical data and patient and physician feedback. Microbot also expects to continue to innovate in the micro-robotics field by continuing to find ways of using its technology to solve unmet needs, with the overarching goal of providing a safer, more effective and more efficient surgical environment for patients and physicians.
- **Establish and leverage relationships with key institutions and leading clinicians.** Microbot intends to develop relationships with a relatively small number of hospitals and clinics through its clinical stage. Microbot's objective will be to maintain clinical focus with such hospitals and clinics so as to establish the SCS, as well as other future products, as the standard of care in such institutions for their respective procedures. Microbot also expects to identify key clinicians with hydrocephalus specialties with the expectation that such clinical focus will accelerate the adoption of its candidate products.
- **Continuously invest in research and development.** Microbot's most significant expense has historically been research and development, and Microbot expects that this will continue in the foreseeable future, including expenses it expects to incur to improve on its prototype products in order to respond to clinical data, to develop additional applications using its technologies and to develop future product candidates.
- **Explore partnerships for the introduction of Microbot's products.** Microbot intends to focus its marketing and sales efforts initially on pursuing collaborations with global medical device companies that have established sales and distribution networks. Microbot will seek to enter collaborations and partnerships with strategic players that offer synergies with Microbot's product candidates and expertise.
- **Seek additional IP and technologies to complement and strengthen Microbot's current IP portfolio.** Microbot intends to continue exploring new technologies, IP and know-how to add to its current portfolio through licensing, mergers and/or acquisitions and to allow Microbot to enter new spaces and strengthen its overall product portfolio.

SCS Opportunities

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

- Primary shunt placement; and
- Shunt replacement.

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

TipCAT Opportunities

Microbot is currently exploring the use of the TipCAT for minimally invasive neurological and endovascular applications.

CardioSert Technology Opportunities

Microbot is currently exploring the integration of the CardioSert technology into the LIBERTY endovascular robotic system for a range of potential applications in the cardiovascular, peripheral vascular and neurovascular spaces.

LIBERTY Opportunities

The LIBERTY endovascular robotic system is being designed to remotely maneuvering guidewires, microcatheters and over-the-wire devices within the body's vasculature. The device is being designed to be the size of a personal device and to be fully disposable and affordable. We are aiming LIBERTY to be capable of supporting whole-endovascular procedures by providing "One & Done" solutions which would be based in part on CardioSert's proprietary technology or possibly other guidewire/microcatheter technologies. With control over tip curvature and stiffness for maneuverability and access – and without the need for constant tool exchanges – the "One & Done" feature, when integrated into the system, is expected to drastically reduce the procedure time and costs, while enhancing the operator experience. We believe LIBERTY's addressable markets are the Interventional Cardiology, Interventional Radiology and Interventional Neuroradiology markets.

The unique characteristics of LIBERTY – compact, mobile, disposable and remotely controlled - open the opportunity of expanding telerobotic interventions to patients with limited access to life-saving procedures, such as mechanical thrombectomy in ischemic stroke.

Competition

SCS Competitive Landscape

Several academic research groups, such as at the New Jersey Institute of Technology, are currently researching sensing and obstruction-resistant catheter designs, and the Smart Sensors and Integrated Microsystems (SSIM) Program at Wayne State University has publicized that it is engaging in smart shunt development activity. However, based in part on its knowledge of the patented technologies, Microbot believes that these technologies are still early in the research and development cycle. Although we believe the SCS may face direct competition from Anuncia Inc., a spin-off of Alycone Lifesciences Inc., which received a CE Mark and FDA 510k clearance for the Alivio ReFlow™ Ventricular System for the treatment of hydrocephalus, the commercialization status of the device is not clear. The SCS also faces non-direct competition from Aqueduct Neurosciences, Inc., which we believe is developing a non-shunt, electro-mechanical technology platform to control the draining of cerebrospinal fluid, and from Cerevasc Inc., which is developing the eShunt™ System that aims to eliminate the need for passing a rigid catheter through cerebral cortex and subcortical white matter.

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

TipCAT Competitive Landscape

Microbot has not at this time completed its evaluation of the current competitive landscape in the endovascular space for potential uses of the TipCAT.

CardioSert Technology Competitive Landscape

Competition includes moveable-core guidewires from companies such as Boston Scientific and Rapid Medical, and steerable and deflectable sheaths and catheters from companies such as Bendit Technologies and Merit Medical. To our knowledge, the CardioSert device is the only device that combines an inner moveable guidewire and an outer microcatheter, with the ability to control the shape and stiffness of the distal tip in a continuous, gradual manner, and intends to compete on that basis.

We believe the main competitor to the LIBERTY system is the CorPath GRX vascular robotics system by Corindus Vascular Robotics, a Siemens Healthineers company. The CorPath GRX system has FDA approvals for percutaneous coronary interventions (PCI) and peripheral vascular interventions (PVI) and is pending an approval for neurovascular interventions. Other competitors include Robocath (CE Marked for PCI only) and Hansen Medical (a J&J Company with FDA approval for PVI). We believe these systems have drawbacks, such as limited maneuverability, the requirement to exchange and use multiple expensive surgical tools, being cumbersome to set-up and operate, and requiring significant capital expenditures. We further believe that these systems have captured a marginal market share to date.

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

Intellectual Property

General

The SCS and TipCAT are based on technological platforms licensed from The Technion Research and Development Foundation Ltd., or TRDF, as further discussed below. The LIBERTY platform core technology is co-owned by Microbot and TRDF. The CardioSert device is based on technologies acquired by Microbot. Microbot plans to develop other micro-robotic solutions through internal research and development, to strengthen its intellectual property position, and to continue exploring strategic collaborations and accretive acquisition opportunities. Microbot currently holds an intellectual property portfolio of 42 patents issued/allowed and 23 patent applications pending worldwide. It also has registered trademarks in Israel and Europe relating to its LIBERTY platform, and also has trademark applications pending in Israel, US, Europe and China relating to its proprietary Microbot Medical tradename and logo.

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

Microbot requires its employees and consultants to execute confidentiality agreements in connection with their employment or consulting relationships with Microbot. Microbot also requires its employees and consultants who work on its product candidates to agree to disclose and assign to Microbot all inventions conceived during the term of their service, while using Microbot property, or which relate to Microbot's business.

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

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

Microbot's issued U.S. patents, which cover Microbot's product candidates, will expire between 2026 and 2033, not including any patent term adjustments that may be available. Issued patents outside of the United States directed to Microbot's product candidates will expire between 2026 and 2036.

License Agreement with the Technion

In June 2012, Microbot entered into a license agreement with TRDF, the technology transfer subsidiary of The Technion Institute of Technology, pursuant to which it obtained an exclusive, worldwide, royalty-bearing, sub-licensable license to certain patents and inventions relating to the SCS and TipCAT technology platforms invented by Professor Moshe Shoham, a former director of and an advisor to the Company, and in certain circumstances other TRDF-related persons. Pursuant to the terms of the license agreement, in order to maintain the license with respect to each platform, Microbot must use commercially reasonable efforts to develop products covered by the license, including meeting certain agreed upon development milestones. The milestones for both SCS and TipCAT include commencing first in human clinical trials by December 2021. Failure to meet any development milestone will give TRDF the right to terminate the license with respect to the technology underlying the missed milestone.

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

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

In addition to the licensed SCS and TipCAT technologies, the LIBERTY platform, which was invented by employees of Microbot together with Professor Moshe Shoham of the Technion, in his capacity as a consultant to Microbot, is co-owned by Microbot and TRDF, and a process is being conducted for establishing the LIBERTY platform as a "Joint Invention" in accordance with the terms of the License Agreement. Once the Joint Invention is established, Microbot will have to pay TRDF royalties of between 1.5% and 3.0% of net sales of products covered by this Joint Invention.

Research and Development

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

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

Microbot has obtained grants from the Israeli Innovation Authority ("IIA") for participation in research and development activities since 2013 through 2020. During this time, Microbot has received grant revenues of approximately \$1,500,000. In return, Microbot is obligated to pay royalties amounting to 3%-3.5% of its future sales up to the amount of the grant. The grant is linked to the exchange rate of the dollar to the New Israeli Shekel and bears interest of USD LIBOR per annum.

Under the terms of the grants and applicable law, Microbot is restricted from transferring any technologies, know-how, manufacturing or manufacturing rights developed using the grant outside of Israel without the prior approval of the Israel Innovation Authority. Microbot has no obligation to repay the grant, if the SCS project fails, is unsuccessful or aborted before any sales are generated. The financial risk is assumed completely by the IIA.

Microbot expects to continue to access government funding in the future.

For the fiscal year ended December 31, 2020, Microbot incurred research and development expenses of approximately \$3,396,000 compared to research and development expenses of approximately \$3,048,000 for the fiscal year ended December 31, 2019.

SCS

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

Microbot has completed the development of an SCS prototype and is currently continuing the safety testing, general proof of concept testing and performance testing for the device, which Microbot began in mid-2013. In May 2018, Microbot previously 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, 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 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 conducted a follow-up study to further evaluate the safety of the SCS. The follow-up study was also conducted by leading hydrocephalus experts at Washington University and Wayne State University. The study included a larger sample size compared to the initial studies and the primary and secondary endpoints seek to validate the safety and efficacy of the SCS that will be activated in both in-vitro (lab) and in-vivo (animal) models. In that in-vivo study, the major finding was that the SCS system is as safe to use as currently marketed devices.

In conjunction with conducting the follow-up study, Microbot also contracted with Envigo CRS Israel, to conduct an in-vitro study designed to evaluate the operational performance of the SCS. The first Envigo study that was conducted in 2018 used human brain glioblastoma cells 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 four weeks and then exposed to an activated SCS device. We believe 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.

The SCS™ was further validated in a broader follow-up in-vitro lab study which commenced in July 2019 and concluded on August 14, 2019 and clearly demonstrated the device prevented shunt occlusion under the parameters of that study. This follow-up study was also conducted by Envigo CRS Israel. Human brain glioblastoma cells were used in order to assess performance of the SCS™ in a test system with accelerated cell growth rate, accumulation and obstruction rates. Specifically, the study demonstrated:

- Significant cell growth and accumulation in a non-operating SCS as well as a standard of care surgical shunt.
- A significant inhibition in cell growth in daily (5-10 minutes) or weekly (up to 2 hours over the week) operating SCS with little cell attachment on the robotic brush (ViRob) and on the opening where the robotic brush (ViRob) operates.
- The effectiveness of the Company's SCS devices in preventing cells blockage as compare to standard of care surgical shunts.

The follow-up in vitro (lab) study at Wayne State University included a larger sample size compared to the initial study and the primary and secondary end points seek to validate the efficacy of the SCS while being activated in-vitro (lab). Generally, the data from this study did not reveal statistically significant trends indicating a strong preference for any of the designs tested, including the SCS; therefore, these tests as they stand are inconclusive but have provided us with trends which Microbot may decide to further explore.

After submitting the existing data to the FDA, on January 27, 2021 we announced the completion of successful discussions with the FDA, for the SCS™. After review of our existing pre-clinical data, the FDA's feedback will allow us to apply for the EFS. We expect to continue to work with the FDA towards finalizing the SCS™ design, and to incorporate their feedback prior to submitting the IDE to seek authorization to begin the EFS clinical trial. While there can be no assurance that the FDA will approve the EFS study, the agency's recent feedback indicates that the agency will be receptive to allowing a first-in-human study to proceed based on existing data. After completing the EFS, we would then seek FDA input on the device design as finalized through the EFS process in a subsequent IDE filing for approval of a clinical study proposal. Consequently, the timeline for the First-in-Human clinical trial under the EFS is expected to commence in the third quarter of 2022.

At this time, we can give no assurance that the FDA will agree that an EFS is warranted, in which case we will have to re-commence animal trials or otherwise re-evaluate the FDA approval process, which could delay and hinder our ability to commercialize the SCS device.

LIBERTY

The LIBERTY prototype system was tested at our laboratories in an in-vitro silicone model, using off-the-shelf guidewires and microcatheters, and showing an ability to successfully provide linear and rotational movements of the guidewires and linear motion of the microcatheters. We also conducted a single preliminary animal trial with the LIBERTY prototype.

The LIBERTY prototype is designed to control the CardioSert device; however, the CardioSert technology is not currently expected to be integrated into the next version of the LIBERTY device. Additionally, we are exploring and evaluating additional innovative guidewire/microcatheter technologies to be integrated and combined with the LIBERTY robotic platform to further enhance the performance of the system.

Since the CardioSert device was originally designed for chronic total occlusion, we are currently working with subcontractors and guidewire design-houses to perfect the performance of the CardioSert device to the indication that will be selected for the LIBERTY platform. These may include procedures in the peripheral, coronary or neurovascular spaces.

Manufacturing

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

Commercialization

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

Government Regulation

General

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

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

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

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

U.S. Regulation

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

- product design, and development;
- product safety, testing, labeling and storage;
- record keeping procedures; and
- product marketing.

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

- the timely submission of product listing and establishment registration information, along with associated establishment user fees;
- continued compliance with the Quality System Regulation, or QSR, which require specification developers and manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance or approval of product modifications that could significantly affect the safety or effectiveness of the device or that would constitute a major change in intended use;
- Medical Device Reporting regulations (MDR), which require that manufacturers keep detailed records of investigations or complaints against their devices and to report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- adequate use of the Corrective and Preventive Actions process to identify and correct or prevent significant systemic failures of products or processes or in trends which suggest same;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and
- notices of correction or removal and recall regulations.

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

- Class I devices, which are low risk and subject to only general controls (e.g., registration and listing, medical device labeling compliance, MDRs, Quality System Regulations, and prohibitions against adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements;
- Class II devices, which are moderate risk and generally require 510(k) or 510(k) de-novo premarket clearance before they may be commercially marketed in the United States as well as general controls and potentially special controls like performance standards or specific labeling requirements; and
- Class III devices, which are devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device. Class III devices generally require the submission and approval of a PMA supported by clinical trial data.

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

- Development of comprehensive product description and indications for use;
- Comprehensive review of predicate devices and development of data supporting the new product's substantial equivalence to one or more predicate devices; and
- If appropriate and required, certain types of clinical trials (IDE submission and approval may be required for conducting a clinical trial in the US).

When clinical evidence is necessary because non-clinical or animal testing is unavailable or inadequate to provide the information needed to advance device development, an Early Feasibility Study (EFS) for a limited clinical investigation of the device may be applicable and which we are evaluating with respect to the SCS device. If the FDA agrees to the EFS approach in general, we will work to finalize the design of the device, to resolve any questions from the FDA, and to incorporate the FDA's feedback prior to submitting the IDE to seek authorization to begin the EFS clinical trial. After completing the EFS study, we will then seek FDA input on the device design as finalized through the EFS process in a subsequent IDE filing for approval of a pivotal clinical study proposal.

Clinical trials involve use of the medical device on human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices (GCPs), including the requirement that all research subjects provide informed consent for their participation in the clinical study. A written protocol with predefined end points, an appropriate sample size and pre-determined patient inclusion and exclusion criteria, is required before initiating and conducting a clinical trial. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's Investigational device Exemption, or IDE, regulations that among other things, govern investigational device labeling, prohibit promotion of the investigational device, and specify recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," as defined by the FDA, the agency requires the device sponsor to submit an IDE application, which must become effective prior to commencing human clinical trials. The IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA denies the application or notifies the company that the investigation is on hold and may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE that requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but it must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. 510(k) clearance typically involves the following:

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

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

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

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

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

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

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

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

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

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

Microbot is currently evaluating whether it is appropriate for it to seek 510(k) clearance, given the technological features of the SCS device and the FDA's recent announcements about enhancing the 510(k) process to further ensure safety and efficacy. However, the Company believes that given the similarities between the SCS and some cleared predicate devices, there is a reasonable likelihood that a de novo application might be acceptable to the FDA.

Foreign Regulation

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

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

Europe. The primary regulatory body in Europe is the European Union, or E.U., which consists of 27 member states and has a coordinated system for the authorization of medical devices.

The E.U. has adopted legislation, in the form of directives to be implemented in each member state, concerning the regulation of medical devices within the European Union. The directives include, among others, the Medical Device Regulation, or MDR, that establishes certain requirements with which medical devices must comply before they can be commercialized in the European Economic Area, or EEA (which comprises the member states of the E.U. plus Norway, Liechtenstein and Iceland). Under the MDR, medical devices are classified into four Classes, I, IIa, IIb, and III, with Class I being the lowest risk and Class III being the highest risk.

In order to commercialize medical devices in the European Union, a CE Mark certificate is needed. This certification verifies that a device meets all regulatory requirements for medical devices, which will soon change under the new Medical Devices Regulation (MDR 2017/745). The CE approval process in Europe is summarized below:

1. To obtain CE Marking certification, comply with European Commission Regulation (EU) No. 2017/745, commonly known as the Medical Device Regulation (MDR).
2. Appoint a Person Responsible for regulatory compliance. Determine classification of device - Class I (self-certified); Class I (sterile, measuring or reusable surgical instrument); Class IIa, Class IIb, or Class III.
3. For all devices except Class I (self-certified), implement a Quality Management System (QMS) in accordance with the MDR. Companies usually apply the EN ISO 13485 standard to achieve compliance. The QMS must include Clinical Evaluation, Post-Market Surveillance (PMS) and Post Market Clinical Follow-up (PMCF) plans. Make arrangements with suppliers about unannounced Notified Body audits. For Class I (self-certified), implement a QMS though Notified Body intervention is not required.
4. Prepare a CE Technical File or Design Dossier (Class III) providing information about the device and its intended use plus testing reports, Clinical Evaluation Report (CER), risk management file, Instruction For Use (IFU), labeling and more. Obtain a Unique Device Identifier (UDI) for the device. All devices, even legacy products in use for decades, will require clinical data. Most of these data should refer to the subject device. Clinical studies are generally required for implantable and Class III devices. Existing clinical data may be acceptable. Clinical trials in Europe must be pre-approved by a European Competent Authority.
5. If the company does not have a location in Europe, appoint an Authorized Representative (EC REP) located in the EU who is qualified to handle regulatory issues. Place the EC REP name and address on device label. Obtain a Single Registration Number from the regulators.
6. For all devices except Class I (self-certified), the QMS and Technical File or Design Dossier must be audited by a Notified Body, a third party accredited by European authorities to audit medical device companies and products.
7. For all devices except Class I (self-certified), the company will be issued a European CE Marking Certificate for the device and an ISO 13485 certificate for the company's facility following successful completion of the Notified Body audit. ISO 13485 certification must be renewed every year. CE Marking certificates are typically valid for a maximum of 5 years, but are typically reviewed during the annual surveillance audit.

8. Prepare a Declaration of Conformity, a legally binding document prepared by the manufacturer stating that the device is in compliance with the applicable European requirements. At this time, the CE Marking may be affixed.
9. Register the device and its Unique Device Identifier (UDI) in the EUDAMED database. UDI must be on label and associated with the regulatory documents.
10. For Class I (self-certified), annual NB audits are not required. However, CER, Technical File, and PMS activities must be kept updated. For all other classes, the company will be audited each year by a Notified Body to ensure ongoing compliance with the MDR. Failure to pass the audit will invalidate the CE Marking certificate. The company must perform Clinical Evaluation, PMS, and PMCF.

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

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

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

- Name and address of the manufacturer, and of the importer as applicable;
- Description of the intended use of the medical device and of its medical indications;
- Technical details of the medical device and of its components, and in the event that the device or the components are not new, information should be provided on the date or renovation;
- Certificate attesting to the safety of the device, issued by a competent authority of one of the following countries: Australia, Canada, European Community (EC), Member States (MSs), Israel, Japan, or the United States;
- Information on any risk which may be associated with the use of the device (including precautionary measures to be taken);
- Instructions for use of the device in Hebrew; the MOH may allow the instructions to be in English for certain devices;
- Details of the standards to which the device complies;
- Description of the technical and maintenance services, including periodic checks and inspections; and
- Declaration, as appropriate: of the local manufacturer/importer, and of the foreign manufacturer.

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

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

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

- Reside and maintain a place of business in Israel and serve as the regulatory representative.
- Respond to questions from AMAR concerning the registered products.
- Report adverse events to AMAR.
- Renew the registration on time to keep the market approval active.

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

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

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

Employees

Microbot's Chief Executive Officer, President and Chairman, Harel Gadot, along with 2 full-time employees, are based in Microbot's U.S. office located in Hingham, Massachusetts. Additionally, Microbot currently has 12 full-time employees based in its office located in Yokneam, Israel. These employees oversee day-to-day operations of the Company supporting management and leading engineering, manufacturing, intellectual property and administration functions of the Company. As required, Microbot also engages consultants to provide services to the Company, including regulatory, legal and corporate services. We are subject to labor laws and regulations within our locations in the U.S. and Israel. These laws and regulations principally concern matters such as pensions, paid annual vacation, paid sick days, length of the workday and work week, minimum wages, overtime pay, insurance for work-related accidents, severance pay and other conditions of employment. Microbot has no unionized employees.

Item 1A. Risk Factors

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. Our business, operating results, financial performance, and share price may be materially adversely affected by a number of factors, including but not limited to the following risk factors, any one of which could cause actual results to vary materially from anticipated results or from those expressed in any forward-looking statements made by us in this Annual Report on Form 10-K or in other reports, press releases or other statements issued from time to time. Additional factors that may cause such a difference are set forth elsewhere in this Annual Report on Form 10-K. Forward-looking statements speak only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statements.

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

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

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

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

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

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

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

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

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

To date, Microbot has funded its operations primarily through offerings of debt and equity securities, grants and loans. Microbot does not know when, or if, it will generate any revenue, but does not expect to generate significant revenue unless and until it obtains regulatory clearance or approval of and commercializes one of its current or future product candidates. It is anticipated that the Company will continue to incur losses for the foreseeable future, and that losses will increase as it continues the development of, and seeks regulatory review of, its product candidates, and begins to commercialize any approved or cleared products following a successful regulatory review.

Microbot expects the research and development expenses of the Company to increase substantially in future periods as it conducts pre-clinical studies in large animals and potentially clinical trials for its product candidates, and especially if it initiates additional research programs for future product candidates, including LIBERTY. In addition, if the Company obtains marketing clearance or approval for any of its product candidates, it expects to incur significant commercialization expenses related to product manufacturing, marketing and sales. Microbot may also require additional funds for operations if it loses its current lawsuit with Empery and Hudson Bay, discussed in great detail elsewhere in this Annual Report on Form 10-K. Furthermore, Microbot incurs substantial costs associated with operating as a public company in the United States. Accordingly, the Company may need to obtain substantial additional funding in connection with its continuing operations through its projected profitability, of which it can give no assurance of success. If the Company is unable to raise capital when needed or on attractive terms, it could be forced to delay, reduce or eliminate its research and development programs or any future commercialization efforts.

