
**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): March 31, 2022

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:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|--------------------------------|-------------------|---|
| 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 March 31, 2022, Microbot Medical Inc. (the “Company”) issued a press release to announce that it has filed its pre-submission package for the LIBERTY[®] Robotic System with the U.S. Food and Drug Administration (FDA), addressing the regulatory pathway for the LIBERTY[®] Robotic System. This is in line with the Company’s previously stated Q1 timeline. The Company expects to meet with the FDA following a normal review process to discuss the pre-submission and ensure the testing protocols and regulatory pathway are aligned with the FDA to obtain clearance for LIBERTY.

The press release, which is 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 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

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: March 31, 2022



Microbot Medical Achieves Significant Regulatory Milestone for the LIBERTY® Robotic System; Files FDA Pre-Submission Package for Regulatory Pathway

Pre-Clinical Trial on Track for Third Quarter

HINGHAM, Mass., March 31, 2022 – The operational momentum that Microbot Medical Inc. (Nasdaq: MBOT) experienced at the end of 2021 has continued well into the 2022 first quarter. The Company filed its pre-submission package for the LIBERTY® Robotic System with the U.S. Food and Drug Administration (FDA), addressing the regulatory pathway for the LIBERTY® Robotic System. This is in line with the Company’s previously stated Q1 timeline. The Company expects to meet with the FDA following a normal review process to discuss the pre-submission and ensure the testing protocols and regulatory pathway are aligned with the FDA to obtain clearance for LIBERTY.

“The significant progress we achieved in the first quarter demonstrates the team is highly focused on delivering key milestones on time,” commented Harel Gadot, Chairman, CEO and President. “The pre-submission filing with the FDA is an important milestone, and although it is the initial phase in the regulatory process, it gives us the confidence to commence implementing plans to scale up the Company’s organizational infrastructure to support future commercial success.”

About Microbot Medical Inc.

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 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, risks inherent in the development and/or commercialization of potential products, including LIBERTY 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.

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