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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: September 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):

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## CONTENTS

Attached hereto and incorporated herein is PolyPid Ltd.'s (the "Registrant") press release issued on September 28, 2022, titled "PolyPid Announces Eligibility for European Medicines Agency Centralized Procedure for D-PLEX<sub>100</sub> for the Prevention of Surgical Site Infections in Abdominal Surgery."

The first and second 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 September 28, 2022, titled “PolyPid Announces Eligibility for European Medicines Agency Centralized Procedure for D-PLEX<sub>100</sub> for the Prevention of Surgical Site Infections 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.

**POLYPID LTD.**

Date: September 28, 2022

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

## **PolyPid Announces Eligibility for European Medicines Agency Centralized Procedure for D-PLEX<sub>100</sub> for the Prevention of Surgical Site Infections in Abdominal Surgery**

*Centralized Procedure Allows for Submission of a Single Marketing Application to the European Medicines Agency that, if Approved, Would Allow D-PLEX<sub>100</sub> to be Marketed in All EU Member States*

*D-PLEX<sub>100</sub> is Eligible for Centralized Procedure Under the Therapeutic Innovation Criteria*

**PETACH TIKVA, Israel, September 28, 2022** -- PolyPid Ltd. (Nasdaq: PYPD) (“PolyPid” or the “Company”), a late-stage biopharma company aiming to improve surgical outcomes, today announced that it has received confirmation from the European Medicines Agency (EMA) that D-PLEX<sub>100</sub> is eligible for submission of a Marketing Authorization Application (MAA) in the European Union (EU) under the Agency’s centralized procedure.

The centralized procedure allows the submission of a single marketing application to the EMA that, if approved, enables the product to be marketed in all EU member states as well as in Iceland, Liechtenstein and Norway. The centralized process eligibility is granted to D-PLEX<sub>100</sub> under the Therapeutic Innovation criteria which underscores that D-PLEX<sub>100</sub> provides a new alternative to patients in preventing post abdominal surgical site infections (SSIs).

“We view the EMA’s decision to deem D-PLEX<sub>100</sub> eligible for a centralized regulatory review under the Therapeutic Innovation category as reflective of the potential innovation behind our lead product candidate,” said Dikla Czaczkes Akselbrad, PolyPid’s Chief Executive Officer. “This decision by the EMA allows us to potentially pursue registration of D-PLEX<sub>100</sub> through the more efficient centralized review process. We are currently further evaluating the top-line results of SHIELD I, our recently concluded Phase 3 trial for D-PLEX<sub>100</sub> for the prevention of surgical site infections (SSIs) in abdominal surgery, and intend to discuss these data and potential next steps with U.S. and EU regulatory authorities in the first quarter of 2023”.

### **About D-PLEX<sub>100</sub>**

D-PLEX<sub>100</sub>, 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<sub>100</sub> 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<sub>100</sub> received Breakthrough Therapy Designation from the U.S. FDA for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX<sub>100</sub> 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<sub>100</sub> 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.

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## **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, the potential innovation behind its lead product candidate, that the decision by the EMA allows the Company to potentially pursue registration of D-PLEX<sub>100</sub> through the more efficient centralized review process and its intention to discuss the top-line results of SHIELD I and potential next steps with U.S. and EU regulatory authorities in the first quarter of 2023. 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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