The Company intends to continue to opportunistically strengthen its balance sheet by raising additional funds through equity offerings, including possibly through an At-the-Market offering, or otherwise in order to meet expected future liquidity needs, including the introduction of the SCS device into the hydrocephalus and NPH market, and the introduction of LIBERTY. The Company's future capital requirements, generally, will depend on many factors, including:

- the timing and outcomes of the product candidates' regulatory reviews, subsequent approvals or clearances, or other regulatory actions;
- the final outcome of the Company's existing lawsuit with Empery and Hudson Bay;
- the costs, design, duration and any potential delays of the clinical trials that could be conducted at the FDA's request using Microbot's product candidates;
- the costs of acquiring, licensing or investing in new and existing businesses, product candidates and technologies;
- the costs to maintain, expand and defend the scope of Microbot's intellectual property portfolio;
- the costs to secure or establish sales, marketing and commercial manufacturing capabilities or arrangements with third parties regarding same;
- the Company's need and ability to hire additional management and scientific and medical personnel; and
- the costs to operate as a public company in the United States.

An epidemic of the coronavirus disease is ongoing and may result in significant disruptions to our clinical trials or other business operations, which could have a material adverse effect on our business.

An epidemic of the coronavirus disease is ongoing throughout the world. Although we have not yet commenced clinical trials, in the event the pandemic is continuing when we are prepared to commence such trials, the coronavirus disease may cause significant delays and disruptions to our clinical trials and our interactions with the FDA. If the patients involved with any such clinical trials become infected with the coronavirus disease, we may have more AEs and deaths in our clinical trials as a result. We may also face difficulties enrolling patients in our clinical trials if the patient populations that are eligible for our clinical trials are impacted by the coronavirus disease. Additionally, if our clinical trial patients are unable to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from the coronavirus disease, we may experience higher drop-out rates or delays in our clinical trials, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which could impact our ability to determine the efficacy or safety of our SCS or LIBERTY device. Site initiation and patient enrollment may also be delayed due to prioritization of hospital resources toward the coronavirus disease outbreak.

Additionally, travel restrictions and expanded screenings have been implemented worldwide in an effort to contain the coronavirus disease. As such, we and our contract research organizations may be unable to visit our trial sites and monitor the data from our trials on timely basis. Our employees may also face travel restrictions, which would impact our business. Furthermore, some of our manufacturers and suppliers are in Europe and may be impacted by port closures and other restrictions resulting from the coronavirus outbreak, which may disrupt our supply chain or limit our ability to obtain sufficient materials for our products.

The ultimate impact of the coronavirus disease outbreak or a similar health epidemic is highly uncertain and subject to change, and we cannot presently predict the scope and severity of any further potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, contract research organizations, regulators, including the FDA health care providers and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business and operations could be materially and negatively impacted, which could prevent or delay us from obtaining approval for our SCS and LIBERTY devices.

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

Unsuccessful animal studies, clinical trials or procedures relating to product candidates under development could have a material adverse effect on Microbot's prospects.

The regulatory approval process for new products and new indications for existing products requires extensive data and procedures, including the development of regulatory and quality standards and, potentially, certain clinical studies. Unfavorable or inconsistent data from current or future clinical trials or other studies conducted by Microbot or third parties, or perceptions regarding such data, could adversely affect Microbot's ability to obtain necessary device clearance or approval and the market's view of Microbot's future prospects. Specifically, the interim data of our animal trial with respect to the SCS device suggests that the animal trial results are inconclusive to assess safety. As a result, we have submitted the existing data to the FDA as part of a pre-submission meeting and we intend to apply for a limited clinical investigation of the device known as an Early Feasibility Study (EFS).

Failure to successfully complete these studies, or any similar studies with respect to any of our other product candidates, in a timely and cost-effective manner could have a material adverse effect on Microbot's prospects with respect to the SCS device or such other product candidates. Because animal trials, clinical trials and other types of scientific studies are inherently uncertain, there can be no assurance that these trials or studies will be completed in a timely or cost-effective manner or result in a commercially viable product. Clinical trials or studies may experience significant setbacks even if earlier preclinical or animal studies have shown promising results. Furthermore, preliminary results from clinical trials may be contradicted by subsequent clinical analysis. Results from clinical trials may also not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long-term studies or clinical experience, Microbot's business could be adversely affected. Clinical trials also may be suspended or terminated by us, the FDA or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks. The FDA may disagree with our interpretation of the data from our clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate safety and effectiveness of the product candidate. The FDA may also require additional pre-clinical studies or clinical trials which could further delay approval of our product candidates.

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

As stated above, we intend to apply for an EFS for the SCS device. After completing the EFS, we would then seek FDA input on the device design as finalized through the EFS process in a subsequent IDE filing for approval of a clinical study proposal. Consequently, the timeline for the First-in-Human clinical trial under the EFS is expected to commence in the third quarter of 2022.

Generally, after all necessary clinical and performance data supporting the safety and effectiveness of the SCS or LIBERTY devices, or any other product candidate, 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 device and/or the LIBERTY device, or any of our other product candidates from time to time. The success of commercializing any of our product candidates, include the SCS and LIBERTY devices, will depend on a number of factors, including the following:

- our ability to obtain additional capital;
- With respect to the SCS device, approval of the FDA to participate in an EFS program and/or successful completion of animal studies and, if necessary, additional human clinical trials (beyond the EFS trials) and the collection of sufficient data to demonstrate that the device is safe and effective for its intended use;
- With respect to all of our product candidates, 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, if and when approved, whether alone or in collaboration with other entities;
- acceptance of our product candidates, if and when commercially launched, by the medical community, patients and third-party payors;
- effectively competing with existing and competitive products on the market and any new competing products that may enter the market; and
- maintaining quality and an acceptable safety profile of our products 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 the SCS, LIBERTY or any other product candidate, which would materially harm its business.

Microbot's ability to expand its 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 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.

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.

Although Microbot has identified a predicate device for its lead product candidate, the SCS, which it intended to use in its 510(k) application, it may determine that a 510(k) de novo application is more appropriate for the SCS. If the Company determines to proceed with the 510(k) application and the FDA agrees with the Company's determination, the SCS will be classified by the FDA as Class II and eligible for marketing pursuant to FDA clearance through the 510(k) application. However, in light of recent initiatives by the FDA relating to safety, efficacy and the inconclusive results of the animal and laboratory trial, 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). The FDA also may request additional data in response to a 510(k), or require Microbot to conduct further testing or compile more data in support of its 510(k). 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 or any other 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, LIBERTY or any other product candidate 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, LIBERTY or any other product candidate, 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.

The FDA may disagree with Microbot’s determination that the SCS is a Class II device or that the chosen predicate device (or any predicate device) is appropriate for a substantial equivalence comparison to the SCS.

Although the Company intended to submit a 501(k) application for the SCS, the Company is now considering that the FDA may determine that the SCS is a Class III device because there is no appropriate predicate device for substantial equivalence comparison, which would require Microbot to submit a De Novo classification request or an application for premarket approval (“PMA”). Both De Novo requests and PMA applications require applicants to prepare information and data about device safety and efficacy in addition to the 510(k) requirements, including a benefit-risk analysis, a discussion of proposed general and special controls to eliminate or mitigate device risks, and additional testing data. PMA applications almost always require data from human clinical studies, and while De Novo requests do not require human clinical study data, in most cases, such data is necessary to demonstrate that the FDA can appropriately classify the device as Class II.

Any type of clinical study performed in humans (including the EFS) 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.

Furthermore, if Microbot is required to submit a De Novo request or PMA application instead of a 510(k), the FDA review process may take significantly more time. While the FDA commits to reviewing 510(k)s in 90 days, the review period for De Novo requests and PMA applications is 150 days and 180 days, respectively. After an initial review of our De Novo request or PMA application, the FDA may request additional information or data which can significantly delay an ultimate decision on our submission.

Thus, submitting a De Novo request or PMA application for the SCS would significantly increase the costs associated with developing and commercializing the product and delay the timing of U.S. regulatory authorization. Microbot and its business, financial condition and operating results could be materially and adversely affected as a result of any such costs or delays.

Microbot's CardioSert technology is subject to a buy-back clause which, if triggered, could cause us to lose rights to the technology and delay or curtail the development of our products.

Pursuant to the Agreement we entered into in January 2018 to acquire the CardioSert technology, we are required to meet certain commercialization deadlines or CardioSert may terminate the agreement and buy back the technology for \$1.00, subject to certain limited exceptions. The next such commercialization deadline is in 2022. At this time, we can give no assurance that we will meet the commercialization deadlines.

Failure to meet the applicable commercialization deadlines and any resulting sale back of the technology to CardioSert could materially adversely affect our ability to develop and commercialize, or materially delay the development and commercialization of, our planned LIBERTY device.

Microbot has no prior experience in conducting clinical trials and will depend upon the ability of third parties, including contract research organizations, collaborative academic groups, future clinical trial sites and investigators, to conduct or to assist the Company in conducting clinical trials for its product candidates, if such trials become necessary.

As a development-stage, pre-clinical company, Microbot has no prior experience in designing, initiating, conducting and monitoring human clinical trials. Microbot will depend upon its ability and/or the ability of future collaborators, contract research organizations, clinical trial sites and investigators to successfully design, initiate, conduct and monitor such clinical trials.

Failure by Microbot or by any of these future collaborating parties to timely and effectively initiate, conduct and monitor a future clinical trial could significantly delay or materially impair Microbot's ability to complete those clinical trials and/or obtain regulatory clearance or approval of its product candidates and, consequently, could delay or materially impair its ability to generate revenues from the commercialization of those products.

If the commercial opportunity for SCS, LIBERTY and any other commercial products that may be developed by Microbot is smaller than Microbot anticipates, Microbot's future revenue from SCS, LIBERTY and such other products will be adversely affected and Microbot's business will suffer.

If the size of the commercial opportunities in any of Microbot's target markets is smaller than it anticipates, Microbot may not be able to achieve profitability and growth. For instance, Microbot is developing SCS as a device for the treatment of hydrocephalus and NPH. It is difficult to predict the penetration, future growth rate or size of the market for Microbot's product candidate.

The commercial success of the SCS, LIBERTY or any other product candidates will require broad acceptance of the devices by the doctors and other medical professionals who specialize in the procedures targeted by each device, a limited number of whom may be able to influence device selection and purchasing decisions. If Microbot's technologies are not broadly accepted and perceived as having significant advantages over existing medical devices, then it will not meet its business objectives. Such perceptions are likely to be based on a determination by medical facilities and physicians that Microbot's product candidates are safe and effective, are cost-effective in comparison to existing devices, and represent acceptable methods of treatment. Microbot cannot assure that it will be able to establish the relationships and arrangements with medical facilities and physicians necessary to support the market uptake of its product candidates. In addition, its competitors may develop new technologies for the same markets Microbot is targeting that are more attractive to medical facilities and physicians. If doctors and other medical professionals do not consider Microbot product candidates to be suitable for application in the procedures we are targeting and an improvement over the use of existing or competing products, Microbot's business goals will not be realized.

Customers will be unlikely to buy the SCS, LIBERTY or any other product candidates unless Microbot can demonstrate that they can be produced for sale to consumers at attractive prices.

To date, Microbot has focused primarily on research and development of the first generation versions of the SCS, as well as initial development of the LIBERTY device. Consequently, Microbot has no experience in manufacturing its product candidates, and intends to manufacture its product candidates through third-party manufacturers. Microbot can offer no assurance that either it or its manufacturing partners will develop efficient, automated, low-cost manufacturing capabilities and processes to meet the quality, price, engineering, design and production standards or production volumes required to successfully mass produce its commercial products. Even if its manufacturing partners are successful in developing such manufacturing capability and quality processes, including the assurance of GMP-compliant device manufacturing, there can be no assurance that Microbot can timely meet its product commercialization schedule or the production and delivery requirements of potential customers. A failure to develop such manufacturing processes and capabilities could have a material adverse effect on Microbot's business and financial results.

The proposed price of Microbot's product candidates, once approved for sale, will be dependent on material and other manufacturing costs. Microbot cannot offer any assurances that its manufacturing partner will be able to manufacture its product candidates at a competitive price or that achieving cost reductions will not cause a reduction in the performance, reliability and longevity of its product candidates.

Microbot will rely on third party design houses for the redesign of the CardioSert guidewire to other specific indications.

Since the CardioSert Guidewire was originally designed for treating chronic total occlusions, the design will need to be modified to treat other indications. As we do not specialize in the design of guidewires and microcatheters, Microbot is currently working with two leading third party design houses that specialize in this type of design. Such designs may require several design and regulatory iterations prolonging the product release and certification, which could delay the commercialization of our planned LIBERTY device.

Microbot has relied on, and intends to continue to rely on, third-party manufacturers to produce its product candidates.

Microbot currently relies, and expects to rely for the foreseeable future, on third-party manufacturers to produce and supply its product candidates, and it expects to rely on third parties to manufacture the commercialized products as well, should they receive the necessary regulatory clearance or approval. Reliance on third-party manufacturers entails risks to which Microbot would not be subject if Microbot manufactured its product candidates or future commercial products itself, including:

- limitations on supply availability resulting from capacity, internal operational problems or scheduling constraints of third parties;
- potential regulatory non-compliance or other violations by the third-party manufacturer that could result in quality assurance issues or government enforcement action that has a negative effect on Microbot's product candidates and distribution strategy;
- the possible breach of manufacturing agreements by third parties because of various factors beyond Microbot's control; and
- the possible termination or non-renewal of manufacturing agreements by third parties for various reasons beyond Microbot's control, at a time that is costly or inconvenient to Microbot.

If Microbot is not able to maintain its key manufacturing relationships, Microbot may fail to find replacement manufacturers or develop its own manufacturing capabilities, which could delay or impair Microbot's ability to obtain regulatory clearance or approval for its product candidates and could substantially increase its costs or deplete profit margins, if any. If Microbot does find replacement manufacturers, Microbot may not be able to enter into agreements with them on terms and conditions favorable to it and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

Additionally, the existing design of the CardioSert device was produced in very low quantities by the seller of the technology. Accordingly, the scaling-up to high volume production may require significant changes to the existing design and production methods. These changes are currently being carried out by two leading third party companies that specialize in design and high volume production of guidewires and microcatheters. These design changes/modifications may have significant negative implications in price and time to market of the CardioSert system.

If Microbot's product candidates are not considered to be a safe and effective alternative to existing technologies, Microbot will not be commercially successful.

The SCS, LIBERTY and TipCAT rely on new technologies, and Microbot's success will depend on acceptance of these technologies by the medical community as safe, clinically effective, cost effective and a preferred device as compared to products of its competitors. Microbot does not have long-term data regarding efficacy, safety and clinical outcomes associated with the use of SCS, LIBERTY or TipCAT. Any data that is generated in the future may not be positive or may not support the product candidates' regulatory dossiers, which would negatively affect market acceptance and the rate at which its product candidates are adopted. Equally important will be physicians' perceptions of the safety of Microbot's product candidates because Microbot's technologies are relatively new. If, over the long term, Microbot's product candidates do not meet surgeons' expectations as to safety, efficacy and ease of use, they may not become widely adopted.

Market acceptance of Microbot's product candidates will also be affected by other factors, including Microbot's ability to convince key opinion leaders to provide recommendations regarding its product candidates; convince distributors that its technologies are attractive alternatives to existing and competing technologies; supply and service sufficient quantities of products directly or through marketing alliances; and price products competitively in light of the current macroeconomic environment, which is becoming increasingly price sensitive.

Microbot may be subject to penalties and may be precluded from marketing its product candidates if Microbot fails to comply with extensive governmental regulations.

Microbot believes that its medical device product candidates will be categorized as Class II devices, which typically require a 510(k) or 510(k) de-novo premarket submission to the FDA. However, the FDA has not made any determination about whether Microbot's medical product candidates are Class II medical devices and may disagree with that classification. If the FDA determines that Microbot's product candidates should be reclassified as Class III medical devices, Microbot could be precluded from marketing the devices for clinical use within the United States for months, years or longer, depending on the specifics of the change in classification. Reclassification of any of Microbot's product candidates as Class III medical devices could significantly increase Microbot's regulatory costs, including the timing and expense associated with required clinical trials and other costs.

The FDA and non-U.S. regulatory authorities require that Microbot product candidates be manufactured according to rigorous standards. These regulatory requirements significantly increase Microbot's production costs, which may prevent Microbot from offering products within the price range and in quantities necessary to meet market demands. If Microbot or one of its third-party manufacturers changes an approved manufacturing process, the FDA may need to review the process before it may be used. Failure to comply with applicable pre-market and post-market regulatory requirements could subject Microbot to enforcement actions, including warning letters, fines, injunctions and civil penalties, recall or seizure of its products, operating restrictions, partial suspension or total shutdown of its production, and criminal prosecution.

If Microbot is not able to both obtain and maintain adequate levels of third-party reimbursement for procedures involving its product candidates after they are approved for marketing and launched commercially, it would have a material adverse effect on Microbot's business.

Healthcare providers and related facilities are generally reimbursed for their services through payment systems managed by various governmental agencies worldwide, private insurance companies, and managed care organizations. The manner and level of reimbursement in any given case may depend on the site of care, the procedure(s) performed, the final patient diagnosis, the device(s) utilized, available budget, or a combination of these factors, and coverage and payment levels are determined at each payor's discretion. The coverage policies and reimbursement levels of these third-party payors may impact the decisions of healthcare providers and facilities regarding which medical products they purchase and the prices they are willing to pay for those products. Microbot cannot assure you that its sales will not be impeded and its business harmed if third-party payors fail to provide reimbursement for Microbot products that healthcare providers view as adequate.

In the United States, Microbot expects that its product candidates, once approved, will be purchased primarily by medical institutions, which then bill various third-party payors, such as the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program through Medicare Administrative Contractors, and other government health care programs and private insurance plans, for the healthcare products and services provided to their patients. The process involved in applying for coverage and incremental reimbursement from CMS is lengthy and expensive. Moreover, many private payors look to CMS in setting their reimbursement policies and amounts. If CMS or other agencies limit coverage for procedures utilizing Microbot's products or decrease or limit reimbursement payments for doctors and hospitals utilizing Microbot's products, this may affect coverage and reimbursement determinations by many private payors.

If a procedure involving a medical device is not reimbursed separately by a government or private insurer, then a medical institution would have to absorb the cost of Microbot's products as part of the cost of the procedure in which the products are used. At this time, Microbot does not know the extent to which medical institutions would consider insurers' payment levels adequate to cover the cost of its products. Failure by hospitals and surgeons to receive an amount that they consider to be adequate reimbursement for procedures in which Microbot products are used could deter them from purchasing Microbot products and limit sales growth for those products.

Microbot has no control over payor decision-making with respect to coverage and payment levels for its medical device product candidates, once they are approved. Additionally, Microbot expects many payors to continue to explore cost-containment strategies (e.g., comparative and cost-effectiveness analyses, so-called "pay-for-performance" programs implemented by various public government health care programs and private third-party payors, and expansion of payment bundling initiatives, and other such methods that shift medical cost risk to providers) that may potentially impact coverage and/or payment levels for Microbot's current product candidates or products Microbot develops in the future.

As Microbot's product offerings are used across diverse healthcare settings, they will be affected to varying degrees by the different payment systems.

Clinical outcome studies for the SCS may not provide sufficient data to make Microbot's product candidates the standard of care.

Microbot's business plan relies on the broad adoption by surgeons of the SCS for primary shunt placement procedures to prevent shunt occlusions. Although Microbot believes the occurrence of shunt occlusion complications is well known among physicians practicing in the relevant medical fields, SCS may be adopted for replacement shunt surgeries only. Neurosurgeons may adopt SCS for primary shunt placement procedures only upon additional clinical studies with longer follow up periods, if at all. It may also be necessary to provide outcome studies on the preventative capabilities of the SCS in order to convince the medical community of its safety and efficacy. Clinical studies may not show an advantage in SCS based procedures in a timely manner, or at all, and outcome studies have not been designed at this time, and may be too large and too costly for Microbot to conduct. Both situations could prevent broad adoption of the SCS and materially impact Microbot's business.

Microbot products may in the future be subject to mandatory product recalls that could harm its reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could pose a risk of injury to patients. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death, although in most cases this mandatory recall authority is not used because manufacturers typically initiate a voluntary recall when a device violation is discovered. In addition, foreign governmental bodies have the authority to require the recall of Microbot products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by Microbot or one of its distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any Microbot products would divert managerial and financial resources and have an adverse effect on Microbot's financial condition and results of operations, and any future recall announcements could harm Microbot's reputation with customers and negatively affect its sales. In addition, the FDA could take enforcement action, including any of the following sanctions for failing to timely report a recall to the FDA:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- detention or seizure of Microbot products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) clearance or premarket approval of new products or modified products;
- withdrawing 510(k) clearances or other types of regulatory authorizations -that have already been granted;
- refusing to grant export approval for Microbot products; or
- criminal prosecution.

If Microbot's future commercialized products cause or contribute to a death or a serious injury, Microbot will be subject to Medical Device Reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under FDA regulations, Microbot will be required to report to the FDA any incident in which a marketed medical device product may have caused or contributed to a death or serious injury or in which a medical device malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in European Union markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred.

Microbot anticipates that in the future it is likely that we may experience events that would require reporting to the FDA pursuant to the Medical Device Reporting (MDR) regulations. Any adverse event involving a Microbot product could result in future voluntary corrective actions, such as product actions or customer notifications, or agency actions, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending Microbot in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Microbot could be exposed to significant liability claims if Microbot is unable to obtain insurance at acceptable costs and adequate levels or otherwise protect itself against potential product liability claims.

The testing, manufacture, marketing and sale of medical devices entail the inherent risk of liability claims or product recalls. Product liability insurance is expensive and may not be available on acceptable terms, if at all. A successful product liability claim or product recall could inhibit or prevent the successful commercialization of Microbot's products, cause a significant financial burden on Microbot, or both, which in any case could have a material adverse effect on Microbot's business and financial condition.

The results of Microbot's research and development efforts are uncertain and there can be no assurance of the commercial success of Microbot's product candidates.

Microbot believe that its success will depend in part on its ability to expand its product offerings and continue to improve its existing product candidates in response to changing technologies, customer demands and competitive pressures. As such, Microbot expects to continue dedicating significant resources in research and development. The product candidates and services being developed by Microbot may not be technologically successful. In addition, the length of Microbot's product candidates and service development cycle may be greater than Microbot originally expected.

