Microbot Medical Announces FDA Pre-Submission Milestones for 2019

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Regulatory Pre-Submission of the Self-Cleaning Shunt (SCS™) Remains the Primary Operational Objective

HINGHAM, Mass., Jan. 07, 2019 (GLOBE NEWSWIRE) -- Microbot Medical Inc. (Nasdaq CM: MBOT) announced today anticipated operational and product milestones, including pivotal pre-clinical study and FDA pre-submission milestones, for 2019. The progress and successful execution of key objectives in 2018, which included, among other things, Microbot's successful completion of the first phase of the ongoing pre-clinical trials, the expansion of Microbot's portfolio of technologies and intellectual property and the strengthening of Microbot's management team to meet the next phase of the Company's development efforts, are expected to position Microbot to achieve the milestones listed below during 2019.

Key 2018 Operational and Product Achievements

- Successfully completed and announced the results of two pre-clinical studies which were performed by leading U.S. academic institutions.
  - 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 in-vivo animal study, which was performed at Washington University in St. Louis School of Medicine, supports the safety profile of the Company's SCS ™ as a CSF catheter.
- Demonstrated to leading neurologists for the first time, the activated SCS™ from a working prototype of its customized headset at the 2018 International Hydrocephalus Conference, held in Bologna, Italy in October 2018.
- Presented the results of the in-vivo animal study supporting the initial safety profile of the SCS™ at the 2018 International Hydrocephalus Conference, held in Bologna, Italy in October 2018
- Initiated a pivotal pre-clinical study with a larger sample size to further evaluate the safety and efficacy of the SCS™ in the same in-vitro and in-vivo (animal) models. Microbot plans to use the findings for its future regulatory submissions in the US, Europe and other jurisdictions.
- Acquired a novel technology from CardioSert Ltd., which the Company believes will bring added value to its current technologies.
- Strengthened its IP Portfolio with Global Patent Allowances resulting in a total of 30 patents granted and 18 patent applications pending approval.
- Was awarded a non-dilutive grant from the European Commission to continue developing the SCS™. The Commission's decision, in part, was based upon substantial demand for the SCS™ with the potential to create new market opportunities.
- Relocated its global Research & Development operations to a state-of-the-art facility to meet the next phase of the Company's development efforts .
- Strengthened its management team and enhanced its Scientific Advisory Board with leading medical device expertise.

Anticipated 2019 Operational and Product Milestones

- Announce the results of an independent in-vitro study validating the operational effectiveness of the SCS™.
- Complete the pivotal pre-clinical study to further evaluate the safety and efficacy of the SCS™ being performed at Washington University in St. Louis School of Medicine and Wayne State University in the third quarter of 2019.
- Finalize the FDA regulatory pre-submission request for the SCS™ in the second half of 2019.
- Strengthen the balance sheet, including through non-dilutive sources of cash such as grants, to execute its near and long-term business plan.
- Explore related market opportunities with significant medical needs and high procedure volumes that will benefit from the Company's technologies.
- Expand and protect the Company's global IP portfolio which creates barriers to entry.
- Build out the Company's senior leadership.

About Microbot Medical, Inc.

Microbot™, which was founded in 2010 and commenced operations in 2011, became a NASDAQ listed company on November 28, 2016. The Company specializes in transformational micro-robotic medical technologies leveraging the natural and artificial lumens within the human body. Microbot's current technological platforms platforms, ViRob ™, TipCAT™ and CardioSert™, are comprised of three highly advanced technologies, from which the Company is currently developing its first product candidate: the Self Cleaning Shunt, or SCS™, for the treatment of hydrocephalus and Normal Pressure Hydrocephalus, or NPH. The Company also is focused on the development of a Multi Generation Pipeline Portfolio (MGPP) utilizing all technologies. Further information about Microbot Medical is available at http://www.microbotmedical.com.

The ViRob™ technology is a revolutionary autonomous crawling micro-robot which can be controlled remotely or within the body. Its miniature dimensions allow it to navigate and crawl in different spaces within the human body, including blood vessels, the digestive tract and the respiratory system. Its unique structure gives 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. To learn more about ViRob™ please visit http://www.microbotmedical.com/technology/virob/.

TipCAT™ is a transformational self-propelled, flexible, and semi-disposable locomotive device providing see & treat capabilities within tubular lumens in the human body such as the colon, blood vessels, and the urinary tract. Its locomotion mechanism is perfectly suitable to navigate and crawl through natural & artificial tubular lumens, applying the minimal necessary pressure to achieve the adequate friction required for gentle, fast, and safe advancement within the human body. To learn more about TipCAT™, visit http://www.microbotmedical.com/technology/tipcat/.

CardioSert™ technology contemplates a unique combination of a guidewire and microcatheter, technologies that are broadly used for endoluminal surgery. The CardioSert™ technology features unique steering and stiffness control capabilities, and it was originally developed to support interventional cardiologists in crossing the most complex lesions called chronic total occlusion (CTO) during percutaneous coronary intervention (PCI) procedures and has the potential to be used in other spaces and applications, such as peripheral intervention, neurosurgery and urology. CardioSert™ was part of a technological incubator supported by the Israel Innovation Authorities (formerly known as the Office of the Chief Scientist, or OCS), and its device has successfully completed pre-clinical testing.

Safe Harbor

Statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for Microbot Medical Inc. and its subsidiaries, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as “will,” “believes,” “plans,” “anticipates,” “expects” and “estimates”) should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, the outcome of its studies to evaluate the SCS and other existing and future technologies, uncertainty in the results of pre-clinical and clinical trials or regulatory pathways and regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the businesses of Microbot Medical Inc. particularly those mentioned in the cautionary statements found in Microbot Medical Inc.’s filings with the Securities and Exchange Commission. Microbot Medical disclaims any intent or obligation to update these forward-looking statements.

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