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: January 2023 (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

CONTENTS

Attached hereto and incorporated herein is PolyPid Ltd.'s (the "Registrant") press release issued on January 24, 2023, titled "PolyPid Provides Positive Regulatory Update for D-PLEX100 for the Prevention of Surgical Site Infections in Abdominal Colorectal Surgery."

The first two 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 January 24, 2023, titled "PolyPid Provides Positive Regulatory Update for D-PLEX100 for the Prevention of Surgical Site Infections in Abdominal Colorectal 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.

POLYPID LTD.

Date: January 24, 2023

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

Exhibit 99.1

PolyPid Provides Positive Regulatory Update for D-PLEX$_{100}$ for the Prevention of Surgical Site Infections in Abdominal Colorectal Surgery

● *Regulatory Pathway for a Potential NDA Submission Clarified Following Recent Interactions with the FDA*

● *FDA Acknowledged that SHIELD I Pre-specified Subgroup Results May Provide Supportive Evidence and Proposed that Current SHIELD II Trial Could Potentially Serve to Complete Clinical Testing for NDA*

● *FDA Also Recognized that D-PLEX$_{100}$'s Proposed Indication is for the Prevention of Infection and Has the Potential for Wide Use*

PETACH TIKVA, Israel, January 24, 2023 -- PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a late-stage biopharma company aiming to improve surgical outcomes, today provided a positive regulatory update for D-PLEX$_{100}$ for the prevention of abdominal colorectal surgical site infections (SSIs). Following a recent type D meeting communication with the U.S. Food and Drug Administration (FDA) on the SHIELD I Phase 3 data, the Company now has clarity regarding the regulatory pathway toward a potential New Drug Application (NDA) submission.

PolyPid provided to the FDA currently available data from the SHIELD I study evaluating D-PLEX$_{100}$ for the prevention of abdominal colorectal SSIs. Based on the data, particularly the 54% reduction observed in the primary endpoint in complex surgeries in a pre-specified subgroup analysis of patients with large incisions (>20 cm) (p=0.0032, n=423) compared to standard of care, the FDA acknowledged that the SHIELD I results may provide supportive evidence on this population and recommended that the Company conduct an additional study to support a potential NDA submission. The FDA stated that the ongoing SHIELD II study, which to date has enrolled over 200 patients, could potentially serve as such a study. PolyPid is now working expeditiously to finalize the design of the revised SHIELD II trial and expects to resume patient recruitment next quarter.

"We are pleased with the outcome of our recent interactions with the FDA and are grateful to the Agency for their supportive feedback," stated Ms. Dikla Czaczkes Akselbrad, PolyPid's Chief Executive Officer. "We now have a clear regulatory pathway for the possible approval of D-PLEX$_{100}$ in United States, and we remain highly confident in the potential of our promising late-stage product candidate. We are focused on evaluating the most appropriate measures to implement the FDA's recommendations and are also preparing for near-term interactions with the EU regulatory authorities regarding D-PLEX$_{100}$. We look forward to providing further clinical and regulatory updates on both U.S. and European markets."

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 30 days 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 (APIs), 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 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 ongoing SHIELD II study could potentially serve as a study to support a potential NDA submission, that the Company is now working expeditiously to finalize the design of the revised SHIELD II trial and expects to resume patient recruitment next quarter, its confidence in the potential of its promising late-stage product candidate, the Company's focus on evaluating the most appropriate measures to implement the FDA's recommendations and its preparations for the near-term interactions with the EU regulatory authorities regarding D-PLEX$_{100}$. 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.

Contacts:

PolyPid Ltd.
Ori Warshavsky
COO – US
908-858-5995
IR@Polypid.com

Investors:

Brian Ritchie
LifeSci Advisors
212-915-2578
britchie@lifesciadvisors.com