If Microbot fails to retain certain of its key personnel and attract and retain additional qualified personnel, Microbot might not be able to pursue its growth strategy effectively.

Microbot is dependent on its senior management, in particular Harel Gadot, Microbot's Chairman, President and Chief Executive Officer. Although Microbot believes that its relationship with members of its senior management is positive, there can be no assurance that the services of any of these individuals will continue to be available to Microbot in the future. Microbot's future success will depend in part on its ability to retain its management and scientific teams, to identify, hire and retain additional qualified personnel with expertise in research and development and sales and marketing, and to effectively provide for the succession of senior management, when necessary. Competition for qualified personnel in the medical device industry is intense and finding and retaining qualified personnel with experience in the industry is very difficult. Microbot believes that there are only a limited number of individuals with the requisite skills to serve in key positions at Microbot, particularly in Israel, and it competes for key personnel with other medical equipment and technology companies, as well as research institutions.

Microbot does not carry, and does not intend to carry, any key man life insurance policies on any of its existing executive officers.

Risks Relating to International Business

If Microbot fails to obtain regulatory clearances in other countries for its product candidates under development, Microbot will not be able to commercialize these product candidates in those countries.

In order for Microbot to market its product candidates in countries other than the United States, it must comply with the safety and quality regulations in such countries.

In Europe, these regulations, including the requirements for approvals, clearance or grant of Conformité Européenne, or CE, Certificates of Conformity and the time required for regulatory review, vary from country to country. Failure to obtain regulatory approval, clearance or CE Certificates of Conformity (or equivalent) in any foreign country in which Microbot plans to market its product candidates may harm its ability to generate revenue and harm its business. Approval and CE marking procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval or CE Certificate of Conformity in other countries might differ from that required to obtain FDA clearance. The regulatory approval or CE marking process in other countries may include all of the risks detailed above regarding FDA clearance in the United States. Regulatory approval or the CE marking of a product candidate in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval or a CE Certificate of Conformity in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval or a CE Certificate of Conformity in other countries or any delay or setback in obtaining such approval could have the same adverse effects described above regarding FDA clearance in the United States.

Microbot cannot be certain that it will be successful in complying with the requirements of the CE Certificate of Conformity and receiving a CE Mark for its product candidates or in continuing to meet the requirements of the Medical Devices Directive in the European Economic Area (EEA).

Israel's Medical Devices Law generally requires the registration of all medical products with the Ministry of Health, or MOH, Registrar through the submission of an application to the Ministry of Health Medical Institutions and Devices Licensing Department, or AMAR. If the application includes a certificate issued by a competent authority of a "recognized" country, which includes Australia, Canada, the European Community Member States, Japan or the United States, the registration process is expedited, but is generally still expected to take 6 to 9 months for approval. If certification from a recognized country is not available, the registration process takes significantly longer and a license is rarely issued under such circumstances, as the MOH may require the presentation of significant additional clinical data. Once granted, a license (marketing authorization) for a medical device is valid for five years from the date of registration of the device, except for implants with a life-supporting function, for which the validity is for only two years from the date of registration. Furthermore, the holder of the license must meet several additional requirements to maintain the license. Microbot cannot be certain that it will be successful in applying for a license from the MOH for its product candidates.

Risks Relating to Microbot's Intellectual Property

Microbot's right to develop and commercialize the SCS and TipCAT product candidates are subject to the terms and condition of a license granted to Microbot by Technion Research and Development Foundation Ltd. and termination of the license with respect to one or both of the technology platforms underlying the product candidates would result in Microbot ceasing its development efforts for the applicable product candidate(s).

Microbot entered into a license agreement with Technion Research and Development Foundation Ltd., or TRDF, in 2012 pursuant to which Microbot obtained an exclusive, worldwide, royalty-bearing, sub-licensable license to certain patents and inventions relating to the SCS and TipCAT technology platforms. Pursuant to the terms of the license agreement, in order to maintain the license with respect to each platform, Microbot must use commercially reasonable efforts to develop products covered by the license, including meeting certain agreed upon development milestones. TRDF has the option to terminate a license granted with respect a particular technology in the event Microbot fails to meet a development milestone associated with such technology. Therefore, the failure to meet development milestones may lead to a complete termination of the applicable license agreement and result in Microbot ceasing its development efforts for the applicable product candidate. The milestones for both SCS and TipCAT include commencing first in human clinical trials by December 2021. Failure to meet any development milestone will give TRDF the right to terminate the license with respect to the technology underlying the missed milestone. TRDF has previously demonstrated flexibility with respect to amending the terms of the license to extend the milestone dates, although we can give no assurance at this time that TRDF will continue to be so flexible with respect to amending the terms of the license.

Under the license agreement, Microbot is also subject to various other obligations, including obligations with respect to payment upon the achievement of certain milestones and royalties on product sales. TRDF may terminate the license agreement under certain circumstances, including material breaches by Microbot or under certain bankruptcy or insolvency events. In the case of termination of the license by Microbot without cause or by TRDF for cause, TRDF has the right to receive a non-exclusive license from Microbot with respect to improvements to the licensed technologies made by Microbot.

If TRDF were to terminate the license agreement or if Microbot was to otherwise lose the ability to exploit the licensed patents, Microbot's competitive advantage could be reduced or terminated, and Microbot will likely not be able to find a source to replace the licensed technology.

Additionally, if there is any future dispute between Microbot and TRDF regarding the respective parties' rights under the license agreement, Microbot's ability to develop and commercialize the SCS and TipCAT may be materially harmed.

Microbot may not meet its product candidates' development and commercialization objectives in a timely manner or at all.

Microbot has established internal goals, based upon expectations with respect to its technologies, which Microbot has used to assess its progress toward developing its product candidates. These goals relate to technology and design improvements as well as to dates for achieving specific development results. If the product candidates exhibit technical defects or are unable to meet cost or performance goals, Microbot's commercialization schedule could be delayed and potential purchasers of its initial commercialized products may decline to purchase such products or may opt to pursue alternative products, which would materially harm its business.

Intellectual property litigation and infringement claims could cause Microbot to incur significant expenses or prevent Microbot from selling certain of its product candidates.

The medical device industry is characterized by extensive intellectual property litigation. From time to time, Microbot might be the subject of claims by third parties of potential infringement or misappropriation. Regardless of outcome, such claims are expensive to defend and divert the time and effort of Microbot's management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against Microbot could result in its payment of significant monetary damages and/or royalty payments or negatively impact its ability to sell current or future products in the affected category and could have a material adverse effect on its business, cash flows, financial condition or results of operations.

If Microbot or TRDF are unable to protect the patents or other proprietary rights relating to Microbot's product candidates, or if Microbot infringes on the patents or other proprietary rights of others, Microbot's competitiveness and business prospects may be materially damaged.

Microbot's success depends on its ability to protect its intellectual property (including its licensed intellectual property) and its proprietary technologies. Microbot's commercial success depends in part on its ability to obtain and maintain patent protection and trade secret protection for its product candidates, proprietary technologies, and their uses, as well as its ability to operate without infringing upon the proprietary rights of others.

Microbot currently holds, through licenses or otherwise, an intellectual property portfolio that includes U.S. and international patents and pending patents, and other patents under development. Microbot intends to continue to seek legal protection, primarily through patents, including the TRDF licensed patents, for its proprietary technology. Seeking patent protection is a lengthy and costly process, and there can be no assurance that patents will be issued from any pending applications, or that any claims allowed from existing or pending patents will be sufficiently broad or strong to protect its proprietary technology. There is also no guarantee that any patents Microbot holds, through licenses or otherwise, will not be challenged, invalidated or circumvented, or that the patent rights granted will provide competitive advantages to Microbot. Microbot's competitors have developed and may continue to develop and obtain patents for technologies that are similar or superior to Microbot's technologies. In addition, the laws of foreign jurisdictions in which Microbot develops, manufactures or sells its product candidates may not protect Microbot's intellectual property rights to the same extent as do the laws of the United States.

Adverse outcomes in current or future legal disputes regarding patent and other intellectual property rights could result in the loss of Microbot's intellectual property rights, subject Microbot to significant liabilities to third parties, require Microbot to seek licenses from third parties on terms that may not be reasonable or favorable to Microbot, prevent Microbot from manufacturing, importing or selling its product candidates, or compel Microbot to redesign its product candidates to avoid infringing third parties' intellectual property. As a result, Microbot may be required to incur substantial costs to prosecute, enforce or defend its intellectual property rights if they are challenged. Any of these circumstances could have a material adverse effect on Microbot's business, financial condition and resources or results of operations.

Microbot has the first right, but not the obligation, to control the prosecution, maintenance or enforcement of the licensed patents from TRDF. However, there may be situations in which Microbot will not have control over the prosecution, maintenance or enforcement of the patents that Microbot licenses, or may not have sufficient ability to consult and input into the patent prosecution and maintenance process with respect to such patents. If Microbot does not control the patent prosecution and maintenance process with respect to the TRDF licensed patents, TRDF may elect to do so but may fail to take the steps that are necessary or desirable in order to obtain, maintain and enforce the licensed patents.

Microbot's ability to develop intellectual property depends in large part on hiring, retaining and motivating highly qualified design and engineering staff and consultants with the knowledge and technical competence to advance its technology and productivity goals. To protect Microbot's trade secrets and proprietary information, Microbot has entered into confidentiality agreements with its employees, as well as with consultants and other parties. If these agreements prove inadequate or are breached, Microbot's remedies may not be sufficient to cover its losses.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may result in Microbot's payment of significant monetary damages or impact offerings in its product portfolios.

Microbot's long-term success largely depends on its ability to market technologically competitive product candidates. If Microbot fails to obtain or maintain adequate intellectual property protection, it may not be able to prevent third parties from using its proprietary technologies or may lose access to technologies critical to our product candidates. Also, Microbot currently pending or future patent applications may not result in issued patents, and issued patents are subject to claims concerning priority, scope and other issues.

Furthermore, Microbot has not filed applications for all of our patents internationally and it may not be able to prevent third parties from using its proprietary technologies or may lose access to technologies critical to its product candidates in other countries.

Risks Relating to Operations in Israel

Microbot has facilities located in Israel, and therefore, political conditions in Israel may affect Microbot's operations and results.

Microbot has facilities located in Israel. In addition, one of its seven directors, its Chief Medical Officer and its Chief Financial Officer, as well as substantially all of its research and development team and non-management employees, are residents of Israel. Accordingly, political, economic and military conditions in Israel will directly or indirectly affect Microbot's operations and results. Since the establishment of the State of Israel, a number of armed conflicts have taken place between Israel and its Arab neighbors. An ongoing state of hostility, varying in degree and intensity has led to security and economic problems for Israel. For a number of years there have been continuing hostilities between Israel and the Palestinians. This includes hostilities with the Islamic movement Hamas in the Gaza Strip, which have adversely affected the peace process and at times resulted in armed conflicts. Such hostilities have negatively influenced Israel's economy as well as impaired Israel's relationships with several other countries. Israel also faces threats from Hezbollah militants in Lebanon, from ISIS and rebel forces in Syria, from the government of Iran and other potential threats from additional countries in the region. Moreover, some of Israel's neighboring countries have recently undergone or are undergoing significant political changes. These political, economic and military conditions in Israel could have a material adverse effect on Microbot's business, financial condition, results of operations and future growth.

Political relations could limit Microbot's ability to sell or buy internationally.

Microbot could be adversely affected by the interruption or reduction of trade between Israel and its trading partners. Some countries, companies and organizations continue to participate in a boycott of Israeli firms and others doing business with Israel, with Israeli companies or with Israeli-owned companies operating in other countries. Foreign government defense export policies towards Israel could also make it more difficult for us to obtain the export authorizations necessary for Microbot's activities. Also, over the past several years there have been calls in the United States, Europe and elsewhere to reduce trade with Israel. There can be no assurance that restrictive laws, policies or practices directed towards Israel or Israeli businesses will not have an adverse impact on Microbot's business.

Israel's economy may become unstable.

From time to time, Israel's economy may experience inflation or deflation, low foreign exchange reserves, fluctuations in world commodity prices, military conflicts and civil unrest. For these and other reasons, the government of Israel has intervened in the economy employing fiscal and monetary policies, import duties, foreign currency restrictions, controls of wages, prices and foreign currency exchange rates and regulations regarding the lending limits of Israeli banks to companies considered to be in an affiliated group. The Israeli government has periodically changed its policies in these areas. Reoccurrence of previous destabilizing factors could make it more difficult for Microbot to operate its business and could adversely affect its business.

Exchange rate fluctuations between the U.S. dollar and the NIS currencies may negatively affect Microbot's operating costs.

A significant portion of Microbot's expenses are paid in New Israeli Shekels, or NIS, but its financial statements are denominated in U.S. dollars. As a result, Microbot is exposed to the risks that the NIS may appreciate relative to the U.S. dollar, or the NIS instead devalues relative to the U.S. dollar, and the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the U.S. dollar cost of Microbot's operations in Israel would increase and Microbot's U.S. dollar-denominated results of operations would be adversely affected. Microbot cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the U.S. dollar.

Microbot's primary expenses paid in NIS that are not linked to the U.S. dollar are employee expenses in Israel and lease payments on its Israeli facility. If Microbot is unsuccessful in hedging against its position in NIS, a change in the value of the NIS compared to the U.S. dollar could increase Microbot's research and development expenses, labor costs and general and administrative expenses, and as a result, have a negative impact on Microbot's profits.

Funding and other benefits provided by Israeli government programs may be terminated or reduced in the future and the terms of such funding may have a significant impact on future corporate decisions.

Microbot participates in programs under the auspices of the Israeli Innovation Authority, for which it receives funding for the development of its technologies and product candidates. If Microbot fails to comply with the conditions applicable to this program, it may be required to pay additional penalties or make refunds and may be denied future benefits. From time to time, the government of Israel has discussed reducing or eliminating the benefits available under this program, and therefore these benefits may not be available in the future at their current levels or at all.

Microbot's research and development efforts from inception until now have been financed in part through such Israeli Innovation Authority royalty bearing grants in an aggregate amount of approximately \$1,500,000 through December 31, 2020. With respect to such grants Microbot is committed to pay royalties at a rate of between 3% to 3.5% on sales proceeds up to the total amount of grants received, linked to the dollar, plus interest at an annual rate of USD LIBOR. In addition, as a recipient of Israeli Innovation Authority grants, Microbot must comply with the requirements of the Israeli Encouragement of Industrial Research and Development Law, 1984, or the R&D Law, and related regulations. Under the terms of the grants and the R&D Law, Microbot is restricted from transferring any technologies, know-how, manufacturing or manufacturing rights developed using Israeli Innovation Authority grants outside of Israel without the prior approval of Israeli Innovation Authority. Therefore, if aspects of its technologies are deemed to have been developed with Israeli Innovation Authority funding, the discretionary approval of an Israeli Innovation Authority committee would be required for any transfer to third parties outside of Israel of the technologies, know-how, manufacturing or manufacturing rights related to such aspects. Furthermore, the Israeli Innovation Authority may impose certain conditions on any arrangement under which it permits Microbot to transfer technology or development outside of Israel or may grant such approvals at all.

If approved, the transfer of Israeli Innovation Authority-supported technology or know-how outside of Israel may involve the payment of significant fees, which will depend on the value of the transferred technology or know-how, the total amount Israeli Innovation Authority funding received by Microbot, the number of years since the funding and other factors. These restrictions and requirements for payment may impair Microbot's ability to sell its technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. Furthermore, the amount of consideration available to Microbot's shareholders in a transaction involving the transfer of technology or know-how developed with Israeli Innovation Authority funding outside of Israel (such as through a merger or other similar transaction) may be reduced by any amounts that Microbot is required to pay to the Israeli Innovation Authority.

Some of Microbot's employees and officers are obligated to perform military reserve duty in Israel.

Generally, Israeli adult male citizens and permanent residents are obligated to perform annual military reserve duty up to a specified age. They also may be called to active duty at any time under emergency circumstances, which could have a disruptive impact on Microbot's workforce.

It may be difficult to enforce a non-Israeli judgment against Microbot or its officers and directors.

The operating subsidiary of the Company is incorporated in Israel. Some of Microbot's executive officers and directors are not residents of the United States, and a substantial portion of Microbot's assets and the assets of its executive officers and directors are located outside the United States. Therefore, a judgment obtained against Microbot, or any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not necessarily be enforced by an Israeli court. It also may be difficult to affect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Additionally, it may be difficult for an investor, or any other person or entity, to initiate an action with respect to U.S. securities laws in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law often involves the testimony of expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against Microbot in Israel, it may be impossible to collect any damages awarded by either a U.S. or foreign court.

Risks Relating to Microbot's Securities, Governance and Other Matters

If we fail to comply with the continued listing requirements of The Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed on the Nasdaq Capital Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards. In 2018, we effected a 1:15 reverse stock split to address our stock price falling below the minimum share price required by Nasdaq. Failure to meet applicable Nasdaq continued listing standards could result in a delisting of our common stock. A delisting of our common stock from The Nasdaq Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business opportunities. Additionally, if we are not eligible for quotation or listing on another exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

We do not expect to pay cash dividends on our common stock.

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends on our Common Stock in the future. Investors seeking cash dividends should not invest in our Common Stock for that purpose.

Anti-takeover provisions in the Company's charter and bylaws under Delaware law may prevent or frustrate attempts by stockholders to change the board of directors or current management and could make a third-party acquisition of the Company difficult.

Provisions in the Company's certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors. In addition, because the Company is incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of outstanding voting stock from merging or combining with the Company. Although the Company believes these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with the Company's board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by the Company's stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing members of management.

We are subject to litigation, which may divert management's attention and have a material adverse effect on our business, financial condition and results of operations.

We are the defendant in a lawsuit captioned Empery Asset Master Ltd., Empery Tax Efficient, LP, Empery Tax Efficient II, LP, Hudson Bay Master Fund Ltd., Plaintiffs, against Microbot Medical Inc., Defendant, in the Supreme Court of the State of New York, County of New York (Index No. 651182/2020). The complaint alleged, 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 (the "Financing"), of which the Plaintiffs participated. The complaint sought rescission of the SPA and return of the Plaintiffs' \$6.75 million purchase price with respect to the Financing. We filed a Motion to Dismiss on March 16, 2020, which Motion was denied in February 2021.

Management is unable to assess the likelihood that we would be successful in any trial with respect to the SPA or the Financing, having previously lost another lawsuit with respect to the Financing. Accordingly, no assurance can be given that if we go to trial and ultimately lose, or if we decide to settle at any time, such an adverse outcome would not be material to our consolidated financial position. Additionally, in any such case, we will likely be required to use available cash, or the proceeds from future offerings, towards the rescission or settlement, 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, or delay, curtail or cease the commercialization of some or all of our product candidates.

General Risks

Raising additional capital may cause dilution to the Company's investors, restrict its operations or require it to relinquish rights to its technologies or product candidates.

Until such time, if ever, as the Company can generate substantial product revenues, it expects to finance its cash needs through a combination of equity offerings, including through a possible At-the-Market offering, licensing, collaboration or similar arrangements, grants and debt financings. The Company does not have any committed external source of funds. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interest of its stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holder of the Company's common stock. Debt financing, if available, may involve agreements that include covenants limiting or restricting the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or other distributions, selling or licensing intellectual property rights, and other operating restrictions that could adversely affect the Company's ability to conduct its business.

If the Company raises additional funds through licensing, collaboration or similar arrangements, it may have to relinquish valuable rights to its technologies, future revenue streams, research and development programs or product candidates or to grant licenses on terms that may not be favorable to the Company. If the Company is unable to raise additional funds through equity or debt financings or other arrangements when needed, it may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market product candidates that it would otherwise prefer to develop and market itself.

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 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, LIBERTY and other 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, LIBERTY 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.

Our business strategy in part relies on identifying, acquiring and developing complementary technologies and products, which entails risks which could negatively affect our business, operations and financial condition.

We may pursue other acquisitions of businesses and technologies. Acquisitions entail numerous risks, including:

- difficulties in the integration of acquired operations, services and products;
- failure to achieve expected synergies;
- diversion of management's attention from other business concerns;
- assumption of unknown material liabilities of acquired companies;
- amortization of acquired intangible assets, which could reduce future reported earnings;
- potential loss of clients or key employees of acquired companies; and
- dilution to existing stockholders.

As part of our growth strategy, we may consider, and from time to time may engage in, discussions and negotiations regarding transactions, such as acquisitions, mergers and combinations within our industry. The purchase price for possible acquisitions could be paid in cash, through the issuance of common stock or other securities, borrowings or a combination of these methods.

We cannot be certain that we will be able to identify, consummate and successfully integrate acquisitions, and no assurance can be given with respect to the timing, likelihood or business effect of any possible transaction. For example, we could begin negotiations that we subsequently decide to suspend or terminate for a variety of reasons. However, opportunities may arise from time to time that we will evaluate. Any transactions that we consummate would involve risks and uncertainties to us. These risks could cause the failure of any anticipated benefits of an acquisition to be realized, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Microbot operations in international markets involve inherent risks that Microbot may not be able to control.

Microbot's business plan includes the marketing and sale of its proposed product candidates internationally, and specifically in Europe and Israel. Accordingly, Microbot's results could be materially and adversely affected by a variety of factors relating to international business operations that it may or may not be able to control, including:

- adverse macroeconomic conditions affecting geographies where Microbot intends to do business;
- closing of international borders, including as a result of biohazards or pandemics;
- foreign currency exchange rates;
- political or social unrest or economic instability in a specific country or region;
- higher costs of doing business in certain foreign countries;
- infringement claims on foreign patents, copyrights or trademark rights;
- difficulties in staffing and managing operations across disparate geographic areas;
- difficulties associated with enforcing agreements and intellectual property rights through foreign legal systems;
- trade protection measures and other regulatory requirements, which affect Microbot's ability to import or export its product candidates from or to various countries;
- adverse tax consequences;
- unexpected changes in legal and regulatory requirements;
- military conflict, terrorist activities, natural disasters and medical epidemics; and
- Microbot's ability to recruit and retain channel partners in foreign jurisdictions.

Microbot's financial results may be affected by fluctuations in exchange rates and Microbot's current currency hedging strategy may not be sufficient to counter such fluctuations.

Microbot's financial statements are denominated in U.S. dollars and the financial results of the Company are denominated in U.S. dollars, while a significant portion of Microbot's business is conducted, and a substantial portion of its operating expenses are payable, in currencies other than the U.S. dollar. Exchange rate fluctuations may have an adverse impact on Microbot's future revenues or expenses as presented in the financial statements. Microbot may in the future use financial instruments, such as forward foreign currency contracts, in its management of foreign currency exposure. These contracts would primarily require Microbot to purchase and sell certain foreign currencies with or for U.S. dollars at contracted rates. Microbot may be exposed to a credit loss in the event of non-performance by the counterparties of these contracts. In addition, these financial instruments may not adequately manage Microbot's foreign currency exposure. Microbot's results of operations could be adversely affected if Microbot is unable to successfully manage currency fluctuations in the future.

