
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: November 2021 (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 the Registrant's press release issued on November 18, 2021, titled "PolyPid Announces 500th Patient Enrolled in SHIELD I Phase 3 Clinical Trial of D-PLEX₁₀₀ in Abdominal Surgery."

The first three paragraphs and the section titled "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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 November 18, 2021, titled "PolyPid Ltd. Announces 500th Patient Enrolled in SHIELD I Phase 3 Clinical Trial of D-PLEX₁₀₀ in Abdominal Surgery."](#)

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.

Date: November 18, 2021

POLYPID LTD.

By: /s/ Dikla Czaczkes Akselbrad

Name Dikla Czaczkes Akselbrad

Title: Executive Vice President and
Chief Financial Officer

PolyPid Announces 500th Patient Enrolled in SHIELD I Phase 3 Clinical Trial of D-PLEX₁₀₀ in Abdominal Surgery

Company Continues to Expect that the Last Patient Will be Enrolled in the Second Quarter of 2022, Followed by Top-Line Results Two Months Thereafter

PETAH TIKVA, Israel, November 18, 2021 -- PolyPid Ltd. (Nasdaq: PYPD) (“PolyPid” or the “Company”), a phase 3 biopharmaceutical company focused on developing targeted, locally administered, and prolonged-release therapeutics to improve surgical outcomes, announced today that the 500th patient has been enrolled into its ongoing Phase 3 SHIELD I study. SHIELD I is a pivotal study evaluating D-PLEX₁₀₀ for the prevention of surgical site infections (SSIs) in abdominal surgery. The Company continues to expect that the completion of enrollment in SHIELD I will occur during the second quarter of 2022, with top-line results anticipated two months thereafter.

SHIELD I (Surgical site Hospital acquired Infection prEvention with Local D-PLEX) 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 in post-abdominal surgery. The trial will continue with patient enrollment, toward approximately 900 patients, in about 60 centers across the United States, Europe and Israel. A blinded review of the overall event rates will commence once the 500th patient completes the 30-day follow-up and is evaluated for the primary endpoint.

Provided the study results are adequate, the U.S. Food and Drug Administration (FDA) has previously agreed that a single pivotal Phase 3 study is sufficient for potential approval of D-PLEX₁₀₀ for the prevention of SSIs in colorectal surgery.

“Remaining as one of the most frequent complications following abdominal surgery, SSIs often result in significant morbidity, and continue to create substantial healthcare costs,” stated Amir Weisberg, PolyPid’s Chief Executive Officer. “Consistent with our mission of improving surgical outcomes, we are thrilled by the ongoing pace of enrollment in the SHIELD I trial and expect that this study will generate important insights surrounding both the medical and health economic benefits of D-PLEX₁₀₀.”

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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 phase 3 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 the expectation that SHIELD I trial will generate important insights surrounding both the medical and health economic benefits of D-PLEX₁₀₀, the pace of enrollment in the SHIELD I trial, the timing of last-patient-in and 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 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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