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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of: May 2021 (Report No. 3)

Commission File Number: 001-38428

PolyPid Ltd.
(Translation of registrant's name into English)

18 Hasivim Street
Petach Tikva 495376, Israel
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

CONTENTS

Attached hereto and incorporated herein is the Registrant's press release issued on May 19, 2021, titled "PolyPid Announces Positive FDA Type B Meeting Feedback for D-PLEX₁₀₀ Development Program."

The first two and the fourth paragraphs and the section titled "Forward-Looking Statements" in the press release are incorporated by reference into the Registrant's Registration Statement on Form S-8 (Registration No. 333-239517), filed with the Securities and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit No.

99.1	Press Release issued by PolyPid Ltd. on May 19, 2021, titled "PolyPid Announces Positive FDA Type B Meeting Feedback for D-PLEX₁₀₀ Development Program."
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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.

POLYPID LTD.

Date: May 19, 2021

By: /s/ Dikla Czaczkes Akselbrad

Name Dikla Czaczkes Akselbrad

Title: Executive Vice President and
Chief Financial Officer

PolyPid Announces Positive FDA Type B Meeting Feedback for D-PLEX₁₀₀ Development Program

FDA Agreed that a Single Pivotal Phase 3 Study is Sufficient for Potential Approval of D-PLEX₁₀₀ for the Prevention of Surgical Site Infections in Colorectal Surgery.

- *Enrollment in Phase 3 SHIELD I Trial of D-PLEX₁₀₀ in Abdominal Surgery Continues to Advance; Over 200 Patients Enrolled to Date*
- *Top-line Results Expected by Year-end*

PETAH TIKVA, Israel, May 19, 2021 -- PolyPid Ltd. (Nasdaq: PYPD), a late-stage biopharma company aiming to improve surgical outcomes through locally administered, controlled, extended-release therapeutics, announced today it has received written responses from the U.S. Food and Drug Administration (FDA) to a Type B meeting request that the Company submitted regarding its development plan for D-PLEX₁₀₀.

The FDA indicated that PolyPid's proposal for a single Phase 3 pivotal study (SHIELD I), provided the study results are adequate, would provide sufficient evidence of clinical efficacy and safety to support approval of D-PLEX₁₀₀ for the prevention of surgical site infections (SSIs) in colorectal surgery. The Type B meeting was requested following PolyPid's receipt of Breakthrough Therapy Designation from the FDA for D-PLEX₁₀₀ for the prevention of SSIs in patients undergoing elective colorectal surgery.

"We appreciate the thoughtful feedback from the FDA regarding our clinical program, and we are thrilled with the acceptance of our proposed development plan for the potential approval of D-PLEX₁₀₀, which also reduces overall anticipated costs for the program," said Amir Weisberg, PolyPid's CEO. "PolyPid is dedicated to tackling the issue of SSIs that accounts for 20 percent of all healthcare-acquired infections in the U.S., resulting in extended hospital stays and readmission, costing up to \$10 billion in annual medical costs. We will use the responses provided to progress our SHIELD I trial which continues to enroll patients at the expected rate, with over 200 patients enrolled to date, and we anticipate the availability of top-line results by the end of 2021."

Launched in July 2020, SHIELD I is a prospective, multinational, multicenter, randomized, double blind Phase 3 trial designed to assess the efficacy and safety of D-PLEX₁₀₀ for the prevention of incisional SSIs post-abdominal surgery. The primary endpoint of the trial is the combination of incisional SSIs and mortality rate as measured by the proportion of subjects with either an SSI event, as determined by a blinded and independent adjudication committee, or mortality for any reason within 30 days post-surgery. The trial will enroll a minimum of 616 patients, with a maximum of about 900 patients, as defined by the adaptive study design, in more than 60 centers in the United States, Europe and Israel.

About D-PLEX₁₀₀

PolyPid's lead product candidate, D-PLEX₁₀₀, is a novel drug product candidate designed to provide local prolonged and controlled anti-bacterial activity directly at the surgical site to prevent SSIs. Following the administration of D-PLEX₁₀₀ into the surgical site, the PLEX technology enables a prolonged and constant release of the broad-spectrum antibiotic doxycycline, resulting in high local concentration of the drug for a period of four weeks for the prevention of SSIs, with additional potential to prevent SSIs caused by antibiotic-resistant bacteria at the surgical site. D-PLEX₁₀₀ has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX₁₀₀ has also received two Qualified Infectious Disease Product (QIDP) designations as well as two Fast Track designations for the prevention of post-abdominal surgery incisional infection and for the prevention of sternal wound infection post-cardiac surgery.

About PolyPid

PolyPid Ltd. (Nasdaq: PYPD) is a late-stage biopharma company aiming to improve surgical outcomes through locally administered, controlled, extended-release therapeutics. PolyPid's proprietary PLEX (Polymer-Lipid Encapsulation matriX) technology pairs with medications, enables precise delivery of drugs at effective release rates, over durations ranging from several days to months. PolyPid's lead product candidate D-PLEX₁₀₀ is in Phase 3 clinical trials for the prevention of sternal and abdominal surgical site infections (SSIs).

For additional company information, please visit <http://www.polypid.com> and follow us on Twitter and LinkedIn.

Forward-looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act and other securities laws. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates” and similar expressions or variations of such words are intended to identify forward-looking statements. For example, the Company is using forward-looking statements when it discusses its ongoing clinical trials, plans to use the guidance provided by the FDA to progress with its SHIELD I program, the timing of top-line results of the SHIELD I trial, and the size and design of the SHIELD I trial. Forward-looking statements are not historical facts, and are based upon management’s current expectations, beliefs and projections, many of which, by their nature, are inherently uncertain. Such expectations, beliefs and projections are expressed in good faith. However, there can be no assurance that management’s expectations, beliefs and projections will be achieved, and actual results may differ materially from what is expressed in or indicated by the forward-looking statements. Forward-looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward-looking statements. For a more detailed description of the risks and uncertainties affecting the Company, reference is made to the Company’s reports filed from time to time with the Securities and Exchange Commission (“SEC”), including, but not limited to, the risks detailed in the Company’s Annual Report on Form 20-F filed on March 5, 2021. Forward-looking statements speak only as of the date the statements are made. The Company assumes no obligation to update forward-looking information to reflect actual results, subsequent events or circumstances, changes in assumptions or changes in other factors affecting forward-looking information except to the extent required by applicable securities laws. If the Company does update one or more forward-looking statements, no inference should be drawn that the Company will make additional updates with respect thereto or with respect to other forward-looking statements.

References and links to websites have been provided as a convenience, and the information contained on such websites is not incorporated by reference into this press release. PolyPid is not responsible for the contents of third-party websites.

Corporate Contact

PolyPid, Ltd.
Dikla Czaczkes Akselbrad
EVP & CFO
Tel: +972-747195700

Investor Contact

Bob Yedid
LifeSci Advisors
646-597-6989
bob@lifesciadvisors.com

Media Contact

Nechama Feuerstein
551-444-0784
Nechama.Feuerstein@finnpartners.com