The market price for our Common Stock may be volatile.

The market price for our Common Stock may be volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours;
- announcements by us or our competitors of new products, acquisitions, strategic partnerships, joint ventures or capital commitments;
- our intellectual property position; and
- general economic or political conditions in the United States, Israel or elsewhere.

In addition, the securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our Common Stock.

The issuance of shares upon exercise of outstanding warrants and options could cause immediate and substantial dilution to existing stockholders.

The issuance of shares upon exercise of warrants and options could result in substantial dilution to the interests of other stockholders since the holders of such securities may ultimately convert and sell the full amount issuable on conversion.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 2. Description of Property.

Microbot's principal executive office is located at 25 Recreation Drive, Unit 108, Hingham, MA 02043. Microbot also occupies facilities in premises of approximately 6,975 square feet at 6 Hayozma St., Yokneam, P.O.B. 242, Israel. This facility is expected to provide the space and infrastructure necessary to accommodate its development work based on its current operating plan. Microbot does not own any real property.

Item 3. Legal Proceedings.

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

Litigation Resulting from 2017 Financing

We were named as the defendant in a lawsuit captioned Empery Asset Master Ltd., Empery Tax Efficient, LP, Empery Tax Efficient II, LP, Hudson Bay Master Fund Ltd., Plaintiffs, against Microbot Medical Inc., Defendant, in the Supreme Court of the State of New York, County of New York (Index No. 651182/2020). The complaint alleges, among other things, that we breached multiple representations and warranties contained in the SPA, of which the Plaintiffs participated, and fraudulently induced Plaintiffs into signing the Securities Purchase Agreement (the "SPA") related to our June 8, 2017 equity financing (the "Financing"). The complaint seeks rescission of the SPA and return of the Plaintiffs' \$6.75 million purchase price with respect to the Financing. We filed a Motion to Dismiss on March 16, 2020, which Motion was denied in February 2021. Management is unable to assess the likelihood that we will succeed at trial with respect to the SPA or the Financing, having previously lost another lawsuit with respect to the Financing.

Alliance Litigation

On April 28, 2019, we brought an action against Alliance Investment Management, Ltd. (“Alliance”), later amended to include Joseph Mona (“Mona”) as a defendant, in the Southern District of New York under Section 16(b) of the Securities Exchange Act of 1934, 15 U.S.C. 78p(b), to compel Alliance and Mona to disgorge short swing profits realized from purchases and sales of our securities within a period of less than six months. The case is *Microbot Medical Inc. v. Alliance Investment Management, Ltd.*, No. 19-cv-3782-GBD (SDNY). The amount of profits was estimated in the complaint to be approximately \$468,000.

On October 28, 2019, Alliance filed a motion for summary judgment requesting that the Court dismiss the claims against Alliance. On February 4, 2020, Mona answered the 16(b) claim we asserted against him by claiming various equitable defenses, and filed a counterclaim against Microbot under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, claiming a net loss on trading Microbot stock of \$150,954.

On March 6, 2020, we filed a motion for judgment on the pleadings with respect to our 16(b) claim against Mona, together with a motion to dismiss Mona’s 10(b) counterclaim.

On September 17, 2020, the Court issued a Memorandum Decision & Order that, among other things, granted Alliance’s summary judgment motion. Our Section 16(b) claim against Mona remained pending following the Court’s dismissal of the 16(b) claim against Alliance.

On December 18, 2020, the Magistrate Judge issued a Report & Recommendation, which recommended that: (i) judgment of \$484,614.30 be entered in our favor on our Section 16(b) claim against Mona; and (ii) Mona’s Section 10(b) claim be dismissed with prejudice (except as to allegations regarding statements purportedly made by employees of Integra Consulting, an outside investor relations firm, which the Magistrate recommended be dismissed without prejudice). On January 4, 2021, Mona filed objections to the Magistrate’s Report & Recommendation, which is pending. Given the Magistrate’s recommendation of judgment in our favor on all outstanding claims, we did not file any objection to the Report.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is listed on the NASDAQ Capital Market under the symbol “MBOT” since November 29, 2016. Prior to that, our common stock was traded under the symbol “STEM.”

As of March 29, 2021, there were approximately 137 holders of record of our common stock, and the closing sales price of our common stock as reported on the NASDAQ Capital Market was \$7.89.

Dividend Policy

We have never paid cash dividends on our common stock and we do not anticipate paying cash dividends on common stock in the foreseeable future. The payment of dividends on our common stock will depend on earnings, financial condition, debt covenants in place, and other business and economic factors affecting us at such time as our Board of Directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on a stockholders’ investment will only occur if our stock price appreciates.

Equity Compensation Plan Information Table

The following table provides information about shares of our common stock that may be issued upon the exercise of options under all of our existing compensation plans as of December 31, 2020.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders:			
2017 Equity Incentive Plan	436,299	\$ 11.33	187,419
2020 Omnibus Performance Award Plan	-	\$ -	1,420,652
Equity compensation plans not approved by security holders:			
Microbot Israel Employee Stock Option Plan(1)	61,577	\$ 0.0	-
Stock Options (2)	77,846	\$ 4.2	-
Total	575,222		1,608,071

- (1) Such options were originally issued by Microbot Israel under its Employee Stock Option Plan, and represented the right to purchase an aggregate of 500,000 of Microbot Israel's ordinary shares. As of the effective time of the Merger, such options were retroactively adjusted to reflect the Merger and now represent the right to purchase shares of our common stock.
- (2) Such options were originally issued by Microbot Israel to MEDX Ventures Group LLC, of which Mr. Gadot is the Chief Executive Officer, Company Group Chairman and majority equity owner, and represented the right to purchase an aggregate of 403,592 of Microbot Israel's ordinary shares. As of the effective time of the Merger, such options were retroactively adjusted to reflect the Merger and now represent the right to purchase shares of our common stock.

Item 6. Selected Financial Data.

This item is not required for a smaller reporting company.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Forward Looking Statements

Certain information contained in this MD&A includes "forward-looking statements." Statements which are not historical reflect our current expectations and projections about our future results, performance, liquidity, financial condition and results of operations, prospects and opportunities and are based upon information currently available to us and our management and their interpretation of what is believed to be significant factors affecting our existing and proposed business, including many assumptions regarding future events. Actual results, performance, liquidity, financial condition and results of operations, prospects and opportunities could differ materially and perhaps substantially from those expressed in, or implied by, these forward-looking statements as a result of various risks, uncertainties and other factors, including those risks described in detail in the section of this Annual Report on Form 10-K entitled "Risk Factors" as well as elsewhere in this Annual Report.

Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words "may," "should," "would," "will," "could," "scheduled," "expect," "anticipate," "estimate," "believe," "intend," "seek," or "project" or the negative of these words or other variations on these words or comparable terminology.

In light of these risks and uncertainties, and especially given the nature of our existing and proposed business, there can be no assurance that the forward-looking statements contained in this section and elsewhere in this Annual Report on Form 10-K will in fact occur. Potential investors should not place undue reliance on any forward-looking statements. Except as expressly required by the federal securities laws, there is no undertaking to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances or any other reason.

Overview

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 redefining surgical robotics while improving surgical outcomes for patients.

Microbot's current technological platforms, ViRob™, TipCAT™ and LIBERTY™ (including certain CardioSert assets), are comprised of proprietary innovative technologies. Using the ViRob platform, Microbot is currently developing the Self Cleaning Shunt for the treatment of hydrocephalus and Normal Pressure Hydrocephalus, or NPH. Utilizing the LIBERTY and CardioSert platforms, Microbot is developing the first ever fully disposable robot for various endovascular interventional procedures. In addition, the Company is focused on the development of a Multi Generation Pipeline Portfolio utilizing all of its proprietary technologies.

Microbot has a patent portfolio of 42 issued/allowed patents and 23 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.

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.

CardioSert

On May 25, 2018, Microbot acquired a patent-protected technology from CardioSert Ltd., a privately-held medical device company based in Israel that was part of a technological incubator supported by the Israel Innovation Authorities. 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.

LIBERTY

On January 13, 2020, Microbot unveiled what it believes is the world's first fully disposable robotic system for use in Endovascular Interventional procedures, such as cardiovascular, peripheral and neurovascular. The LIBERTY robotic system features a unique compact design with the capability to be operated remotely, reduce radiation exposure and physical strain to the physician, as well as the potential to eliminate the use of multiple consumables when used with its "One & Done" capabilities, based in part on the CardioSert platform or possibly other guidewire/microcatheter technologies.

On August 17, 2020, Microbot announced the successful conclusion of its feasibility animal study using the LIBERTY robotic system. The study met all of its end points with no intraoperative adverse events, which supports Microbot's objectives to allow physicians to conduct a catheter-based procedure from outside the catheterization laboratory (cath-lab), avoiding radiation exposure, physical strain and the risk of cross contamination. The study was performed by two leading physicians in the neuro vascular and peripheral vascular intervention spaces, and the results demonstrated robust navigation capabilities, intuitive usability and accurate deployment of embolic agents, most of which was conducted remotely from the cath-lab's control room.

We are continuously exploring and evaluating additional innovative guidewire/microcatheter technologies to be integrated and combined with the LIBERTY robotic platform.

Financial Operations Overview

Research and Development Expenses

Research and development expenses consist primarily of salaries and related expenses and overhead for Microbot's research, development and engineering personnel, prototype materials and research studies, obtaining and maintaining Microbot's patent portfolio. Microbot expenses its research and development costs as incurred.

General and Administrative Expenses

General and administrative expenses consist primarily of the costs associated with management salaries and benefits, professional fees for accounting, auditing, consulting and legal services, and allocated overhead expenses.

Microbot expects that its general and administrative expenses may increase in the future as it expands its operating activities, maintains and expands its patent portfolio and maintains compliance with exchange listing and SEC requirements. Microbot expects these potential increases will likely include management costs, legal fees, accounting fees, directors' and officers' liability insurance premiums and expenses associated with investor relations.

Income Taxes

Microbot has incurred net losses and has not recorded any income tax benefits for the losses. It is still in its development stage and has not yet generated revenues, therefore, it is more likely than not that sufficient taxable income will not be available for the tax losses to be fully utilized in the future.

Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of Microbot's financial condition and results of operations are based on its consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these consolidated financial statements requires Microbot to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Microbot bases its estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

While Microbot's significant accounting policies are described in more detail in the notes to its consolidated financial statements, Microbot believes the following accounting policies are the most critical for fully understanding and evaluating its consolidated financial condition and results of operations.

Contingencies

Management records and discloses legal contingencies in accordance with ASC Topic 450 *Contingencies*. A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company monitors the stage of progress of its litigation matters to determine if any adjustments are required.

Fair Value of Financial Instruments

The Company measures the fair value of certain of its financial instruments on a recurring basis.

A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

Level 1 - Quoted prices (unadjusted) in active markets for identical assets and liabilities.

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Results of Operations

Comparison of Years Ended December 31, 2020 and 2019

The following table sets forth the key components of Microbot's results of operations for the years ended December 31, 2020 and 2019 (in thousands):

	Years Ended December 31,		Change
	2020	2019	
Research and development expenses, net	\$ 3,396	\$ 3,048	\$ 348
General and administrative expenses	5,693	4,192	1,501
Financing expenses, net	80	103	(23)
Capital gains	-	(96)	96

Research and Development Expenses. Microbot's research and development expenses were approximately \$3,396,000 for the year ended December 31, 2020, compared to approximately \$3,048,000 for the same period in 2019. The increase in research and development expenses of approximately \$348,000 in 2020 was primarily due to increased salaries, professional services and patent expenses compared to the prior year. Microbot expects its research and development expenses to continue to increase over time as Microbot advances its development programs and begins pre-clinical and clinical trials for the SCS, LIBERTY and TipCAT research programs.

General and Administrative Expenses. General and administrative expenses were approximately \$5,693,000 for the year ended December 31, 2020, compared to approximately \$4,192,000 for the same period in 2019. The increase in general and administrative expenses of approximately \$1,501,000 in 2020 was primarily due to increased salaries, government fees, share based compensation, insurance, and public and investor relations compared to 2019, partially offset by a decrease in 2020 in professional services and travel expenses compared to 2019. Microbot believes its general and administrative expenses may increase over time as it advances its programs, increases its headcount and operating activities and incurs expenses associated with public-company compliance.

Financing Expenses. Financing expenses were approximately \$80,000 for the year ended December 31, 2020, compared to approximately \$103,000 for the same period in 2019. The decrease in 2020 was primarily due to financing income from convertible loan offset by exchange rate differences related to lease liability contracts at Microbot Israel.

Capital Gains. Capital gains in 2019 were approximately \$96,000, where Microbot incurred capital gains primarily from the sale of certain property and equipment. We did not incur capital gains in 2020.

Liquidity and Capital Resources

Microbot has incurred losses since inception and negative cash flows from operating activities for the years ended December 31, 2020 and 2019. As of December 31, 2020, Microbot had a net working capital of approximately \$23,908,000, consisting primarily of cash and cash equivalents. Microbot anticipates that it will continue to incur net losses for the foreseeable future as it continues research and development efforts of its product candidates, hires additional staff, including clinical, scientific, operational, financial and management personnel, and continues to incur costs associated with being a public company.

Microbot has funded its operations through the issuance of capital stock, grants from the Israeli Innovation Authority, and convertible debt. Since inception (November 2010) through December 31, 2020, Microbot has raised net cash proceeds of approximately \$54,770,000, and incurred a total cumulative loss of approximately \$44,280,000. Microbot returned \$3,375,000 (before interest) of such proceeds as a result of an adverse outcome in a litigation that concluded in the first quarter of 2020, and is now subject to an additional lawsuit seeking the return of an additional \$6,750,000 of such proceeds.

Microbot Israel obtained from the Israeli Innovation Authority (“IIA”) grants for participation in research and development for the years 2013 through December 31, 2020 in the total amount of approximately \$1,500,000 and, in return, Microbot Israel is obligated to pay royalties amounting to 3%-3.5% of its future sales up to the amount of the grant. The grant is linked to the exchange rate of the dollar to the New Israeli Shekel and bears interest at an annual rate of USD LIBOR. Under the terms of the grant and applicable law, Microbot is restricted from transferring any technologies, know-how, manufacturing or manufacturing rights developed using the grant outside of Israel without the prior approval of the Israel Innovation Authority. Microbot has no obligation to repay the grant, if the SCS project fails, is unsuccessful or aborted before any sales are generated. The financial risk is assumed completely by the IIA.

Microbot believes that its net cash will be sufficient to fund its operations for at least 24 months and fund operations necessary to continue development activities of the SCS, LIBERTY and TipCAT. However, in the event we are unsuccessful in our current litigation with Empery and Hudson Bay, pursuant to which they are seeking the return of \$6,750,000 in proceeds we received from them in a 2017 stock offering, we may have funds for less than 24 months.

Microbot plans to continue to fund its research and development and other operating expenses, other development activities relating to additional product candidates, and the associated losses from operations, through its existing cash and possibly additional grants from the Israeli Innovation Authority. Microbot intends to also raise capital through future issuances of debt and/or equity securities, including registered offerings under its existing Registration Statement on Form S-3 for up to \$75 million of securities, which it may draw down from time to time. These issuances may be opportunistic and even if the Company has enough funds at such time for operations for more than 12-24 months. The capital raises from issuances of convertible debt and equity securities could result in additional dilution to Microbot’s shareholders. In addition, to the extent Microbot determines to incur additional indebtedness, Microbot’s incurrence of additional debt could result in debt service obligations and operating and financing covenants that would restrict its operations. Microbot can provide no assurance that financing will be available in the amounts it needs or on terms acceptable to it, if at all. If Microbot is not able to secure adequate additional working capital when it becomes needed, it may be required to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned research programs. Any of these actions could materially harm Microbot’s business.

Cash Flows

The following table provides a summary of the net cash flow activity for each of the periods set forth below (in thousands):

	Years ended December 31,	
	2020	2019
Net cash flows from operating activities	\$ (7,252)	\$ (6,451)
Net cash flows from investing activities	(2,768)	(2,453)
Net cash flows from financing activities	(3,375)	36,770
Net (decrease) increase in cash and cash equivalents	<u>\$ (13,395)</u>	<u>\$ 27,866</u>

Comparison of the Years Ended December 31, 2020 and 2019

Cash used in operating activities for the year ended December 31, 2020 was approximately \$7,252,000, compared to \$6,451,000 in 2019. The increase was from higher net losses in 2020 partially offset by increased non-cash stock-based compensation.

Net cash flows from investing activities decreased in 2020 compared to 2019 primarily from the net purchase of marketable securities.

Net cash flows from financing activities decreased in 2020 due primarily to issuance of common stock of \$36,770,000 during 2019, while in 2020 there was a payback of \$3,375,000 to investors due to the outcome of litigation with such investors.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Microbot's cash and cash equivalents as of December 31, 2020 consisted of readily available checking and money market funds. Microbot's primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in Microbot's portfolio, a sudden change in market interest rates would not be expected to have a material impact on Microbot's financial condition and/or results of operations. Microbot does not believe that its cash or cash equivalents have significant risk of default or illiquidity. While Microbot believes its cash and cash equivalents do not contain excessive risk, Microbot cannot provide absolute assurance that in the future its investments will not be subject to adverse changes in market value. In addition, Microbot maintains significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

Foreign Exchange Risks

Our financial statements are denominated in U.S. dollars and financial results are denominated in U.S. dollars, while a significant portion of our business is conducted, and a substantial portion of our operating expenses are payable, in currencies other than the U.S. dollar.

Exchange rate fluctuations may have an adverse impact on our future revenues, if any, or expenses as presented in the financial statements. We may in the future use financial instruments, such as forward foreign currency contracts, in its management of foreign currency exposure. These contracts would primarily require us to purchase and sell certain foreign currencies with or for U.S. dollars at contracted rates. We may be exposed to a credit loss in the event of non-performance by the counterparties of these contracts. In addition, these financial instruments may not adequately manage our foreign currency exposure. Our results of operations could be adversely affected if we are unable to successfully manage currency fluctuations in the future.

Effects of Inflation

Inflation generally affects Microbot by increasing its clinical trial costs. Microbot does not believe that inflation and changing prices had a significant impact on its results of operations for any periods presented herein.

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements and supplementary data required by this item are included in this Annual Report on Form 10-K immediately following Part IV and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures. We maintain a system of disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). As required by Rule 13a-15(b) under the Exchange Act, management of the Company, under the direction of our Chief Executive Officer and Chief Financial Officer, reviewed and performed an evaluation of the effectiveness of design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of December 31, 2020. Based on that review and evaluation, the Chief Executive Officer and Chief Financial Officer, along with the management of the Company, have determined that as of December 31, 2020, the disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and were effective to provide reasonable assurance that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Management's Annual Report on Internal Control Over Financial Reporting. Our management is responsible for establishing and maintaining effective internal control over financial reporting (as defined in Rule 13a – 15(f) of the Exchange Act). There are inherent limitations to the effectiveness of any internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal controls can provide only reasonable assurance with respect to financial statement preparation. Further, because of changes in conditions, the effectiveness of internal control may vary over time. We have assessed the effectiveness of our internal controls over financial reporting (as defined in Rule 13a -15(f) of the Exchange Act) as of December 31, 2020, and have concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

Board of Directors

We currently have seven directors serving on our Board. The following table lists the names, ages and positions of the individuals who serve as directors of the Company, as of March 29, 2021:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Harel Gadot	48	President, Chief Executive Officer and Chairman of the Board of Directors
Yoseph Bornstein(1)(3)	63	Director
Scott Burell(1)(2)	56	Director
Martin Madden(1)(3)	59	Director
Prattipati Laxminarain(2)	63	Director
Aileen Stockburger(3)	58	Director
Tal Wenderow(2)	46	Director

(1) Member of Audit Committee.

(2) Member of Corporate Governance Committee.

(3) Member of Compensation Committee.

We have a classified Board, with each of our directors serving a staggered three-year term. The following table shows the current composition of the three classes of our Board:

Class I Directors (terms scheduled to expire in 2022):

Harel Gadot
Martin Madden
Tal Wenderow

Class II Directors (term scheduled to expire in 2023):

Scott Burell
Aileen Stockburger

Class III Directors (term scheduled to expire in 2021):

Yoseph Bornstein
Prattipati Laxminarain

Harel Gadot, became President, Chief Executive Officer and Chairman of the Company's Board following the consummation of the merger of C&RD Israel Ltd, a wholly owned subsidiary of the Company, with and into Microbot Israel, with Microbot Israel surviving as a wholly owned subsidiary of the Company (the "Merger"). Mr. Gadot is a co-founder of Microbot Israel and has served as Microbot Israel's Chief Executive Officer since Microbot Israel was founded in November 2010. He has been the Chairman of Microbot Israel's board of directors since July 2014. He also serves as the Chairman of XACT Robotics Ltd., an Israel-based private company seeking to develop a novel platform technology for robotic needle steering in minimally invasive interventional procedures such as biopsies and ablations, since August 2013 and MEDX Xelerator L.P., a medical device and digital health Israeli incubator, since July 2016. From December 2007 to April 2010 Mr. Gadot was a Worldwide Group Marketing Director at Ethicon Inc., a Johnson and Johnson Company, where he was responsible for the global strategic marketing of the Company. Mr. Gadot also held management positions, as well as leading regional strategic position for Europe, Middle-East and Africa, as well as In Israel, while at Johnson and Johnson. Mr. Gadot served as director for ConTIPI Ltd. from August 2010 until November 2013 when ConTIPI Ltd. was acquired by Kimberly-Clark Corporation. Mr. Gadot holds a B.Sc.in Business from Siena College, Loudonville NY, and an M.B.A. from the University of Manchester, UK. The Company believes that Mr. Gadot is qualified to serve as Chairman of the Board and as President and Chief Executive Officer of the Company due to his extensive experience in strategic marketing and general management in the medical device industry.

