
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: December 2022
(Report No. 2)

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 PolyPid Ltd.'s (the "Registrant") press release issued on December 12, 2022, titled "PolyPid Announces Scheduling of Type D Meeting with U.S. FDA to Discuss SHIELD I Phase 3 Results and Regulatory Pathway for D-PLEX₁₀₀ for the Prevention of Surgical Site Infections in Abdominal Colorectal Surgery."

The first and third paragraphs and the section captioned "Forward-Looking Statements" in the press release are incorporated by reference into the Registrant's registration statements on [Form F-3](#) (File No. 333-257651) and [Form S-8](#) (File 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 INDEX

Exhibit No.

99.1	Press Release issued by PolyPid Ltd. on December 12, 2022, titled "PolyPid Announces Scheduling of Type D Meeting with U.S. FDA to Discuss SHIELD I Phase 3 Results and Regulatory Pathway for D-PLEX₁₀₀ for the Prevention of Surgical Site Infections in Abdominal Colorectal Surgery"
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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: December 12, 2022

By: /s/ Dikla Czaczkes Akselbrad
Name: Dikla Czaczkes Akselbrad
Title: Chief Executive Officer

PolyPid Announces Scheduling of Type D Meeting with U.S. FDA to Discuss SHIELD I Phase 3 Results and Regulatory Pathway for D-PLEX₁₀₀ for the Prevention of Surgical Site Infections in Abdominal Colorectal Surgery

Meeting Scheduled for January 2023

PolyPid Recently Provided FDA with Currently Available Data from Completed SHIELD I Phase 3 Study in Advance of Meeting

PETACH TIKVA, Israel, December 12, 2022 -- PolyPid Ltd. (Nasdaq: PYPD) (“PolyPid” or the “Company”), a late-stage biopharma company aiming to improve surgical outcomes, today announced that a Type D meeting has been scheduled for January 2023 with the U.S. Food and Drug Administration (FDA) to discuss the results of SHIELD I Phase 3 study and regulatory requirements to support the indication of D-PLEX₁₀₀ for the prevention of abdominal colorectal surgical site infections (SSIs). In advance of the meeting, PolyPid recently provided the FDA with currently available data from the completed SHIELD I study.

“We look forward to a constructive dialogue with the FDA with regard to the outcomes of SHIELD I and possible next steps for D-PLEX₁₀₀ for the prevention of abdominal colorectal SSIs,” said Dikla Czaczkes Akselbrad, PolyPid’s Chief Executive Officer. “Based on the significant reduction in SSIs in complex surgeries with large incisions demonstrated in SHIELD I, we remain highly confident in the potential of D-PLEX₁₀₀. The recent open market stock purchases by myself and by our Board Chairman, Mr. Jacob Harel, about five- digit numbers worth each, are indicative of this high level of confidence.”

The FDA established Type D meetings to provide an opportunity for companies to address more focused issues on a shorter timeline than other meeting types normally allow. A Type D meeting is focused on a narrow set of issues and is limited to no more than two focused topics. The FDA aims to conduct Type D meetings with companies within 50 calendar days after receipt of the meeting request.

About D-PLEX₁₀₀

D-PLEX₁₀₀, PolyPid’s lead product candidate, is 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 (Polymer-Lipid Encapsulation matrix) technology pairs with Active Pharmaceutical Ingredients, enabling a prolonged and continuous release of the broad-spectrum antibiotic doxycycline, resulting in high local concentration of the drug for a period of 30 days for the prevention of SSIs, with additional potential to prevent SSIs caused by antibiotic-resistant bacteria at the surgical site. D-PLEX₁₀₀ received Breakthrough Therapy Designation from the U.S. FDA for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX₁₀₀ also received three Qualified Infectious Disease Product (QIDP) designations, and three Fast Track designations for the prevention of SSIs in patients undergoing elective colorectal surgery, 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, prolonged-release therapeutics, PolyPid’s proprietary PLEX (Polymer-Lipid Encapsulation matrix) technology pairs with Active Pharmaceutical Ingredients (APIs), enabling precise delivery of drugs at optimal 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 soft tissue abdominal and sternal surgical site infections. In addition, the Company is currently in preclinical stages to test the efficacy of OncoPLEX for treatment of solid tumors, beginning with glioblastoma.

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 possible next steps for D-PLEX₁₀₀ for the prevention of abdominal colorectal SSIs and its high level of confidence in the potential of D-PLEX₁₀₀. 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 February 28, 2022. Forward-looking statements speak only as of the date the statements are made. The Company assumes no obligation to update forward-looking statements 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.

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