

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 27, 2021

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

Delaware
(State or other jurisdiction
of incorporation)

000-19871
(Commission
File Number)

94-3078125
(IRS Employer
Identification No.)

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

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

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| <u>Title of each class</u> | <u>Trading Symbol(s)</u> | <u>Name of each exchange on which registered</u> |
|--------------------------------|--------------------------|--|
| Common Stock, \$0.01 par value | MBOT | NASDAQ Capital Market |

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

Emerging Growth Company

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

Item 7.01 Regulation FD Disclosure.

On January 27, 2021, Microbot Medical Inc. (the “Company”) issued a press release announcing the completion of successful discussions with the U.S. Food and Drug Administration (FDA) for its Self-Cleaning Shunt (SCS). After review of the Company’s existing pre-clinical data, the FDA’s feedback will allow the Company to apply for a limited clinical investigation known as an Early Feasibility Study (EFS), which is designed for novel technologies such as the SCS. Consequently, the Company reiterates its timeline for the First-in-Human (FIH) clinical trial under the EFS, expected to commence in the third quarter of 2022.

The press release furnished as Exhibit 99.1 to this Current Report on Form 8-K is incorporated herein by reference. The information in this report (including Exhibit 99.1) is being furnished pursuant to Item 7.01 and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. This report will not be deemed an admission as to the materiality of any information herein (including Exhibit 99.1).

Item 9.01. Financial Statements and Exhibits.*(d) Exhibits*

| Exhibit Number | Description |
|---------------------------|--------------------|
|---------------------------|--------------------|

| | |
|------|-------------------------------|
| 99.1 | Press Release |
|------|-------------------------------|

SIGNATURES

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

MICROBOT MEDICAL INC.

By: /s/ Harel Gadot

Name: Harel Gadot

Title: Chief Executive Officer, President and Chairman

Date: January 27, 2021



Microbot Medical Announces Successful Outcome of its Discussions with FDA Regarding Regulation of Self-Cleaning Shunt

FDA Feedback Reflects Strength of Pre-Clinical Safety Data; Maintains Q3 2022 Projected Commencement of First-in-Human Clinical Trial

HINGHAM, Mass., January 27, 2021 – Microbot Medical Inc. (Nasdaq: MBOT) announced the completion of successful discussions with the U.S. Food and Drug Administration (FDA) for its Self-Cleaning Shunt (SCS). After review of the Company’s existing pre-clinical data, the FDA’s feedback will allow the Company to apply for a limited clinical investigation known as an Early Feasibility Study (EFS), which is designed for novel technologies such as the SCS. Consequently, the Company reiterates its timeline for the First-in-Human (FIH) clinical trial under the EFS, expected to commence in the third quarter of 2022.

“The FDA’s response is a significant milestone for our SCS product, as it affirms the novelty of the technology and our pathway as we advance to the next developmental, clinical and regulatory phase,” commented Harel Gadot, Chief Executive Officer, President, and Chairman. “Throughout the pre-submission process with the FDA, we have sufficiently provided information which we believe exhibits the strength of our data and provide us with high level of confidence in the continued progression towards the successful commercialization of our novel SCS.”

As anticipated, the FDA review focused on product-specific, regulatory and scientific topics related to the SCS, and included in the pre-submission were pre-clinical study data conducted by leading U.S. academic institutions. The Company expects to continue to work with the FDA towards finalizing the SCS device design, and to incorporate their feedback prior to submitting the Investigational Device Exemption (IDE) to seek authorization to begin the EFS clinical trial. While there can be no assurance that FDA will approve the EFS study, the agency’s recent feedback indicates that the agency will be receptive to allowing this FIH study to proceed based on existing data. After completing the EFS, the Company 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.

The Company’s innovative SCS is designed to be a transformative device which prevents obstruction in the cerebrospinal fluid (CSF) catheters implanted in the ventricle of the brain of patients who suffer from hydrocephalus or Normal Pressure Hydrocephalus (NPH).

About Microbot Medical

Microbot Medical Inc. (NASDAQ: MBOT) is a pre-clinical medical device company that specializes in transformational micro-robotic technologies, focused primarily on both natural and artificial lumens within the human body. Microbot's current proprietary technological platforms provide the foundation for the development of a Multi Generation Pipeline Portfolio (MGPP).

Microbot Medical was founded in 2010 by Harel Gadot, Prof. Moshe Shoham, and Yossi Bornstein with the goals of improving clinical outcomes for patients and increasing accessibility through the use of micro-robotic technologies. Further information about Microbot Medical is available at <http://www.microbotmedical.com>.

Safe Harbor

Statements pertaining to the registered direct offering, timing, the amount and anticipated use of proceeds and 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 within the meaning of the Private Securities Litigation Reform Act of 1995 and the Federal securities laws. 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, market conditions and the satisfaction of customary closing conditions, risks inherent in the development and/or commercialization of potential products, including LIBERTYTM and SCS, the outcome of its studies to evaluate LIBERTY, SCS and other existing and future technologies, uncertainty in the results of pre-clinical and clinical trials or regulatory pathways and regulatory approvals, uncertainty resulting from the COVID-19 pandemic, need and ability to obtain future capital, and maintenance of intellectual property rights. Additional information on risks facing Microbot Medical can be found under the heading "Risk Factors" in Microbot Medical's periodic reports filed with the Securities and Exchange Commission (SEC), which are available on the SEC's web site at www.sec.gov. Microbot Medical disclaims any intent or obligation to update these forward-looking statements, except as required by law.

Investor Contact:

Michael Polyviou
EVC Group
mpolyviou@evcgroup.com
732-933-2754