Yoseph Bornstein, became a director of the Company following the Merger. Mr. Bornstein is a co-founder of Microbot Israel and has been a member of the Board of Directors since Microbot Israel was founded in November 2010. Mr. Bornstein founded Shizim Ltd., a life science holding group in October 2000 and has served as its president since then. Mr. Bornstein is the Chairman of GCP Clinical Studies Ltd., a provider of clinical research services and educational programs in Israel since January 2002. He is the Chairman of Biotis Ltd., a service company for the bio-pharmaceutical industry, since June 2000. In addition, he is the Chairman of Dolphin Medical Ltd., which supplies the medical device industry, since April 2012, and the Chairman of ASIS Enterprises B.B.G. Ltd., a business development company focusing on creating business ties between Israeli and Japanese entities, since August 2007. Mr. Bornstein is a co-founder and director of XACT Robotics, which is developing a novel platform technology for robotic needle steering in minimally invasive interventional procedures, and is the founder of ShizimXL and ShizimVS Innovation Centers. In October 1992, Mr. Bornstein founded Pharmateam Ltd., an Israeli company that specialized in representing international pharmaceutical companies which was sold in 2000. Mr. Bornstein is also a founder of a number of other privately held life-science companies. Mr. Bornstein served as the Biotechnology Committee Chairman of the United States-Israel Science & Technology Commission (the “USISTC”) from September 2002 to February 2005 as well as a consultant for USISTC from September 2002 to February 2005. He is also the founder of ILSI-Israel Life Science Industry Organization (who was integrated into IATI) and ITTN-Israel Tech Transfer Organization. The Company believes that Mr. Bornstein is qualified to serve as a member of the Board due to his extensive experience in, and knowledge of, the life sciences industry and international business.

Scott R. Burell, became a director of the Company following the Merger. Since August 1, 2018, Mr. Burell has been the Chief Financial Officer of AIVITA Biomedical, Inc., an Irvine California-based immuno-oncology company focused on the advancement of commercial and clinical-stage programs utilizing curative and regenerative medicines. From November 2006 until its sale to Invitae Corp. (NYSE: NVTA) in November 2017, he was the Chief Financial Officer, Secretary and Treasurer of CombiMatrix Corporation (NASDAQ: CBMX), a family health-focused clinical molecular diagnostic laboratory specializing in pre-implantation genetic screening, prenatal diagnosis, miscarriage analysis, and pediatric developmental disorders. He successfully led the split-off of CombiMatrix in 2007 from its former parent, has led several successful public and private debt and equity financing transactions as well as CombiMatrix’s reorganization in 2010. Prior to this, Mr. Burell had served as CombiMatrix’s Vice President of Finance since November 2001 and as its Controller from February 2001 to November 2001. From May 1999 to first joining CombiMatrix in February 2001, Mr. Burell was the Controller for Network Commerce, Inc. (NASDAQ: SPNW), a publicly traded technology and information infrastructure company located in Seattle. Prior to this, Mr. Burell spent nine years with Arthur Andersen’s Audit and Business Advisory practice in Seattle. During his tenure in public accounting, Mr. Burell worked with many clients, both public and private, in the high-tech and healthcare markets, and was involved in numerous public offerings, spin-offs, mergers and acquisitions. Mr. Burell is a Board member of Mer Telemanagement Solutions Ltd. (Nasdaq: MTSL), an Israeli-based publicly traded telecommunications services company. Mr. Burell obtained his Washington state CPA license in 1992 and is a certified public accountant (currently inactive). He holds Bachelor of Science degrees in Accounting and Business Finance from Central Washington University. The Company believes Mr. Burell’s qualifications to serve on the Board include his experience as an executive of a public life sciences company and knowledge of financial accounting in the medical technology field.

Martin Madden, has been a director of the Company since February 6, 2017. Mr. Madden has held various positions at Johnson & Johnson and its affiliates from 1986 to January 2017, most recently as Vice President, Research & Development of DePuy Synthes, a Johnson & Johnson Company, from February 2016 to January 2017. Prior to that, from July 2015 to February 2016, Mr. Madden was the Vice President, New Product Development of Johnson & Johnson Medical Devices. From January 2012 to July 2015, Mr. Madden was the Vice President, Research & Development of Johnson & Johnson’s Global Surgery Group. During his thirty-year tenure with Johnson & Johnson’s Medical Device organization, he was an innovator and research leader for nearly every medical device business including Cardiology, Electrophysiology, Peripheral Vascular Surgery, General and Colorectal Surgery, Aesthetics, Orthopaedics, Sports Medicine, Spine, and Trauma. As an executive of Johnson & Johnson, Mr. Madden served on the management boards of Johnson & Johnson’s Global Surgery Group, Ethicon, Ethicon Endo-Surgery, DePuy-Synthes, and Cordis, with responsibility for research and development – inclusive of organic and licensed/acquired technology. He was also Chairman of J&J’s Medical Device Research Council, with responsibility for talent strategy and technology acceleration. Mr. Madden serves on the Board of Directors of Novocure (NASDAQ: NVCR), a global oncology company, and is an advisor to numerous medical device start-ups. Mr. Madden holds a MBA from Columbia University, a M.S. from Carnegie Mellon University in Mechanical Engineering, and a B.S. from the University of Dayton in Mechanical Engineering. The Company believes that Mr. Madden is qualified to serve as a member of the Board due to his extensive experience in research and development, portfolio planning, technology assessment and assimilation, and project management and budgeting.

Prattipati Laxminarain, has been a director of the Company since December 6, 2017. From April 2006 through October 2017, Mr. Laxminarain served as Worldwide President at Codman Neuro, a global neurosurgery and neurovascular company that offers a portfolio of devices for hydrocephalus management, neuro intensive care and cranial surgery and other technologies, and which was part of DePuy Synthes Companies of Johnson & Johnson. Mr. Laxminarain is currently the CEO of Deinde Medical Corporation, and is a Board Member of Oculogica Inc., Millar Inc., and GT Medical Inc. He has a degree in Mechanical Engineering from Osmania University, Hyderabad, India and an MBA from Indian Institute of Management. The Company believes that Mr. Laxminarain is qualified as a Board member of the Company because of his extensive experience working with medical device companies and knowledge of the industries in which the Company intends to compete.

Aileen Stockburger was appointed by the Board on March 26, 2020 to fill a vacancy on the Board and to serve as a Class II director of the Company, with a term commencing on April 1, 2020. Since February 2018, Ms. Stockburger has provided M&A consulting and advisory services through Aileen Stockburger LLC. Prior to that, from 1989 through January 2018, Ms. Stockburger held various positions in Johnson & Johnson, most recently as Vice President, Worldwide Business Development & Strategic Planning for the DePuy Synthes Group of Johnson & Johnson, and as a member of its Worldwide Board and Group Operating Committee, from 2010-2018. In that role, she oversaw the group’s merger and acquisition activities, including deal structuring, negotiations, contract design and review, and deal terms. Before joining Johnson & Johnson, Ms. Stockburger spent several years at PriceWaterhouseCoopers, and earned her CPA certification. She is also a Non-Executive Director of Next Science Limited (ASX: NXS), a medical technology company headquartered in Sydney, Australia, with a primary focus in the development and continued commercialization of its proprietary technology to reduce the impact of biofilm based infections in human health. Ms. Stockburger received her MBA and BS from The Wharton School, University of Pennsylvania. The Company believes that Ms. Stockburger is qualified as a Board member of the Company because of her extensive experience in strategizing, managing and closing sizable, complex worldwide mergers and acquisitions, licensing agreements and divestitures, as well as her expertise in business development, strategic planning and finance.

Tal Wenderow was appointed by the Board on July 29, 2020 to fill a vacancy on the Board and to serve as a Class I director of the Company, with a term commencing on August 1, 2020. Since February 2019, Mr. Wenderow serves as the President and CEO of Vocalis Health Inc., an AI healthtech company pioneering the development of vocal biomarkers. Previously, Mr. Wenderow co-founded Corindus Vascular Robotics in 2002, which was a New York Stock Exchange-listed company upon its acquisition by Siemens Healthineers in 2019. Mr. Wenderow held various positions at Corindus from founder, Chief Executive Officer and director at inception, Executive Vice President Product & Business Development to his most recent role as Executive Vice President of International & Business Development. Mr. Wenderow received a B.Sc. in Mechanical Engineering at the Technion – Israel Institute of Technology, Haifa, Israel. The Company believes that Mr. Wenderow is qualified as a Board member of the Company because of his extensive knowledge of the medical robotics space with specific focus on interventional procedures, as well as his medical devices start up experience.

Executive Officers

Following are the name, age and other information for our executive officers, as of March 25, 2021. All company officers have been appointed to serve until their successors are elected and qualified or until their earlier resignation or removal. Information regarding Harel Gadot, our Chairman, President and Chief Executive Officer, is set forth above under “Board of Directors.”

Name	Age	Position
Harel Gadot	48	President, Chief Executive Officer and Chairman of the Board of Directors
David Ben Naim	52	Chief Financial Officer
Eyal Morag	56	Chief Medical Officer

David Ben Naim, became the Company’s part-time Chief Financial Officer following the consummation of the Merger. Mr. Ben Naim is the general manager of DBN Finance Services Ltd., a company which provides outsourcing financial services to public and private companies, since 2014, including the Company. Through DBN Finance Services, Mr. Ben Naim has acted as the outsourced CFO for Emerald Medical Applications Corp. (OTC:MRLA), a digital health startup company engaged in the development, sale and service of imaging solutions, Tempramed Inc., a private medical device company, Vonetize PLC (TASE:VNTZ), an Israeli company that offers video on demand and over-the-top content services, Unet Credit Finance Services Ltd. (TASE:UNCR-M), and Todos Medical Ltd. (OTC:TOMDF), an Israeli cancer in-vitro-diagnostic company engaging in the development of a series of blood tests for the early detection of a variety of cancers. Prior to that, Mr. Ben Naim served as Chief Financial Officer for several companies in the biomedical and technology industries. From July 2012 to September 2014, Mr. Ben Naim served as Chief Financial Officer for Insuline Medical Ltd. (TASE: INSL), an Israel-based company focused on improving performance of insulin treatment methods. From 2008 until 2011, Mr. Ben Naim served as Chief Financial Officer of Crow Technologies 1977 Ltd. (OTC:CRWTF), a company that designs, develops, manufactures and sells a broad range of security and alarm systems. From 2007 to 2008, Mr. Ben Naim served as Chief Financial Officer of Ilex Medical Ltd. (TASE:ILX), a leading company in the medical diagnostics field. From 2003 to 2007, Mr. Ben Naim was the Corporate Controller of Tadiran Telecom Ltd. He started his career in 1998 at Deloitte & Touche where he left in 2003 as an Audit Senior Manager. Mr. Ben Naim holds a B.A. in social sciences from Open University, Israel, a CPA license from Ramat Gan College, Israel, and an M.B.A. from Ono Academic College, Israel.

Eyal Morag, has served as the Company's Chief Medical Officer ("CMO") since May 2020. As CMO, Dr. Morag leads the development and execution of the clinical strategy of the Company, including its current development of the SCS and LIBERTY products as well as its future pipeline. Dr. Morag is a member of the Company's Scientific Advisory Board since November 1, 2017. Dr. Morag is certified by the American Board of Radiology, and from March 2017 through May 2020 has been the Chairman of Radiology at Assuta Ashdod Medical Center, Ashdod, Israel. Previously, from July 2014 through March 2017, he was the senior Radiologist at URG Teleradiology LLC, the largest provider of subspecialty radiology and teleradiology services in New Jersey. He is a graduate of Boston University School of Medicine and completed both his Radiology residency and Fellowship in Cardiovascular & Interventional Radiology at the Beth Israel Deaconess Medical Center & Harvard Medical School. Following his clinical training, Dr. Morag then joined a private practice in western Massachusetts, where he served as Chief of Radiology at Holyoke Medical Center for several years. He has also served as the Regional Radiology Director at Mercy Health Partners Hospitals in Toledo, Ohio, and was a member of the University Radiology Group where he headed the International Investment efforts for the Ventures division. Dr. Morag's international experience developing and establishing radiology-related businesses includes teleradiology, interventional Radiology services, and free-standing imaging centers. During his fellowship, Dr. Morag co-founded InTek Technology, a medical device startup company. Later he founded Global Versa Radiology ("GVR"), an Israeli and U.S. based teleradiology company. GVR has established imaging centers in Russia and Ukraine and provided teleradiology services in countries outside the U.S. and Israel. Dr. Morag served as GVR's Chief Medical Officer and Vice-President. He continues to be involved in several startup companies ranging from AI to medical devices. Dr. Morag is also a member of the Advisory Board of MEDX Xelerator, a medical device and digital health incubator, of which Mr. Gadot is Chairman.

Committees of the Board of Directors

Presently, the Board has three standing committees — the Audit Committee, the Compensation and Stock Option Committee (the "Compensation Committee"), and the Corporate Governance and Nominating Committee (the "Corporate Governance Committee"). All members of the Audit Committee, the Compensation Committee, and the Corporate Governance Committee are, and are required by the charters of the respective committees to be, independent as determined under Nasdaq Listing rules.

Audit Committee

The Audit Committee is composed of Messrs. Burell, Madden and Bornstein. Each of the members of the Audit Committee is independent, and the Board has determined that Mr. Burell is an "audit committee financial expert," as defined in SEC rules. The Audit Committee acts pursuant to a written charter which is available through our website at www.microbotmedical.com. The Audit Committee held four meetings during the fiscal year ended December 31, 2020 and acted by unanimous written consent one time.

The primary function of the Audit Committee is to assist the Board of Directors in fulfilling its oversight responsibilities. The Audit Committee does this primarily by reviewing the Company's financial reports and other financial information as well as the Company's systems of internal controls regarding finance, accounting, legal compliance, and ethics that management and the Board of Directors have established. The Audit Committee also assesses the Company's auditing, accounting and financial processes more generally. The Audit Committee recommends to the Board of Directors the appointment of a firm of independent auditors to audit the financial statements of the Company and meets with such personnel of the Company to review the scope and the results of the annual audit, the amount of audit fees, the company's internal accounting controls, the Company's financial statements contained in this proxy statement, and other related matters.

Compensation Committee

The Compensation Committee is composed of Messrs. Madden (Chairman), Bornstein and Stockburger. Each of the members of the Compensation Committee is independent. The Compensation Committee acts pursuant to a written charter which is available through our website at www.microbotmedical.com. The Compensation Committee held 11 meetings during the fiscal year ended December 31, 2020 and acted by unanimous written consent two times.

The Compensation Committee acts pursuant to a written charter. The Compensation Committee makes recommendations to the Board of Directors and management concerning salaries in general, determines executive compensation and approves incentive compensation for employees and consultants.

Corporate Governance Committee

The Corporate Governance Committee is composed of Messrs. Laxminarain, Burell and Wenderow. Each of the members of the Corporate Governance Committee is independent. The Corporate Governance Committee acts pursuant to a written charter which is available through our website at www.microbotmedical.com. The Corporate Governance Committee acted by unanimous written consent two times during the fiscal year ended December 31, 2020.

The Corporate Governance Committee oversees nominations to the Board and considers the experience, ability and character of potential nominees to serve as directors, as well as particular skills or knowledge that may be desirable in light of the Company's position at any time. From time to time, the Corporate Governance Committee may engage the services of a paid search firm to help the Corporate Governance Committee identify potential nominees to the Board. The Corporate Governance Committee and Board seek to nominate and appoint candidates to the Board who have significant business experience, technical expertise or personal attributes, or a combination of these, sufficient to suggest, in the Board's judgment, that the candidate would have the ability to help direct the affairs of the Company and enhance the Board as a whole. The Corporate Governance Committee may identify potential candidates through any reliable means available, including recommendations of past or current members of the Board from their knowledge of the industry and of the Company. The Corporate Governance Committee also considers past service on the Board or on the board of directors of other publicly traded or technology focused companies. The Corporate Governance Committee has not adopted a formulaic approach to evaluating potential nominees to the Board; it does not have a formal policy concerning diversity, for example. Rather, the Corporate Governance Committee weighs and considers the experience, expertise, intellect, and judgment of potential nominees irrespective of their race, gender, age, religion, or other personal characteristics. The Corporate Governance Committee may look for nominees that can bring new skill sets or diverse business perspectives. Potential candidates recommended by security holders will be considered as provided in the company's "Policy Regarding Shareholder Candidates for Nomination as a Director," which sets forth the procedures and conditions for such recommendations. This policy is available through our website at www.microbotmedical.com.

Director Oversight and Qualifications

While management is responsible for the day-to-day management of the risks the company faces, the Board, as a whole and through its committees, has responsibility for the oversight of risk management. An important part of risk management is not only understanding the risks facing the company and what steps management is taking to manage those risks, but also understanding what level of risk is appropriate for the company. In support of this oversight function, the Board receives regular reports from our Chief Executive Officer and members of senior management on operational, financial, legal, and regulatory issues and risks. The Audit Committee additionally is charged under its charter with oversight of financial risk, including the company's internal controls, and it receives regular reports from management, the company's internal auditors and the company's independent auditors. The chairman of the Board and independent members of the Board work together to provide strong, independent oversight of the company's management and affairs through its standing committees and, when necessary, special meetings of directors.

Code of Business Conduct and Ethics

We have adopted a Code of Ethics and Conduct that applies to all of our directors, officers, employees, and consultants. A copy of our code of ethics is posted on our website at www.microbotmedical.com. We intend to disclose any substantive amendment or waivers to this code on our website. There were no substantive amendments or waivers to this code in 2020.

Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers, directors, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC reports of ownership of our securities and changes in reported ownership. Executive officers, directors and greater than 10% beneficial owners are required by SEC rules to furnish us with copies of all Section 16(a) reports they file. Based solely on a review of the copies of such forms furnished to us, or written representations from the reporting persons that no Form 5 was required, we believe that, during the fiscal year ended December 31, 2020, all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners have been met, except for Mr. Wenderow, who failed to timely file a Form 3 and a Form 4 showing one transaction.

Item 11. Executive Compensation.

The following table sets forth information regarding each element of compensation that was paid or awarded to the named executive officers of the Company for the periods indicated.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)(1)	Non-Equity Incentive Plan Compensation (\$)	All Other Compensation (\$)	Total (\$)
Harel Gadot CEO, President & Chairman	2020	450,000	270,000	–	1,622,446	–	13,800(2)	2,356,246
	2019	360,000	144,000(3)	–	482,493	–	13,800(2)	1,000,293
Eyal Morag(4) Chief Medical Officer	2020	243,000	–	–	21,622	–	7,079(5)	271,701
	2019	–	–	–	–	–	–	–
David Ben Naim Chief Financial Officer	2020	82,242	–	–	20,308	–	–	102,550
	2019	74,268	–	–	20,308	–	–	94,576

(1) Amounts shown do not reflect cash compensation actually received by the named executive officer. Instead, the amounts shown are the non-cash aggregate grant date fair values of stock option awards made during the periods presented as determined pursuant to ASC Topic 718 and excludes the effect of forfeiture assumptions. The assumptions used to calculate the fair value of stock option awards are set forth under Note 9 to the Consolidated Financial Statements of the Company included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

(2) All Other Compensation includes Mr. Gadot's monthly automobile allowance and tax gross-up.

(3) Represents Mr. Gadot's bonus for the 2019 fiscal year, which amount was actually paid in 2020.

(4) Dr. Morag commence employment on May 1, 2020. Dr. Morag entered into an Employment Agreement with the Company as of February 18, 2020.

(5) All Other Compensation includes Dr. Morag's yearly automobile allowance.

Outstanding Equity Awards at Fiscal Year-End

The following table presents the outstanding equity awards held by each of the named executive officers as of the end of the fiscal year ended December 31, 2020.

Name	Option Awards				Stock Awards			
	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested	Market value of Shares of Units of Stock That Have Not Vested	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Rights That Have Not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Rights That Have Not Vested
Harel Gadot	77,846	–	\$ 4.20	1/01/2025	–	–	–	–
	108,148	12,699	15.75	9/14/2027	–	–	–	–
	–	166,666	9.64	2/25/2030	–	–	–	–
Eyal Morag	6,250	18,750	6.16	7/14/2030	–	–	–	–
David Ben Naim	5,000	–	15.30	12/28/2027	–	–	–	–

Executive Employment Agreements

Harel Gadot Employment Agreement

The Company entered into an employment agreement (the “Gadot Agreement”) with Harel Gadot on November 28, 2016, to serve as the Company’s Chairman of the Board of Directors and Chief Executive Officer, on an indefinite basis subject to the termination provisions described in the Agreement. Pursuant to the terms of the Gadot Agreement, as amended most recently on February 25, 2020, Mr. Gadot shall receive an annual base salary of \$450,000. The salary is reviewed on an annual basis by the Compensation Committee of the Company to determine potential increases taking into account such performance metrics and criteria as established by Mr. Gadot and the Company. Accordingly, for the 2021 fiscal year, Mr. Gadot’s annual base salary was increased to \$500,000.

Effective as of January 1, 2020, Mr. Gadot shall also be entitled to receive a target annual cash bonus of up to a maximum amount of 60% of base salary, which maximum amount was paid for the 2020 fiscal year. In addition, Mr. Gadot received in February 202 a one-time special bonus equal to \$270,000.

Mr. Gadot shall be further entitled to a monthly automobile allowance and tax gross up on such allowance of \$1,150, and shall be granted options to purchase shares of common stock of the Company representing 5% of the issued and outstanding shares of the Company, based on vesting and other terms to be determined by the Compensation Committee of the Board of Directors.

In the event Mr. Gadot’s employment is terminated as a result of death, Mr. Gadot’s estate would be entitled to receive any earned annual salary, bonus, reimbursement of business expenses and accrued vacation, if any, that is unpaid up to the date of Mr. Gadot’s death.

In the event Mr. Gadot’s employment is terminated as a result of disability, Mr. Gadot would be entitled to receive any earned annual salary, bonus, reimbursement of business expenses and accrued vacation, if any, incurred up to the date of termination.

In the event Mr. Gadot’s employment is terminated by the Company for cause, Mr. Gadot would be entitled to receive any compensation then due and payable incurred up to the date of termination.

In the event Mr. Gadot’s employment is terminated by the Company without cause, he would be entitled to receive (i) any earned annual salary; (ii) 12 months’ pay and full benefits, (iii) a pro rata bonus equal to the maximum target bonus for that calendar year; (iv) the dollar value of unused and accrued vacation days; and (v) applicable premiums (inclusive of premiums for Mr. Gadot’s dependents) pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1986, as amended, for twelve (12) months from the date of termination for any benefits plan sponsored by the Company. In addition, 100% of any unvested portion of his stock options shall immediately vest and become exercisable.

The agreement contains customary non-competition and non-solicitation provisions pursuant to which Mr. Gadot agrees not to compete and solicit with the Company. Mr. Gadot also agreed to customary terms regarding confidentiality and ownership of intellectual property.

David Ben Naim Services Agreement

We entered into a services agreement (the "Services Agreement") with DBN Finance Services effective October 31, 2016, to provide outsourced CFO services. Pursuant to the terms of the Services Agreement, DBN Finance Services will provide its services exclusively through Mr. David Ben Naim, who will serve as the principal financial and accounting officer of Microbot Israel and the Company. Mr. Ben Naim's engagement will continue on an indefinite basis subject to the termination provisions described in the Agreement.

