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 2022 (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 PolyPid Ltd.'s (the "Registrant") press release issued on May 23, 2022, titled "PolyPid Announces Recommendation by Data Safety Monitoring Board to Conclude Enrollment of Phase 3 SHIELD I Trial of D-PLEX$_{100}$ at the Minimum Number of Patients Targeted Following Unblinded Interim Efficacy Analysis."

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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 May 23, 2022, titled "PolyPid Announces Recommendation by Data Safety Monitoring Board to Conclude Enrollment of Phase 3 SHIELD I Trial of D-PLEX$_{100}$ at the Minimum Number of Patients Targeted Following Unblinded Interim Efficacy Analysis."

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 23, 2022

By: /s/ Dikla Czaczkes Akselbrad

Name Dikla Czaczkes Akselbrad
Title: Executive Vice President and Chief Financial Officer

Exhibit 99.1

PolyPid Announces Recommendation by Data Safety Monitoring Board to Conclude Enrollment of Phase 3 SHIELD I Trial of D-PLEX$_{100}$ at the Minimum Number of Patients Targeted Following Unblinded Interim Efficacy Analysis

● *Enrollment of 950 Patients, the Minimum Number of Patients Targeted for the SHIELD I Study, Expected Within Days*

● *Top-line Results Expected by End of Q3 2022; Potential NDA and MAA Submissions Targeted for H1 2023*

● *Conference Call Scheduled for Today at 8:30 a.m. ET*

PETACH TIKVA, Israel, May 23, 2022 -- PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a late-stage biopharma company aiming to improve surgical outcomes, announced today that following the independent Data Safety Monitoring Board (DSMB) review of unblinded efficacy data from the first 750 enrolled patients in the SHIELD I Phase 3 study of D-PLEX$_{100}$ for the prevention of surgical site infections (SSIs) in abdominal tissue surgery, the recommendation was to conclude the study upon enrollment of 950 patients, which is the minimum number of targeted patients in the study protocol. The enrollment of the 950th patient is expected to occur within days.

The SHIELD I study is designed to demonstrate at least a 50 percent reduction in incisional SSIs in the D-PLEX$_{100}$ treatment arm compared to the control arm, with 90 percent power and a maximum alpha level of 0.04.

The Company anticipates reporting top-line results by the end of the third quarter of 2022, followed by a potential New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) and a European Union Marketing Authorization Application (MAA) filing, both targeted for the first half of 2023.

"We are pleased with the DSMB recommendation and expect to conclude the SHIELD I trial shortly," stated Amir Weisberg, PolyPid's CEO. "SSIs represent a major unmet medical need and a large commercial opportunity for D-PLEX$_{100}$. We look forward to completing the SHIELD I study and advancing preparations for our planned NDA submission and pre-launch activities, while expediting partnership discussions in and outside of the United States."

"D-PLEX$_{100}$, if approved, could significantly alter the surgical landscape, where postoperative infections remain a costly problem," stated Dr. Kyle Cologne, Associate Professor of Colorectal Surgery, University of Southern California, who serves as an advisor to PolyPid. "SSIs are among the most prevalent complications following surgery, occurring in 6-26 percent of patients undergoing abdominal surgeries, particularly after open colorectal resection. Currently, the lack of effective infection prevention methods exposes patients to higher risk. When they occur, SSIs lead to hospital readmission, increased resource utilization and cost the U.S. healthcare system nearly $10 billion annually. The opportunity to make significant inroads to reduce these numbers is an exciting possibility with D-PLEX$_{100}$."

Conference Call Dial-In & Webcast Information:

Date: Monday, May 23, 2022
Time: 8:30 AM Eastern Time
United States: +1 877-870-9135
Israel: +972 1809 213-985
International: +44 (0) 2071 928338
Conference ID: 4857305
Webcast: https://edge.media-server.com/mmc/p/84mxrrtd

About SHIELD I

SHIELD I (Surgical site **H**ospital acquired **I**nfection pr**E**vention with **L**ocal **D**-PLEX) is a prospective, multinational, randomized, double blind Phase 3 trial designed to assess the efficacy and safety of D-PLEX100 administered concomitantly with standard of care (SoC), which includes prophylactic systemic antibiotics, compared to a SoC alone arm, in prevention of post abdominal surgery incisional infection. 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 SSIs event, as determined by a blinded and independent adjudication committee, or mortality for any reason within 30 days post-surgery. The trial has enrolled patients in more than 60 centers in the United States, Europe and Israel.

About D-PLEX$_{100}$

D-PLEX$_{100,}$ 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-PLEX$_{100}$ 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 four weeks for the prevention of SSIs, with additional potential to prevent SSIs caused by antibiotic-resistant bacteria at the surgical site. D-PLEX$_{100}$ received Breakthrough Therapy Designation from the U.S. FDA for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX$_{100}$ 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, enabling precise delivery of drugs at optimal release rates over durations ranging from several days to months. PolyPid's lead product candidate D-PLEX$_{100}$ is in Phase 3 clinical trials for the prevention of soft tissue abdominal and sternal bone 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 that the enrollment of the 950th patient is expected to occur within days, the Company's anticipation to report top-line results by the end of the third quarter of 2022, followed by potential NDA submission to FDA and a European Union MAA filing targeted for the first half of 2023, expedition of partnership discussions in and outside of the United States, that D-PLEX$_{100}$, if approved, could significantly alter the surgical landscape, that the opportunity to make significant inroads to reduce these numbers is an exciting possibility with D-PLEX$_{100}$ and the potential for D-PLEX$_{100}$ to reduce hospital readmissions, resource utilization and costs. 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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