
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: August 2020

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 August 3, 2020, titled "PolyPid granted Fast Track Designation from FDA for D-PLEX₁₀₀ for Prevention of Surgical Site Infections in Abdominal Surgery."

The first two paragraphs and the section titled "Forward-Looking Statements" in the press release are incorporated by reference into the Registrant's Registration Statement on Form S-8 (Registration 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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	Description
99.1	Press Release issued by PolyPid Ltd. on August 3, 2020, titled "PolyPid granted Fast Track Designation from FDA for D-PLEX₁₀₀ for 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: August 3, 2020

By: /s/ Dikla Czaczkes Akselbrad

Name Dikla Czaczkes Akselbrad

Title: Executive Vice President and
Chief Financial Officer



POLYPID

OPTIMIZED THERAPEUTICS

PolyPid granted Fast Track Designation from FDA for D-PLEX₁₀₀
for Prevention of Surgical Site Infections in Abdominal Surgery

PETAH TIKVA, Israel, August 3, 2020 – PolyPid Ltd. (Nasdaq: PYPD), a Phase 3 clinical-stage biopharmaceutical company focused on developing targeted, locally administered and prolonged-release therapeutics using its proprietary PLEX technology, today announced that D-PLEX₁₀₀ has received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for the prevention of post abdominal surgery incisional infections.

The FDA's Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious and life threatening conditions and fill an unmet medical need. Fast Track designation allows for early and frequent communication with the FDA throughout the entire drug development and review process, and allows for a rolling review of a D-PLEX₁₀₀'s New Drug Application ("NDA"). It also enables eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.

"Receiving Fast Track designation from the FDA represents an important achievement for our promising D-PLEX₁₀₀ development program," said Amir Weisberg, PolyPid's CEO. "We view the Fast Track designation as important regulatory validation of the novelty of our PLEX technology and the high clinical unmet need that currently exists in the ability to prevent surgical site infections in complex surgical settings such as abdominal surgeries. We recently initiated our SHIELD I Phase 3 clinical trial of D-PLEX₁₀₀ for the prevention of post-abdominal surgery incisional infections, and look forward to the opportunity to provide a safe and effective solution for surgeons and their patients as quickly as possible."

About D-PLEX₁₀₀

PolyPid's lead product candidate, D-PLEX₁₀₀, is a novel product candidate designed to provide local prolonged 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 up to four weeks for the prevention of SSIs, with additional potential to treat antibiotic-resistant bacteria at the surgical site. D-PLEX₁₀₀ has received two Qualified Infectious Disease Product (QIDP) designations from the FDA for the prevention of sternal wound infection post-cardiac surgery and for the prevention of post-abdominal surgery incisional infection.



POLYPID

OPTIMIZED THERAPEUTICS

About PolyPid

PolyPid is a Phase 3 clinical-stage biopharmaceutical company focused on developing targeted, locally administered and prolonged-release therapeutics using its proprietary PLEX (Polymer-Lipid Encapsulation matrix) technology. PolyPid's product candidates are designed to address diseases with high unmet medical needs by pairing PLEX with drugs to deliver them directly to precise sites in the body at predetermined release rates and over durations ranging from several days to several months. PolyPid's lead product candidate, D-PLEX₁₀₀, is in Phase 3 clinical trials for the prevention of sternal SSIs and abdominal SSIs. PolyPid's technology and products are based on the inventions of Dr. Noam Emanuel, the Founder and the Chief Scientific Officer of the company.

For additional company information, visit www.polypid.com.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other Federal 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, PolyPid is using forward-looking statements in this press release when it discusses the potential of D-PLEX₁₀₀ to prevent SSIs, timing, subject matter and frequency of communications with the FDA, whether D-PLEX₁₀₀ will be eligible for rolling review of its NDA and/or priority review with the FDA, and providing a safe and effective solution for surgeons and their patients as quickly as possible. Because such statements deal with future events and are based on PolyPid's current expectations, they are subject to various risks and uncertainties. Also, while PolyPid has received Fast Track Designation for D-PLEX₁₀₀ for the prevention of surgical site infections, it cannot guarantee that it will be able to maintain such designation due to reasons within our outside of its control. Actual results, performance or achievements of PolyPid could differ materially from those described in or implied by the statements in this press release. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in PolyPid's final prospectus dated June 25, 2020, filed pursuant to Rule 424(b)(4) with the Securities and Exchange Commission ("SEC"), and in any subsequent filings with the SEC. Except as otherwise required by law, PolyPid undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. 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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