Pursuant to the Agreement, the Company shall pay the Service Provider a fixed fee of NIS 22,000, or the equivalent of approximately \$6,380 per month based on an exchange rate of \$.29 for NIS1.0, plus VAT per month, and the Company shall reimburse DBN Finance Services for reasonable and customary out of pocket expenses incurred by it or Mr. Ben Naim connection with the performance of the duties under the Services Agreement. In addition, the Company shall maintain for the benefit of Mr. Ben Naim, a Directors and Officers insurance policy, according to the Company's policy for other directors and officers of the Company.

Both the Company and DBN Finance Services shall have the right to terminate the Agreement for any reason or without reason at any time by furnishing the other party with a 30-day notice of termination. The Company shall further be entitled to terminate the Services Agreement for "cause" without notice, in which case neither DBN Finance Services nor Mr. Ben Naim shall be entitled to any compensation due to such early termination.

DBN Finance Services and Mr. Ben Naim agreed to customary provisions regarding confidentiality and intellectual property ownership. The Services Agreement also contains customary non-competition and non-solicitation provisions pursuant to which DBN Finance Services and Mr. Ben Naim agree not to compete and solicit with the Company during the term of the Agreement and for a period of twelve months following the termination of the Agreement.

Eyal Morag Employment Agreement

We entered into an employment agreement (the "Morag Agreement"), as of February 18, 2020, with Dr. Morag, to serve as the Company's Chief Medical Officer, on an indefinite basis subject to the termination provisions described in the Morag Agreement. Pursuant to the terms of the Morag Agreement, Dr. Morag shall receive a base salary of NIS64,000 per month plus Global Overtime (as defined in the Morag Agreement) of NIS 16,000 per month.

Dr. Morag shall also be entitled to receive a target annual cash bonus, based on certain milestones, of up to a maximum amount of 30% of his annual salary.

Dr. Morag shall be further entitled to a monthly automobile allowance not to exceed NIS 4,800 per month plus expenses and applicable taxes, and shall be granted options to purchase 25,000 shares of common stock of the Company based on vesting and other terms set forth in the Morag Agreement.

Pursuant to the Morag Agreement, the Company shall pay an amount equal to 8.33% of Dr. Morag's salary to be allocated for severance pay, 6.5% of Dr. Morag's salary to be allocated for pension savings and 7.5% to be allocated to an educational fund. The Company may have additional payment obligations for disability insurance as specified in the Morag Agreement.

During the initial 24 months following the Commencement Date ("Initial Period"), either the Company or Dr. Morag may terminate the Morag Agreement at its discretion at any time by providing the other party with a three months (or, following the Initial Period, six months) prior written notice of termination (the "Advance Notice Period").

The Company may terminate the Morag Agreement "For Cause" (as defined in the Morag Agreement) at any time by written notice without the Advance Notice Period.

In the event that the Company terminates Dr. Morag's employment during the Initial Period other than For Cause, Dr. Morag shall be entitled to a one-time payment in an amount equal to his annual salary as of the date of termination of employment multiplied by the balance time between the end of the Advance Notice Period and until the end of the Initial Period.

The Morag Agreement contains customary non-competition and non-solicit provisions pursuant to which Dr. Morag agrees not to compete and solicit with the Company. Dr. Morag also agreed to customary terms regarding confidentiality and ownership of intellectual property.

Indemnification Agreements

The Company generally enters into indemnification agreements with each of its directors and executive officers. Pursuant to the indemnification agreements, the Company has agreed to indemnify and hold harmless these current and former directors and officers to the fullest extent permitted by the Delaware General Corporation Law. The agreements generally cover expenses that a director or officer incurs or amounts that a director or officer becomes obligated to pay because of any proceeding to which he is made or threatened to be made a party or participant by reason of his service as a current or former director, officer, employee or agent of the Company, provided that he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company. The agreements also provide for the advancement of expenses to the directors and officers subject to specified conditions. There are certain exceptions to the Company's obligation to indemnify the directors and officers, and, with certain exceptions, with respect to proceedings that he initiates.

Limits on Liability and Indemnification

We provide directors and officers insurance for our current directors and officers.

Our certificate of incorporation eliminate the personal liability of our directors to the fullest extent permitted by law. The certificate of incorporation further provide that the Company will indemnify its officers and directors to the fullest extent permitted by law. We believe that this indemnification covers at least negligence on the part of the indemnified parties. Insofar as indemnification for liabilities under the Securities Act may be permitted to our directors, officers, and controlling persons under the foregoing provisions or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is therefore unenforceable.

Director Compensation

The Company adopted in January 2021 an amended compensation package for the non-management members of its Board, pursuant to which each such Board member would receive for his or her services \$35,000 per annum. Furthermore, each member of the Audit Committee of the Board receives an additional \$10,000 per annum (\$20,000 if Chairman), each member of the Compensation Committee of the Board receives an additional \$7,500 per annum (\$15,000 if Chairman) and each member of the Corporate Governance and Nominating Committee of the Board receives an additional \$5,000 per annum (\$10,000 if Chairman). Board members are also entitled to receive equity awards. Upon joining the Board, a member would receive an initial grant of \$190,000 of stock options (calculated as the product of the exercise price on the date of grant multiplied by the number of shares underlying the stock option award required to equal \$190,000), with an additional grant of stock options each year thereafter, to purchase such number of shares of the Company's common stock equal to \$95,000.

The following table summarizes cash-based and equity compensation information for our outside directors, including annual Board and committee retainer fees and meeting attendance fees, for the year ended December 31, 2020:

<u>Name</u>	<u>Fees earned or paid in cash</u>	<u>Stock Awards</u>	<u>Option Awards (1)</u>	<u>Non-Equity Incentive Plan Compensation</u>	<u>Nonqualified Deferred Compensation Earnings</u>	<u>All Other Compensation</u>	<u>Total</u>
Yoav Waizer (2)	\$ 24,250	-	\$ 11,550	-	-	-	\$ 35,800
Yoseph Bornstein	\$ 38,750	-	\$ 22,895	-	-	-	\$ 61,645
Scott Burell	\$ 41,250	-	\$ 22,895	-	-	-	\$ 64,145
Martin Madden	\$ 38,750	-	\$ 22,895	-	-	-	\$ 61,645
Prattipati Laxminarain	\$ 29,750	-	\$ 22,895	-	-	-	\$ 52,645
Aileen Stockburger	\$ 13,250	-	\$ 5,123	-	-	-	\$ 18,373
Tal Wenderow	\$ 9,500	-	\$ 4,484	-	-	-	\$ 13,984

(1) Amounts shown do not reflect cash compensation actually received by the director. Instead, the amounts shown are the non-cash aggregate grant date fair values of stock option awards made during the period presented as determined pursuant to ASC Topic 718 and excludes the effect of forfeiture assumptions. The assumptions used to calculate the fair value of stock option awards are set forth under Note 9 to the Consolidated Financial Statements of the Company included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

(2) Mr. Waizer resigned as a director of the Company effective as of June 30, 2020.

Mr. Gadot received compensation for his services to the Company as set forth under the summary compensation table above.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table shows the number of shares of our common stock beneficially owned, as of March 29, 2021, by (i) each of our directors and director nominees, (ii) each of our named executive officers, (iii) all of our current directors and executive officers as a group, and (iv) all those known by us to be to a beneficial owner of more than 5% of the Company's common stock. In general, "beneficial ownership" refers to shares that an individual or entity has the power to vote or dispose of, and any rights to acquire common stock that are currently exercisable or will become exercisable within 60 days of March 29, 2021. We calculated percentage ownership in accordance with the rules of the SEC. The percentage of common stock beneficially owned is based on 7,108,133 shares outstanding as of March 29, 2021. In addition, shares issuable pursuant to options or other convertible securities that may be acquired within 60 days of March 29, 2021 are deemed to be issued and outstanding and have been treated as outstanding in calculating and determining the beneficial ownership and percentage ownership of those persons possessing those securities, but not for any other persons.

This table is based on information supplied by each director, officer and principal stockholder of the Company. Except as indicated in footnotes to this table, the Company believes that the stockholders named in this table have sole voting and investment power with respect to all shares of Common Stock shown to be beneficially owned by them, based on information provided by such stockholders. Unless otherwise indicated, the address for each director, executive officer and 5% or greater stockholders of the Company listed is: c/o Microbot Medical Inc., 25 Recreation Park Drive, Unit 108, Hingham, MA 02043.

Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned
Chasing Value Asset Management Inc. ⁽¹⁾	610,657	8.59%
Harel Gadot ⁽²⁾	489,507	6.56%
Yoseph Bornstein ⁽³⁾	247,950	3.49%
Scott Burell ⁽⁴⁾	7,382	*
Martin Madden ⁽⁴⁾	7,382	*
David Ben Naim ⁽⁴⁾	5,000	*
Prattipati Laxminarain ⁽⁴⁾	7,382	*
Aileen Stockburger ⁽⁴⁾	1,623	*
Dr. Eyal Morag ⁽⁴⁾	8,125	*
Tal Wenderow ⁽⁴⁾	1,592	*
All current directors and executive officers as a group (9 persons) ⁽⁵⁾	775,943	10.33%

* Less than 1%.

- (1) Based on a Schedule 13G filed by the reporting person on January 20, 2021. Sheldon D. Liber is the Chief Executive Officer of the reporting person. The address of the principal business office of the reporting person is 2444 Wilshire Boulevard, Suite 300, Santa Monica, California 90403.
- (2) Includes (i) 136,847 shares of our common stock owned by MEDX Ventures Group LLC, (ii) 77,846 shares of our common stock issuable upon the exercise of options granted to MEDX Ventures Group LLC, and (iii) 274,814 shares of our common stock issuable upon the exercise of options granted to Mr. Gadot. Mr. Gadot is the Chief Executive Officer, Company Group Chairman and majority equity owner of MEDX Venture Group, LLC and thus may be deemed to share voting and investment power over the shares and options beneficially owned by this entity.
- (3) Represents (i) 242,028 shares of our common stock owned by LSA - Life Science Accelerator Ltd. and (ii) 5,922 shares of our common stock issuable to Mr. Bornstein upon exercise of options. Based on representations and other information made or provided to the Company by Mr. Bornstein, Mr. Bornstein is the CEO and Director of LSA - Life Science Accelerator Ltd. and of Shizim Ltd., and Mr. Bornstein is the majority equity owner of Shizim Ltd. Shizim Ltd. is the majority equity owner of LSA - Life Science Accelerator Ltd. Accordingly, Mr. Bornstein may be deemed to share voting and investment power over the shares beneficially owned by these entities and has an address of 16 Irus Street, Rosh-Ha' Ayin Israel 4858022.
- (4) Represents options to acquire shares of our common stock.
- (5) Includes shares of our common stock issuable upon the exercise of options as set forth in footnotes (2), (3) and (4).

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Related parties can include any of our directors or executive officers, certain of our stockholders and their immediate family members. Each year, we prepare and require our directors and executive officers to complete Director and Officer Questionnaires identifying any transactions with us in which the officer or director or their family members have an interest. This helps us identify potential conflicts of interest. A conflict of interest occurs when an individual's private interest interferes, or appears to interfere, in any way with the interests of the company as a whole. Our code of ethics requires all directors, officers and employees who may have a potential or apparent conflict of interest to immediately notify our general counsel, who serves as our compliance officer. In addition, the Corporate Governance Committee is responsible for considering and reporting to the Board any questions of possible conflicts of interest of Board members. Our code of ethics further requires pre-clearance before any employee, officer or director engages in any personal or business activity that may raise concerns about conflict, potential conflict or apparent conflict of interest. Copies of our code of ethics and the Corporate Governance Committee charter are posted on the corporate governance section of our website at www.microbotmedical.com.

There have been no related party transactions or any other transactions or relationships required to be disclosed pursuant to Item 404 of Regulation S-K.

Director Independence

NASDAQ's listing standards and the Company's Corporate Governance Guidelines require that the Company's Board of Directors consist of a majority of independent directors, as determined under the applicable NASDAQ listing rules.

The independent members of our Board are Messrs. Bornstein, Burell, Madden, Laxminarain and Wenderow, and Ms. Stockburger.

Item 14. Principal Accountant Fees and Services.

Audit and Tax Fees

The Board, upon the recommendation of the Audit Committee, has selected the independent accounting firm of Brightman Almagor Zohar & Co., a Member of Deloitte Touche Tohmatsu Limited, to audit the accounts of the Company for the year ending December 31, 2020.

The Audit Committee considered the tax compliance services provided by Brightman Almagor Zohar & Co. and Deloitte Israel & Co., concluded that provision of such services is compatible with maintaining the independence of the independent accountants, and approved the provision by Brightman Almagor Zohar & Co. of tax compliance services with respect to the year ending December 31, 2020.

The Audit Committee received the following information concerning the fees of the independent accountants for the years ended December 31, 2020 and 2019, has considered whether the provision of these services is compatible with independence of the independent accountants, and concluded that it is:

	Years Ended December 31,	
	2020	2019
Audit Fees (1)	\$ 70,000	\$ 50,000
Audit-Related Fees	–	–
Tax Fees	9,500	9,500
All Other Fees (2)	5,000	–

(1) Audit fees represents fees for the audit of our annual consolidated financial statements and reviews of the interim consolidated financial statements, and review of audit-related SEC filings.

(2) Includes fees related to issuing comfort letter and consent(s).

Audit and tax fees include administrative overhead charges and reimbursement for out-of-pocket expenses.

Pre-Approval Policies and Procedures

The Audit Committee has adopted policies and procedures for pre-approving all services (audit and non-audit) performed by our independent auditors. In accordance with such policies and procedures, the Audit Committee is required to pre-approve all audit and non-audit services to be performed by the independent auditors in order to assure that the provision of such services is in accordance with the rules and regulations of the SEC and does not impair the auditors' independence. Under the policy, pre-approval is generally provided up to one year and any pre-approval is detailed as to the particular service or category of services and is subject to a specific budget. In addition, the Audit Committee may pre-approve additional services on a case-by-case basis.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements:

The financial statements are filed as part of this Annual Report on Form 10-K commencing on page F-1 and are hereby incorporated by reference

(2) Financial Statement Schedules:

The financial statement schedules are omitted as they are either not applicable or the information required is presented in the financial statements and notes thereto.

(3) Exhibits:

The documents set forth below are filed herewith or incorporated by reference to the location indicated.

Exhibit Number	Description of Document
2.1	<u>Agreement and Plan of Merger and Reorganization, dated as of August 15, 2016, by and among StemCells, Inc., C&RD Israel Ltd. and Microbot Medical Ltd. (incorporated by reference to the Company's Current Report on Form 8-K filed on August 15, 2016).</u>
3.1	<u>Restated Certificate of Incorporation of the Company (incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and filed on March 15, 2007).</u>
3.2	<u>Certificate of Amendment to the Restated Certificate of Incorporation of the Company (incorporated by reference to the Company's Current Report on Form 8-K filed on November 29, 2016).</u>
3.3	<u>Certificate of Amendment to the Restated Certificate of Incorporation (incorporated by reference to the Company's Current Report on Form 8-K filed on September 4, 2018).</u>
3.4	<u>Amended and Restated By-Laws of the Company (incorporated by reference to the Company's Current Report on Form 8-K filed on May 3, 2016).</u>
3.5	<u>Certificate of Elimination (incorporated by reference to the Company's Current Report on Form 8-K filed on December 12, 2018).</u>
3.6	<u>Certificate of Amendment to the Restated Certificate of Incorporation (incorporated by reference to the Company's Current Report on Form 8-K filed on September 11, 2019).</u>
4.1	<u>Form of Series A Warrant (incorporated by reference to the Registrant's Current Report on Form 8-K filed on December 16, 2016).</u>
4.2	<u>Form of Series B Warrant (incorporated by reference to the Company's Current Report on Form 8-K filed on December 16, 2016).</u>
4.3	<u>Form of Wainwright Warrant (incorporated by reference to the Registrant's Current Report on Form 8-K filed on January 16, 2019).</u>
4.4	<u>Form of Wainwright Warrant (incorporated by reference to the Registrant's Current Report on Form 8-K filed on January 17, 2019).</u>
4.5	<u>Form of Warrant (incorporated by reference to the Registrant's Current Report on Form 8-K filed on January 25, 2019).</u>
4.6	<u>Form of Warrant (incorporated by reference to the Registrant's Current Report on Form 8-K filed on December 27, 2019).</u>
4.7	<u>Form of Wainwright Warrants (incorporated by reference to the Registrant's Current Report on Form 8-K filed on January 25, 2019).</u>
4.8	<u>Form of Warrant (incorporated by reference to the Registrant's Current Report on Form 8-K filed on December 30, 2019).</u>

4.9	Form of Warrant (incorporated by reference to the Registrant's Current Report on Form 8-K filed on December 31, 2019).
4.10	Description of the Company's Securities (incorporated by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2019).
10.1	Form of Indemnification Agreement, between the Company and each of its Directors and Officers (incorporated by reference to the Company's Current Report on Form 8-K filed on November 29, 2016).
10.2*	Employment Agreement with Harel Gadot (incorporated by reference to the Company's Current Report on Form 8-K filed on November 29, 2016).
10.3*	Services Agreement with DBN Finance Services Ltd. (incorporated by reference to the Company's Current Report on Form 8-K filed on November 29, 2016).
10.4	License Agreement, dated June 20, 2012, by and between Technion Research and Development Foundation, and Microbot Medical Ltd. (incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and filed on March 21, 2017).
10.5*	Form of Stock Option Agreement under the Microbot Medical Inc. 2017 Equity Incentive Plan (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2017, filed on November 14, 2017).
10.6	Agreement, dated January 4, 2018, by and between CardioSert Ltd. and Microbot Medical Ltd. (incorporated by reference to the Company's Current Report on Form 8-K filed on January 8, 2018).
10.7*	Employment Agreement with Dr. Eyal Morag (incorporated by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 filed on April 14, 2020).
10.8*	Microbot Medical Inc. 2017 Equity Incentive Plan (incorporated by reference to Exhibit A of the Company's Definitive Proxy Statement on Schedule 14A filed on August 11, 2017).
10.9*	Microbot Medical Inc. 2020 Omnibus Performance Award Plan (incorporated by reference to Exhibit A of the Company's definitive Proxy Statement on Schedule 14A filed on July 31, 2020).
10.10*	Form of Restricted Stock Unit Award Agreement under the Microbot Medical Inc. 2020 Omnibus Performance Award Plan (incorporated by reference to Exhibit 4.2 of the registration Statement on Form S-8 of the Company filed on November 25, 2020)
10.11*	Form of NQO Award Agreement under the Microbot Medical Ltd. 2020 Omnibus Performance Award Plan (incorporated by reference to Exhibit 4.3 of the registration Statement on Form S-8 of the Company filed on November 25, 2020)
10.12*	Form of Restricted Stock Award Agreement under the Microbot Medical Ltd. 2020 Omnibus Performance Award Plan (incorporated by reference to Exhibit 4.4 of the registration Statement on Form S-8 of the Company filed on November 25, 2020)
10.13*	Form of SAR Award Agreement under the Microbot Medical Ltd. 2020 Omnibus Performance Award Plan (incorporated by reference to Exhibit 4.5 of the registration Statement on Form S-8 of the Company filed on November 25, 2020)
10.14*	Form of ISO Award Agreement under the Microbot Medical Ltd. 2020 Omnibus Performance Award Plan (incorporated by reference to Exhibit 4.6 of the registration Statement on Form S-8 of the Company filed on November 25, 2020)
21.1	Subsidiaries of the Company (incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and filed on March 21, 2017).
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification Pursuant to Securities Exchange Act Rule 13(a)-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Harel Gadot, Chief Executive Officer)
31.2	Certification Pursuant to Securities Exchange Act Rule 13(a)-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (David Ben Naim, Chief Financial Officer)
32.1	Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Harel Gadot, Chief Executive Officer)
32.2	Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (David Ben Naim, Chief Financial Officer)
101.INS	XBRL Instance.
101.SCH	XBRL Taxonomy Extension Schema.
101.CAL	XBRL Taxonomy Extension Calculation.
101.DEF	XBRL Taxonomy Extension Definition.
101.LAB	XBRL Taxonomy Extension Labels.
101.PRE	XBRL Taxonomy Extension Presentation.

* Indicates Management contract or compensatory plan or arrangement

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

/s/ Harel Gadot

Harel Gadot

President, Chief Executive Officer and Chairman

Dated: March 31, 2021

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Harel Gadot</u> Harel Gadot	Chairman, President and Chief Executive Officer (Principal Executive Officer)	March 31, 2021
<u>/s/ David Ben Naim</u> David Ben Naim	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2021
<u>/s/ Yoseph Bornstein</u> Yoseph Bornstein	Director	March 31, 2021
<u>/s/ Prattipati Laxminarain</u> Prattipati Laxminarain	Director	March 31, 2021
<u>/s/ Scott Burell</u> Scott Burell	Director	March 31, 2021
<u>/s/ Martin Madden</u> Martin Madden	Director	March 31, 2021
<u>/s/ Aileen Stockburger</u> Aileen Stockburger	Director	March 31, 2021
<u>/s/ Tal Wenderow</u> Tal Wenderow	Director	March 31, 2021

MICROBOT MEDICAL INC.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Microbot Medical Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Microbot Medical Inc. and its subsidiary (the “Company”) as of December 31, 2020 and 2019 and the related consolidated statements of comprehensive loss, changes in shareholders’ equity and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the “financial statements”).

In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Tel Aviv - Main Office

1 Azrieli Center Tel Aviv, 6701101 P.O.B. 16593 Tel Aviv, 6116402 | Tel: +972 (3) 608 5555 | info@deloitte.co.il

Jerusalem

3 Kiryat Ha'Mada
Har Hotzvim Tower
Jerusalem, 914510
D, BOX 45396

Tel: +972 (2) 501 8888
Fax: +972 (2) 537 4173
info-jer@deloitte.co.il

Haifa

5 Ma'aleh Hashichrur
P.O.B. 5648
Haifa, 3105502

Tel: +972 (4) 860 7333
Fax: +972 (4) 867 2528
info-haifa@deloitte.co.il

Eilat

The City Center
P.O.B. 583
Eilat, 8810402

Tel: +972 (8) 637 5676
Fax: +972 (8) 637 1628
info-eilat@deloitte.co.il

Nazareth

9 Marj Ibn Amer St.
Nazareth, 16100

Tel: +972 (73) 399 4455
Fax: +972 (73) 399 4455
info-nazareth@deloitte.co.il

Commitments and Contingencies: Litigation — Refer to Note 2Q and 8 to the financial statements

Critical Audit Matter Description

The Company is involved in a litigation as the defendant resulting from the 2017 financing Litigation from third parties may result in a substantial loss. An estimated loss from a loss contingency is accrued by a charge to expenses or shareholders' equity if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

The Company concluded that the loss from the case is not probable and it cannot be reasonably estimable at this stage and no provision was recorded as of December 31, 2020

The determination of litigation contingency accruals is subject to significant management judgement in assessing the likelihood of a loss being incurred and when determining whether a reasonable estimate of the loss or range of loss can be made.

Given the inherent uncertainty of the outcome of identified litigation, auditing the valuation assertion of litigation contingency required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate management's assessment on the likelihood and magnitude of the contingent loss and whether this litigation is reasonably estimable as of December 31, 2020.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the potential loss contingency liability and disclosure of the litigation included the following, among others:

- We made inquiries with management to obtain an understanding of litigation matter and status that the Company is currently undergoing.
- We obtained legal letters from the external legal counsel.
- We inquired of the external and internal legal counsels to determine the status of the case and to understand the basis for management's conclusion that the loss from the case is not probable and it cannot be reasonably estimable at this stage.
- We evaluated the assumptions used by management to estimate the litigation contingency likelihood and magnitude, including corroborating these assumptions with internal and external legal counsel.
- We evaluated the Company's litigation contingencies disclosure for consistency with our evidence obtained on the litigation matter.

Brightman Almagor Zohar & Co.
Certified Public Accountants
A firm in the Deloitte Global Network

Tel Aviv, Israel
March 31, 2021

MICROBOT MEDICAL INC.
Consolidated Balance Sheets
U.S. dollars in thousands
(Except share and per share data)

	Note	As of December 31, 2020	As of December 31, 2019
ASSETS			
Current assets:			
Cash and cash equivalents		\$ 19,650	\$ 28,771
Marketable securities	3	4,998	2,521
Restricted cash		84	4,358
Prepaid expenses and other assets	4	521	286
Total current assets		25,253	35,936
Property and equipment, net	6	251	228
Operating right-of-use assets	5	775	962
Total assets		\$ 26,279	\$ 37,126
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Accounts payable		\$ 275	\$ 284
Provision for extinguishment dispute	8	-	3,604
Lease liabilities	5	187	143
Accrued liabilities	7	883	795
Total current liabilities		1,345	4,826
Non-current liabilities:			
Long-term lease liabilities	5	626	760
Total liabilities		1,971	5,586
Shareholders' equity:			
Common stock; \$0.01 par value; 60,000,000 shares authorized as of December 31, 2020 and December 31, 2019, 7,108,133 and 7,185,628 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	9	72	72
Additional paid-in capital		68,516	69,954
Treasury shares		-	(3,375)
Accumulated deficit		(44,280)	(35,111)
Total shareholders' equity		24,308	31,540
Total liabilities and shareholders' equity		\$ 26,279	\$ 37,126

The accompanying notes are an integral part of these consolidated financial statements.

MICROBOT MEDICAL INC.
Consolidated Statements of Operations
U.S. dollars in thousands
(Except share and per share data)

	Note	For the Year Ended December 31,	
		2020	2019
Research and development, net	10	\$ 3,396	\$ 3,048
General and administrative	11	5,693	4,192
Operating loss		(9,089)	(7,240)
Financing expenses, net		(80)	(103)
Capital gains		-	96
Net loss		\$ (9,169)	\$ (7,247)
Basic and diluted net loss per share		\$ (1.29)	\$ (1.70)
Basic and diluted weighted average common shares outstanding		7,117,747	4,267,209

The accompanying notes are an integral part of these consolidated financial statements.

MICROBOT MEDICAL INC.
Consolidated Statements of Comprehensive Loss
U.S. dollars in thousands
(Except share and per share data)

	For the Year Ended December 31,	
	2020	2019
Net loss	\$ (9,169)	\$ (7,247)
Net unrealized loss on marketable securities	*	*
Comprehensive loss	\$ (9,169)	\$ (7,247)

(*) Represents amount less than 1 thousand.

The accompanying notes are an integral part of these consolidated financial statements.

MICROBOT MEDICAL INC.
Consolidated Statements of Shareholder's Equity
U.S. dollars in thousands
(Except share and per share data)

	Common Stock		Additional Paid-In Capital	Treasury Shares	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balances, December 31, 2019	7,185,628	\$ 72	\$ 69,954	\$ (3,375)	\$ (35,111)	\$ 31,540
Exercise of options	5,838	1	(1)	-	-	-
Cancellation of treasury Shares	(83,333)	(1)	(3,374)	3,375	-	-
Share-based compensation	-	-	1,937	-	-	1,937
Net loss	-	-	-	-	(9,169)	(9,169)
Balances, December 31, 2020	<u>7,108,133</u>	<u>\$ 72</u>	<u>\$ 68,516</u>	<u>\$ -</u>	<u>\$ (44,280)</u>	<u>\$ 24,308</u>
Balances, December 31, 2018	3,012,343	\$ 31	\$ 32,538	\$ (3,375)	\$ (27,864)	\$ 1,330
Issuance of common stock and warrants net of issuance costs	4,061,465	40	36,317	-	-	36,357
Share-based compensation	-	-	1,099	-	-	1,099
Cashless exercise of warrants	111,820	1	-	-	-	1
Net loss	-	-	-	-	(7,247)	(7,247)
Balances, December 31, 2019	<u>7,185,628</u>	<u>\$ 72</u>	<u>\$ 69,954</u>	<u>\$ (3,375)</u>	<u>\$ (35,111)</u>	<u>\$ 31,540</u>

(*) Less than 1

The accompanying notes are an integral part of these consolidated financial statements.

MICROBOT MEDICAL INC.
Consolidated Statements of Cash Flows
U.S. dollars in thousands
(Except share and per share data)

	For the Year Ended December 31,	
	2020	2019
Operating activities:		
Net loss	\$ (9,169)	\$ (7,247)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	68	84
Capital gains from sales of property and equipment	-	(96)
Unrealized gain from convertible loan	(61)	-
Non-cash and accrued interest	(9)	(25)
Share-based compensation expense	1,937	1,099
Changes in assets and liabilities:		
Prepaid expenses and other assets	222	(126)
Other payables and accrued liabilities	(240)	(140)
Net cash flows used in operating activities	<u>(7,252)</u>	<u>(6,451)</u>
Investing activities:		
Purchase of property and equipment	(91)	(216)
Investment in a convertible loan	(200)	-
Sales of property and equipment	-	259
Proceeds from sales of marketable securities	2,521	-
Purchase of marketable securities	(4,998)	(2,496)
Net cash flows used in investing activities	<u>(2,768)</u>	<u>(2,453)</u>
Financing activities:		
Issuance of common stock and warrants, net of issuance costs	-	36,770
Repayment of shareholders investment	(3,375)	-
Net cash flows (used in) provided by financing activities	<u>(3,375)</u>	<u>36,770</u>
(Decrease) increase in cash, cash equivalents and restricted cash	(13,395)	27,866
Cash, cash equivalents and restricted cash at beginning of period	33,129	5,263
Cash, cash equivalents and restricted cash at ending of period	<u>\$ 19,734</u>	<u>\$ 33,129</u>
Non-cash activities:		
Right-of-use assets obtained in exchange for new operating lease obligations	<u>\$ -</u>	<u>\$ 966</u>
Supplemental disclosure of cash flow information:		
Interest paid from litigation	<u>\$ 236</u>	<u>\$ -</u>
Cash received from interest	<u>\$ 32</u>	<u>\$ 97</u>
Financing fees included in other receivable	<u>\$ -</u>	<u>\$ 412</u>

The accompanying notes are an integral part of these consolidated financial statements.

MICROBOT MEDICAL INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands
(Except share and per share data)

NOTE 1 - GENERAL

A. Description of business:

Microbot Medical Inc. (the “Company”) is a pre-clinical medical device company specializing in the research, design and development of next generation micro-robotics assisted medical technologies targeting the minimally invasive surgery space. The Company is primarily focused on leveraging its micro-robotic technologies with the goal of redefining surgical robotics while improving surgical outcomes for patients.

The Company was incorporated on August 2, 1988 in the State of Delaware under the name Cellular Transplants, Inc. The original Certificate of Incorporation was restated on February 14, 1992 to change the name of the Company to Cyto Therapeutics, Inc. On May 24, 2000, the Certificate of Incorporation as restated was further amended to change the name of the Company to StemCells, Inc.

On November 28, 2016, the Company consummated a transaction pursuant to an Agreement and Plan of Merger, dated August 15, 2016, with Microbot Medical Ltd., a private medical device company organized under the laws of the State of Israel (“Microbot Israel”), pursuant to which, among other things, Microbot Israel became a wholly-owned subsidiary of the Company. On the same day and in connection with the Merger, the Company changed its name from StemCells, Inc. to Microbot Medical Inc. On November 29, 2016, the Company’s common stock began trading on the Nasdaq Capital Market under the symbol “MBOT”.

The Company and its subsidiaries, where applicable, are collectively referred to as the “Company”.

B. Risk Factors:

To date, the Company has not generated revenues from its operations. As of December 31, 2020, the Company had unrestricted cash and cash equivalent balance of approximately \$19,650, which management believes is sufficient to fund its operations for more than 12 months from the date of issuance of these financial statements and sufficient to fund its operations necessary to continue development activities of its current proposed products.

Due to continuing research and development activities, the Company expects to continue to incur additional losses for the foreseeable future. While management of the Company believes that it has sufficient funds for more than 12 months, the Company may seek to raise additional funds through future issuances of either debt and/or equity securities and possibly additional grants from the Israeli Innovation Authority and other government institutions. The Company’s ability to raise additional capital in the equity and debt markets is dependent on a number of factors, including, but not limited to, the market demand for the Company’s stock, which itself is subject to a number of development and business risks and uncertainties, as well as the uncertainty that the Company would be able to raise such additional capital at a price or on terms that are favorable to the Company.

An epidemic of the coronavirus disease (“COVID-19”) is ongoing throughout the world. As the outbreak is still evolving, much of its impact remains unknown. As of this filing, it is impossible to predict the effect and potential spread of the coronavirus disease globally. The coronavirus disease may cause significant delays and disruptions to our pre-clinical studies.

Additionally, travel restrictions have been implemented with respect to certain countries in an effort to contain the coronavirus disease, and several countries have expanded screenings of travelers. As travel restrictions are increasingly implemented and extended to other countries, the Company and its contract research organizations may be unable to visit its clinical trial sites and monitor the data from its clinical trials on timely basis. The Company’s employees may also face travel restrictions, which would impact its business. Furthermore, some of the Company’s manufacturers and suppliers are in Europe and may be impacted by port closures and other restrictions resulting from the coronavirus outbreak, which may disrupt the Company’s supply chain or limit its ability to obtain sufficient materials for our products.

The ultimate impact of the COVID-19 outbreak or similar health epidemics are highly uncertain and subject to changes, and the Company cannot presently predict the scope and severity of any potential business shutdowns or disruptions. However, if the Company or any of the third parties with whom the Company's engages, including the suppliers, animal trial sites, contract research organizations, regulators, including the FDA health care providers and other third parties with whom the Company conducts business, were to experience shutdowns or other business disruptions, the Company's ability to conduct our business and operations could be materially and negatively impacted, which could prevent or delay the Company from obtaining approval for its devices.

C. Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions pertaining to transactions and matters whose ultimate effect on the financial statements cannot precisely be determined at the time of financial statements preparation. Although these estimates are based on management's best judgment, actual results may differ from these estimates.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies applied in the preparation of the financial statements are as follows:

A. Basis of presentation:

The financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("US GAAP").

B. Financial statement in U.S. dollars:

The functional currency of the Company is the U.S. dollar ("dollar") since the dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future.

Transactions and balances denominated in dollars are presented at their original amounts. Transactions and balances denominated in foreign currencies have been re-measured to dollars in accordance with the provisions of ASC 830-10, "Foreign Currency Translation".

All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statement of operations as financial income or expenses, as appropriate.

C. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. Inter-company balances and transactions have been eliminated in consolidation.

D. Cash and cash equivalents:

Cash and cash equivalents consist of cash and demand deposits in banks, and other short-term liquid investments (primarily interest-bearing time deposits) with original maturities of less than three months.

E. Restricted cash:

Restricted cash as of December 31, 2020 included an \$84 collateral account for the Company's lease agreements and credit line from its commercial bank.

Diluted net loss per share is computed by dividing net loss, as adjusted, by the weighted average number of shares of common stock outstanding during the year, plus the number of shares of common stock that would have been outstanding if all potentially dilutive shares of common stock had been issued, using the treasury stock method, in accordance with ASC 260-10 “Earnings per Share”.

All outstanding stock options and warrants have been excluded from the calculation of the diluted loss per share for the years ended December 31, 2020 and December 31, 2019, since all such securities have an anti-dilutive effect.

K. Research and development expenses, net:

Research and development expenses are charged to the consolidated statements of operations as incurred. Grants for funding of approved research and development projects are recognized at the time the Company is entitled to such grants, on the basis of the costs incurred and applied as a deduction from the research and development expenses.

L. Share-based compensation:

The Company applies ASC 718-10, “Share-Based Payment,” which requires the measurement and recognition of compensation expenses for all share-based payment awards made to employees and directors including stock options under the Company’s stock plans based on estimated fair values.

ASC 718-10 requires companies to estimate the fair value of stock options using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company’s statement of operations, which is recognized based on a straight line method.

The Company accounts for shares and warrant grants issued to non-employees using the guidance of ASU No. 2018-07 “Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.” which expand the scope of Topic 718, Compensation - Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services.

The Company estimates the fair value of stock options granted as share-based payment awards using a Black-Scholes options pricing model. The option-pricing model requires a number of assumptions, of which the most significant are expected volatility and the expected option term (the time from the grant date until the options are exercised or expire). Expected volatility is estimated based on volatility of similar companies in the technology sector for equity awards granted prior to the Merger and on the Company’s trading share price for equity awards granted subsequent to the Merger. The Company has historically not paid dividends and has no foreseeable plans to issue dividends. The risk-free interest rate is based on the yield from governmental zero-coupon bonds with an equivalent term. The expected stock option term is calculated for stock options granted to employees and directors using the “simplified” method. Grants to non-employees are based on the contractual term. Changes in the determination of each of the inputs can affect the fair value of the stock options granted and the results of operations of the Company.

M. Reclassification:

Certain prior year amounts have been reclassified to conform to the current year presentation.

N. Income taxes:

The Company provides for income taxes using the asset and liability approach. Deferred tax assets and liabilities are recorded based on the differences between the financial statement and tax bases of assets and liabilities and the tax rates in effect when these differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of December 31, 2020, and 2019, the Company had a full valuation allowance against deferred tax assets.

O. Marketable securities:

Marketable securities are classified as available-for-sale and are carried at fair value. Unrealized gains and losses net of tax, if any, are reported as a separate component of shareholders' equity. The cost of marketable debt securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in finance income. Realized gains and losses and declines in value judged to be other than temporary, if any, are also included in other income, net. Interest earned on securities classified as available-for-sale is included in interest income. The cost of securities sold is based on the specific identification method.

Management evaluates whether available-for-sale securities are other-than-temporarily impaired (OTTI) on a quarterly basis. Debt securities with unrealized losses are considered OTTI if the Company intends to sell the security or if it is more likely than not that the Company will be required to sell such security prior to any anticipated recovery. If management determines that a security is OTTI under these circumstances, the impairment recognized in earnings is measured as the entire difference between the amortized cost and the then-current fair value. During the years 2020 and 2019, no investment OTTI losses were realized.

P. Leases:

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 requires entities that leased assets be recognized on the balance sheet as assets and liabilities for the rights and obligations created by leases with lease terms of more than 12 months. The Company adopted this ASU effective January 1, 2019 using the modified retrospective application, applying the new standard to leases in place as of the adoption date. Prior periods have not been adjusted.

Arrangements that are determined to be leases at inception are recognized as long-term right-of-use assets ("ROU") and lease liabilities in the consolidated balance sheets as of the lease commencement date. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future fixed lease payments over the lease term at the lease commencement date. As most of the Company's leases do not provide an implicit rate, the Company applies its incremental borrowing rate based on the economic environment at the lease commencement date in determining the present value of future payments. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases or payments are recognized on a straight-line basis over the lease term.

ASU 2016-02 provided a number of optional practical expedients upon implementation. The Company elected the transition package of practical expedients available in the standard, which permitted the Company to not reassess under the new standard the Company's prior conclusions about lease identification, lease classification, and initial direct costs and the practical expedient to not account for lease and non-lease components separately.

Q. Contingencies:

Management records and discloses legal contingencies in accordance with ASC Topic 450 *Contingencies*. A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company monitors the stage of progress of its litigation matters to determine if any adjustments are required.

R. Recently issued accounting pronouncements:

From time to time, new accounting pronouncements are issued by the FASB, or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In August 2018, the FASB issued ASU 2018-13, "Changes to Disclosure Requirements for Fair Value Measurements", which will improve the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements, and is effective for the Company beginning on January 1, 2020. The adoption of ASU 2018-13 on January 1, 2020 did not have a material impact on the Company's consolidated financial statements.

S. Recently issued accounting pronouncements not yet adopted:

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments – Credit Losses – Measurement of Credit Losses on Financial Instruments", which introduces a model based on expected losses to estimate credit losses for most financial assets and certain other instruments. In addition, for available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. The ASU is effective for smaller reporting companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2022 (January 1, 2023 for the Company) with early adoption permitted. The Company is currently evaluating the impact this guidance may have on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, "Simplifying the Accounting for Income Taxes" which eliminates the need for an organization to analyze whether the following apply in a given period: (1) exception to the incremental approach for intraperiod tax allocation; (2) exceptions to accounting for basis differences when there are ownership changes in foreign investments; and (3) exceptions in interim period income tax accounting for year-to-date losses that exceed anticipated losses. The ASU also is designed to improve financial statement preparers' application of income tax-related guidance and simplify GAAP for (1) franchise taxes that are partially based on income, (2) transactions with a government that result in a step-up in the tax basis of goodwill, (3) separate financial statements of legal entities that are not subject to tax, and (4) enacted changes in tax laws in interim periods. The standard is effective for the Company on January 1, 2021 with early adoption permitted. The Company is currently evaluating the impact this guidance may have on its consolidated financial statements and related disclosures.

NOTE 3 – FAIR VALUE MEASUREMENTS

The following table summarizes the Company’s financial assets subject to fair value measurement and the level of inputs used in such measurements as of December 31, 2020 and 2019:

	As of December 31, 2020			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	\$ 8,585	\$ 8,585	\$ -	\$ -
Total cash equivalents	<u>8,585</u>	<u>8,585</u>	<u>-</u>	<u>-</u>
Marketable securities:				
Other money market funds	2,000	2,000	-	-
US Treasury Bond	2,998	2,998	-	-
Total marketable securities:	<u>4,998</u>	<u>4,998</u>	<u>-</u>	<u>-</u>
Other assets:				
Convertible loan investment (see Note 4)	270	-	-	270
	<u>270</u>	<u>-</u>	<u>-</u>	<u>270</u>
Total assets	<u>\$ 13,853</u>	<u>\$ 13,583</u>	<u>\$ -</u>	<u>\$ 270</u>

	As of December 31, 2019			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	\$ 1,052	\$ 1,052	\$ -	\$ -
Total cash equivalents	<u>1,052</u>	<u>1,052</u>	<u>-</u>	<u>-</u>
Marketable securities:				
US Treasury Bond	2,521	2,521	-	-
Total marketable securities:	<u>2,521</u>	<u>2,521</u>	<u>-</u>	<u>-</u>
Total assets	<u>3,573</u>	<u>3,573</u>	<u>-</u>	<u>-</u>

The contractual maturity of the marketable securities noted above are one year.

NOTE 4 - OTHER CURRENT ASSETS

	As of December 31,	
	2020	2019
Amounts due from government institutions	\$ 70	\$ 101
Convertible loan investment (1)	270	-
Prepaid expenses and others	181	185
	<u>\$ 521</u>	<u>\$ 286</u>

(1) During 2020, the Company granted a convertible loan in the amount of \$200 bearing annual interest of 5%. The loan and accumulated interest will be converted under certain terms and conditions as detailed in the agreement. Also, the Company has the right to receive back the loan and accumulated interest in cash as detailed in the agreement. In March 2021, the Company converted this loan and received total consideration of \$270.

NOTE 5 - LEASES

We have lease agreements with lease and non-lease components, which we account for as a single lease component. Variable lease payments based on an index or rate are initially measured using the index or rate in effect at the lease commencement and included in the measurement of the lease liability; thereafter, changes to lease payments due to rate or index updates are recorded as rent expense in the period incurred. We have elected not to recognize ROU assets and lease liabilities for short-term leases that have a term of 12 months or less. The effect of short-term leases on our ROU assets and lease liabilities was not material. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants. In addition, we do not have any related party leases and our sublease transactions are de minimis.

Supplemental cash flow information related to operating leases was as follows:

	For the Years Ended December 31,	
	2020	2019
Cash payments for operating leases	\$ 229	\$ 354

Undiscounted maturities of operating lease payments as December 31, 2020 and December 31, 2019 are summarized as follows:

	As of December 31,	
	2020	2019
2020	\$ -	\$ 216
2021	248	234
2022	193	180
2023	187	174
2024	188	176
2025	166	154
Total future lease payments	982	1,134
Less imputed interest	(169)	(231)
Total lease liability balance	\$ 813	\$ 903

Leases recorded on the consolidated balance sheets consist of the following:

	As of December 31,	
	2020	2019
Assets		
Operating lease right-of-use asset	\$ 775	\$ 962
Liabilities		
Operating lease - current	\$ 187	\$ 143
Operating lease - non-current	626	760
	\$ 813	\$ 903

	As of December 31,	
	2020	2019
Operating leases weighted average remaining lease term (in years)	4	2.5
Operating leases weighted average discount rate	9%	9%

NOTE 6 - PROPERTY AND EQUIPMENT, NET

	As of December 31,	
	2020	2019
Cost:		
Research equipment and software	\$ 63	\$ 52
Leasehold improvements	211	161
Furniture and office equipment	190	160
	<u>464</u>	<u>373</u>
Accumulated Depreciation:		
Research equipment and software	54	38
Leasehold improvements	47	4
Furniture and office equipment	112	103
	<u>213</u>	<u>145</u>
	<u>\$ 251</u>	<u>\$ 228</u>

NOTE 7 - ACCRUED LIABILITIES

	As of December 31,	
	2020	2019
Employee-related liabilities	\$ 619	\$ 187
Accrued expenses from the merger	131	131
Accrued expenses	264	464
	<u>\$ 883</u>	<u>\$ 795</u>

NOTE 8 - COMMITMENTS AND CONTINGENCIES**Government Grants:**

Microbot Israel has received grants from the Israeli Innovation Authority (“IIA”) for participation in research and development since 2013 through 2020, totaling approximately \$1,500. In return, the Company is obligated to pay royalties amounting to 3%-3.5% of its future sales from commercialization of the funded research and development, up to the amount of the grants received.

The payment of royalties with respect to the repayment of the grants is contingent upon the successful completion of the Company’s research and development programs and generating sales. The Company has no obligation to repay these grants, if the project fails, is unsuccessful or aborted or if no sales are generated. The financial risk is assumed completely by the Government of Israel.

TRDF Agreement:

Microbot Israel signed an agreement with the Technion Research and Development Foundation (“TRDF”) in June 2012 by which TRDF transferred to Microbot Israel a global, exclusive, royalty-bearing license. As partial consideration for the license, Microbot Israel shall pay TRDF royalties on net sales (between 1.5%-3%) and on sublicense income as detailed in the agreement.

Agreement with CardioSert Ltd.:

On January 4, 2018, Microbot Israel entered into an agreement with CardioSert Ltd. (“CardioSert”) to acquire certain patent-protected technology owned by CardioSert (the “Technology”).

Pursuant to the Agreement, Microbot Israel made an initial payment of \$50 to CardioSert and had 90-days to elect to complete the acquisition. At the end of the 90-day period, at Microbot Israel’s sole option, CardioSert shall assign and transfer the Technology to Microbot Israel and Microbot Israel shall pay to CardioSert additional amounts and securities as determined in the agreement.

On May 25, 2018, Microbot delivered an Exercise Notice to CardioSert Ltd., notifying it that Microbot elected to exercise the option to acquire the Technology owned by CardioSert and therefore made an additional cash payment of \$250 and 6,738 shares of common stock estimated at \$74.

The agreement may be terminated by Microbot Israel at any time for convenience upon 90-days’ notice. The agreement may be terminated by CardioSert in case the first commercial sale does not occur by the third anniversary of the date of signing of the agreement except if Microbot Israel has invested more than \$2,000 in certain development stages, or the first commercial sale does not occur within 50 months. In each of the above termination events, or in case of breach by Microbot Israel, CardioSert shall have the right to buy back the Technology from Microbot Israel for \$1.00, upon 60 days prior written notice, but only 1 year after such termination. Additionally, the agreement may be terminated by either party upon breach of the other (subject to cure).

CardioSert agreed to assist Microbot Israel in the development of the Technology for a minimum of one year, for a monthly consultation fee of NIS 40,000 (or approximately US\$12.40, based on an exchange rate of NIS3.215 to the dollar) covering up to 60 consulting hours per month.

Litigation:

Litigation Resulting from 2017 Financing

The Company lost its appeal of an adverse judgment in the lawsuit captioned Sabby Healthcare Master Fund Ltd. and Sabby Volatility Warrant Master Fund Ltd., Plaintiffs, against Microbot Medical Inc., Defendant, in the Supreme Court of the State of New York, County of New York (Index No. 654581/2017). As a result, the Securities Purchase Agreement (the “SPA”) related to the Company’s June 8, 2017 equity financing (the “Financing”) was rescinded as it related to Sabby Healthcare Master Fund Ltd. and Sabby Volatility Warrant Master Fund Ltd. (“Sabby”), and the Company paid approximately \$3,700 to Sabby in return for the 83,333 shares of common stock Sabby purchased pursuant to the SPA. Soon after, the Company was named as the defendant in a lawsuit captioned Empery Asset Master Ltd., Empery Tax Efficient, LP, Empery Tax Efficient II, LP, Hudson Bay Master Fund Ltd., Plaintiffs, against Microbot Medical Inc., Defendant, in the Supreme Court of the State of New York, County of New York (the “Court”) (Index No. 651182/2020). The complaint alleges, among other things, that the Company breached multiple representations and warranties contained in the SPA, of which the Plaintiffs participated, and fraudulently induced Plaintiffs into signing the SPA. The complaint seeks rescission of the SPA and return of the Plaintiffs’ \$6,750 purchase price with respect to the Financing. The Company filed a Motion to Dismiss on March 16, 2020, which was denied in February 2021.

The Company’s management is unable to assess the likelihood that it would be successful in any trial with respect to the SPA or the Financing, having previously lost the Sabby lawsuit. Accordingly, no assurance can be given that if the Company goes to trial and ultimately loses, or if the Company decides to settle at any time, such an adverse outcome would not be material to the Company’s consolidated financial position.

Alliance Litigation

On April 28, 2019, the Company brought an action against Alliance Investment Management, Ltd. (“Alliance”), later amended to include Joseph Mona (“Mona”) as a defendant, in the Southern District of New York under Section 16(b) of the Securities Exchange Act of 1934, 15 U.S.C. 78p(b), to compel Alliance and Mona to disgorge short swing profits realized from purchases and sales of the Company’s securities within a period of less than six months. The case is Microbot Medical Inc. v. Alliance Investment Management, Ltd., No. 19-cv-3782-GBD (SDNY). The amount of profits was estimated in the complaint to be approximately \$468.

On October 28, 2019, Alliance filed a motion for summary judgment requesting that the Court dismiss the claims against Alliance. On February 4, 2020, Mona answered the 16(b) claim the Company asserted against him by claiming various equitable defenses, and filed a counterclaim against the Company under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, claiming a net loss on trading the Company’s stock of approximately \$151.

On March 6, 2020, the Company filed a motion for judgment on the pleadings with respect to the Company’s 16(b) claim against Mona, together with a motion to dismiss Mona’s 10(b) counterclaim.

On September 17, 2020, the Court issued a Memorandum Decision & Order that, among other things, granted Alliance’s summary judgment motion. The Company’s Section 16(b) claim against Mona remained pending following the Court’s dismissal of the Section 16(b) claim against Alliance.

On December 18, 2020, the Magistrate Judge issued a Report & Recommendation, which recommended that: (i) judgment of \$484,614.30 be entered in the Company’s favor on its Section 16(b) claim against Mona; and (ii) Mona’s Section 10(b) claim be dismissed with prejudice (except as to allegations regarding statements purportedly made by employees of Integra Consulting, an outside investor relations firm, which the Magistrate recommended be dismissed without prejudice). On January 4, 2021, Mona filed Objections to the Magistrate’s Report & Recommendation, which is pending.

NOTE 9 - SHARE CAPITAL

Share Capital Developments:

As of December 31, 2020, and December 31, 2019, the Company had 7,108,133 and 7,185,628 shares of common stock issued and outstanding, respectively.

On January 14, 2019, the Company entered into a Securities Purchase Agreement with an accredited institutional investor providing for the issuance and sale by the Company to the purchaser of an aggregate of (i) 330,000 shares of the Company's common stock, at a purchase price per share of \$6.50 and (ii) 125,323 pre-funded warrants each to purchase one share of common stock, at a purchase price per Pre-Funded Warrant of \$6.49. The gross proceeds to the Company were approximately \$3,000 before deducting placement agent fees and other offering expenses of approximately \$688. The closing of the offering took place on January 15, 2019. The pre-funded warrants were exercised in full in January 2019. As part of the offering the company issued to the underwriter 22,767 warrants for 3.5 years with an exercise price of \$8.125 for total value of \$165.

On January 15, 2019, the Company entered into a Securities Purchase Agreement with certain accredited institutional investors providing for the issuance and sale by the Company to the purchasers of an aggregate of 590,000 shares of the Company's common stock, at a purchase price per share of \$10.00. The gross proceeds to the Company were approximately \$5,900 before deducting placement agent fees and other offering expenses of approximately \$720. The closing of the offering took place on January 17, 2019. As part of the offering the company issued to the underwriter 29,500 warrants for 3.5 years with exercise price of \$12.50 for total value of \$221.

On January 23, 2019 the Company entered into a Securities Purchase Agreement with accredited institutional investors providing for the issuance and sale by the Company to the purchasers of an aggregate of 250,000 shares of the Company's common stock, at a purchase price per share of \$9.875. The investors also purchased warrants to purchase an aggregate of up to 250,000 shares of the Company's common stock, at a purchase price per warrant of \$0.125. The warrants were exercisable for 1 year and had an exercise price of \$10.00 per share, for a total value of \$2,019. The gross proceeds to the Company from the sale of the shares and warrants were approximately \$2,500 before deducting placement agent fees and other offering expenses of approximately \$370. The closing of the offering took place on January 25, 2019. As part of the offering the company issued to the underwriter 12,500 warrants for 1 year with an exercise price of \$12.50 for total value of \$99.

On December 25, 2019 the Company entered into a Securities Purchase Agreement with accredited institutional investors providing for the issuance and sale by the Company to the purchasers of an aggregate of 912,858 shares of the Company's common stock, at a purchase price per share of \$10.50. The gross proceeds to the Company were approximately \$9,585 before deducting placement agent fees and other offering expenses of approximately \$1,090. The closing of the offering took place on December 27, 2019. As part of the offering the Company issued to the underwriter 45,643 warrants for 3.5 years with an exercise price of \$13.125 for total value of \$371.

On December 27, 2019 the Company entered into a Securities Purchase Agreement with accredited institutional investors providing for the issuance and sale by the Company to the purchasers of an aggregate of 952,383 shares of the Company's common stock, at a purchase price per share of \$10.50. The gross proceeds to the Company were approximately \$10,000 before deducting placement agent fees and other offering expenses of approximately \$1,010. The closing of the offering took place on December 30, 2019. As part of the offering the Company issued to the underwriter 47,619 warrants for 3.5 years with an exercise price of \$13.125 for total value of \$366.

On December 30, 2019 the Company entered into a Securities Purchase Agreement with accredited institutional investors providing for the issuance and sale by the Company to the purchasers of an aggregate of 900,901 shares of the Company's common stock, at a purchase price per share of \$11.10. The gross proceeds to the Company were approximately \$10,000 before deducting placement agent fees and other offering expenses of approximately \$1,010. The closing of the offering took place on December 31, 2019. As part of the offering the Company issued to the underwriter 45,045 warrants for 3.5 years with an exercise price of \$13.875 for total value of \$343.

Employee Stock Option Grants

On January 21, 2019, the board of directors approved a grant of 11,630 stock options to purchase an aggregate of up to 11,630 shares of common stock to certain of its directors, at an exercise price per share of \$8.60. The stock options vest over a period of 3 years as outlined in the option agreements. As a result, the Company recognized compensation expenses as of December 31, 2020 and 2019 in the total amount of \$25 and \$43, respectively, included in general and administrative expenses.

On August 12, 2019, the board of directors approved a grant of 17,503 stock options to purchase an aggregate of up to 17,503 shares of common stock to certain of its employees, at an exercise price per share of \$5.95. The stock options vest over a period of 3 years as outlined in the option agreements. As a result, the Company recognized compensation expenses as of December 31, 2020 and 2019 in the total amount of \$32 and \$12, respectively, included in general and administrative expenses.

On October 23, 2019, the board of directors approved a grant of 19,760 stock options to purchase an aggregate of up to 19,760 shares of common stock to certain of its directors, at an exercise price per share of \$5.06. The stock options vest over a period of 3 years as outlined in the option agreements. As a result, the Company recognized compensation expenses as of December 31, 2020 and 2019 in the total amount of \$27 and \$6, respectively, included in general and administrative expenses.

On February 25, 2020, the board of directors approved a grant of 166,666 stock options to purchase an aggregate of up to 166,666 shares of common stock to Mr. Harel Gadot, the Company's Chairman of the Board, President and CEO, at an exercise price per share of \$9.64. The stock options vest over a period of 1 years as outlined in the option agreements. As a result, the Company recognized compensation expenses as of December 31, 2020 in the total amount of \$1,237 included in general and administrative expenses.

On July 14, 2020, the board of directors approved grants of stock options to purchase an aggregate of up to 31,492 shares of common stock to an independent director and to an officer, each at an exercise price per share of \$6.16. The stock options vest over a period of 3 years as outlined in the option agreements. As a result, the Company recognized compensation expenses as of December 31, 2020 in the total amount of \$27, included in general and administrative expenses.

On August 14, 2020, the board of directors approved a grant of stock options to purchase up to 4,902 shares of common stock to an independent director, at an exercise price per share of \$8.16. The stock options vest over a period of 3 years as outlined in the option agreements. As a result, the Company recognized compensation expenses as of December 31, 2020 in the total amount of \$4, included in general and administrative expenses.

On November 5, 2020, the Company granted to independent directors of the Company, options to purchase an aggregate of 11,084 shares of the Company's common stock, at an exercise price per share of \$7.22. The stock options vest over a period of 3 years as outlined in the option agreements. As a result, the Company recognized compensation expenses as of December 31, 2020 in the total amount of \$3 included in general and administrative expenses.

A summary of the Company's option activity related to options to employees and directors, and related information is as follows:

	For the Year ended December 31, 2020	
	Number of stock options	Weighted average exercise price
Outstanding as of December 31, 2019	371,360	\$ 9.19
Granted	214,145	9.0
Exercised	(965)	(*)
Forfeited	-	-
Cancelled	(8,818)	9.10
Outstanding as of December 31, 2020	575,722	\$ 9.14
Vested at end of period	332,104	\$ 9.13

	For the Year ended December 31, 2019	
	Number of stock options	Weighted average exercise price
Outstanding as of December 31, 2018	398,308	\$ 11.50
Granted	48,893	6.20
Forfeited	(28,690)	15.30
Cancelled	(47,151)	19.35
Outstanding as of December 31, 2019	371,360	\$ 9.19
Vested at end of period	270,827	\$ 8.48

(*) Less than \$0.01.

The intrinsic value is calculated as the difference between the fair market value of the common stock and the exercise price, multiplied by the number of in-the-money stock options on those dates that would have been received by the stock option holders had all stock option holders exercised their stock options on those dates as of December 31, 2020 and December 31, 2019, respectively.

As of December 31, 2020, and 2019, the aggregate intrinsic value of the outstanding options is \$702 and \$1,305 respectively, and the aggregate intrinsic value of the exercisable options is \$657 and \$1,115, respectively.

As of December 31, 2020, there were approximately \$730 of total unrecognized compensation costs, net of expected forfeitures, related to unvested share-based compensation awards granted under the Share Incentive Plan. The costs are expected to be recognized over a weighted average period of 0.75 years

The stock options outstanding as of December 31, 2020 and December 31, 2019, summarized by exercise prices, are as follows:

<u>Exercise price \$</u>	<u>Stock options outstanding as of December 31, 2020</u>	<u>Stock options outstanding as of December 31, 2019</u>	<u>Weighted average remaining contractual life – years as of December 31, 2020</u>	<u>Weighted average remaining contractual life – years as of December 31, 2019</u>	<u>Stock options exercisable as of December 31, 2020</u>	<u>Stock options exercisable as of December 31, 2019</u>
4.20	77,846	77,846	4.0	6.0	77,846	77,846
6.16	31,492	-	9.5	-	6,250	-
8.16	4,902	-	9.5	-	-	-
7.22	11,084	-	9.3	-	-	-
15.75	131,007	133,546	6.7	7.8	118,308	90,641
8.60	9,304	11,630	8.1	9.9	7,208	5,515
9.00	10,000	10,000	7.6	8.8	7,750	4,750
9.64	166,666	-	9.2	-	-	-
5.95	17,503	17,503	8.6	9.7	8,312	-
5.06	15,808	19,760	8.8	9.8	6,320	-
15.30	38,533	38,533	7.0	8.0	38,533	29,533
(*)	61,577	62,542	5.3	6.8	61,577	62,542
	<u>575,722</u>	<u>371,360</u>	<u>7.3</u>	<u>8.3</u>	<u>332,104</u>	<u>270,827</u>

(*) Less than \$0.01.

Compensation expense recorded by the Company for its stock-based employee compensation awards in accordance with ASC 718-10 for the Years ended December 31, 2020 and 2019 was \$1,937 and \$1,099, respectively.

The grant date fair values of stock options granted in the years ended December 31, 2020 and 2019 were estimated using the Black-Scholes valuation model with the following:

	<u>Year ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Expected volatility	113.86%-135.21%	132.63%-144.4%
Risk-free interest	0.33%-1.62%	1.49%-2.62%
Dividend yield	0%	0%
Expected life of up to (years)	5.5-5.8	5.3

Warrants

The remaining outstanding warrants and terms as of December 31, 2020 and December 31, 2019 are as follows:

<u>Issuance date</u>	<u>Outstanding as of December 31, 2020</u>	<u>Outstanding as of December 31, 2019</u>	<u>Exercise Price</u>	<u>Exercisable as of December 31, 2020</u>	<u>Exercisable Through</u>
Series A (2013)	183	183	\$ 2,754.00	183	April 9, 2023
Series A (2015)	-	683	\$ 1,377.00	-	April 30, 2020
Series B (2016)	2,770	2,770	\$ 40.50	2,770	March 14, 2022
Warrant to underwriters 1.2019	8,082	22,767	\$ 8.13	8,082	July 14, 2022
Warrant to underwriters 1.2019	29,500	29,500	\$ 12.50	29,500	July 15, 2022
Warrant to underwriters 1.2019	-	12,500	\$ 12.50	-	January 15, 2020
Warrant to underwriters 12.2019	45,643	45,643	\$ 13.13	45,643	June 25, 2023
Warrant to underwriters 12.2019	47,619	47,619	\$ 13.13	47,619	June 27, 2023
Warrant to underwriters 12.2019	45,045	45,045	\$ 13.88	45,045	June 30, 2023

In December 2019, 125,000 outstanding warrants at an exercise price per share of \$10.00, were exercised on a “net exercise” or “cashless” basis into 61,677 shares of common stock, and 125,000 outstanding warrants at an exercise price per share of \$10.00, were exercised on a “net exercise” or “cashless” basis into 50,143 shares of common stock. All of such warrants were issued in January 2019.

In August 2020, 14,685 outstanding warrants at an exercise price per share of \$8.13, were exercised on a “net exercise” or “cashless” basis into 4,873 shares of common stock. All of such warrants were issued in January 2019.

NOTE 10 - RESEARCH AND DEVELOPMENT EXPENSES, NET

	Years ended December 31,	
	2020	2019
Payroll and related expenses	\$ 1,596	\$ 1,404
Share-based compensation	121	131
Professional services	761	585
Materials	273	545
Patents	255	79
Rent	195	178
Office and maintenance expenses	94	61
Depreciation	64	76
Other	37	17
Less: Grants received from IIA & EC	-	(28)
	<u>\$ 3,396</u>	<u>\$ 3,048</u>

NOTE 11 - GENERAL AND ADMINISTRATIVE EXPENSES

	Years ended December 31,	
	2020	2019
Payroll and related expenses	\$ 1,500	\$ 850
Government fees	334	199
Share-based compensation	1,816	968
Professional services	1,036	1,282
Insurance	500	266
Public and investor relations	272	169
Office and maintenance expenses	126	157
Travel	62	246
Other	43	47
Depreciation	4	8
	<u>\$ 5,693</u>	<u>\$ 4,192</u>

NOTE 12 - TRANSACTIONS AND BALANCES WITH RELATED PARTIES

	Year ended December 31,	
	2020	2019
Transactions:		
Payroll and related expenses	\$ 2,974	\$ 1,094
Directors' fees and insurance	807	569
	<u>\$ 3,781</u>	<u>\$ 1,663</u>
	As of December 31,	
	2020	2019
Balances:		
Other accounts payable	\$ 313	\$ 228

MICROBOT MEDICAL INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands
(Except share and per share data)

NOTE 13 - TAXES ON INCOME

The Company is subject to income taxes under the Israeli and U.S. tax laws:

Corporate tax rates

The Company is subject to Israeli corporate tax rate of 23% for the years ended 2020 and 2019.

The Company is subject to a U.S. Federal tax of 21% for the years ended December 31, 2020 and 2019.

As of December 31, 2020, the Company generated net operating losses in Israel of approximately \$19,773 which may be carried forward and offset against taxable income in the future for an indefinite period.

As of December 31, 2020, the Company incurred net operating losses in the U.S. of approximately \$492,487. Net operating losses in the United States are available through 2035. Utilization of U.S. net operating losses may be subject to substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization.

The Company is still in its development stage and has not yet generated revenues, therefore, it is more likely than not that sufficient taxable income will not be available for the tax losses to be utilized in the future. Therefore, a valuation allowance was recorded to reduce the deferred tax assets to its recoverable amounts.

	Year ended December 31,	
	2020	2019
Net operating loss carry-forwards	\$ 512,260	\$ 503,065
Other net deferred tax assets	107,574	115,705
Valuation allowance	(107,574)	(115,705)
Net deferred tax assets	\$ -	\$ -

Reconciliation of Income Taxes:

The following is a reconciliation of the taxes on income assuming that all income is taxed at the ordinary statutory corporate tax rate in Israel and the effective income tax rate:

	Year ended December 31,	
	2020	2019
Net loss in Israel	\$ 4,042	\$ 3,972
Net loss in U.S.	5,127	3,275
Statutory tax rate	21-23%	21-23%
Income Tax under statutory tax rate	2,005	1,601
Change in valuation allowance	(2,005)	(1,601)
Actual provision for income taxes	\$ -	\$ -

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Registration No. 333-221216 and 333-250963) and the Registration Statement on Form S-3 (Registration No. 333-250966) of our report dated March 31, 2021 relating to the consolidated financial statements of Microbot Medical Inc. (the "Company") appearing in the Annual Report on Form 10-K of the Company for the year ended December 31, 2020.

Brightman Almagor Zohar & Co.,
Certified Public Accountants
A firm in the Deloitte Global Network

Tel Aviv, Israel
March 31, 2021

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Harel Gadot, certify that:

1. I have reviewed this annual report on Form 10-K of Microbot Medical Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2021

/s/ HAREL GADOT

Harel Gadot

President and Chief Executive Officer
(principal executive officer)

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David Ben Naim, certify that:

1. I have reviewed this annual report on Form 10-K of Microbot Medical Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2021

/s/ DAVID BEN NAIM

David Ben Naim

Chief Financial Officer

(principal financial and accounting officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Microbot Medical Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, **Harel Gadot**, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the company.

/s/ HAREL GADOT

Harel Gadot

President and Chief Executive Officer

March 31, 2021

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Microbot Medical Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, **David Ben Naim**, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the company.

/s/ DAVID BEN NAIM

David Ben Naim
Chief Financial Officer
March 31, 2021
