
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 2024

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 May 8, 2024, titled "PolyPid Provides Corporate Update and Reports First Quarter 2024 Financial Results."

The bullet points under the section titled "Recent Corporate Highlights," the sections titled "Financial results for the three months ended March 31, 2024," "Balance Sheet Highlights," and "Forward-looking Statements" and the financial statements in the press release are incorporated by reference into the Registrant's registration statements on Form F-3 (File No. [333-257651](#) and File No. [333-276826](#)) and Form S-8 (File No. [333-239517](#), File No. [333-271060](#), and File No. [333-277703](#)), 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 8, 2024, titled "PolyPid Provides Corporate Update and Reports First Quarter 2024 Financial Results."](#)

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 8, 2024

By: /s/ Dikla Czaczkes Akselbrad

Name: Dikla Czaczkes Akselbrad

Title: Chief Executive Officer

PolyPid Provides Corporate Update and Reports First Quarter 2024 Financial Results

More Than 200 Patients Enrolled in Ongoing SHIELD II Phase 3 Trial of D-PLEX₁₀₀ for the Prevention of Abdominal Colorectal Surgical Site Infections

Approximately 50 Centers Currently Open

Unblinded Interim Analysis to be Conducted Once Approximately 400 Patients Complete Their 30-Day Follow-up; Top-line Results Expected in Second Half of 2024

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, May 8, 2024 -- PolyPid Ltd. (Nasdaq: PYPD) (“PolyPid” or the “Company”), a late-stage biopharma company aiming to improve surgical outcomes, today provided a corporate update and reported financial results for the three months ended March 31, 2024.

Recent Corporate Highlights:

- More than 200 patients have been enrolled to date in the ongoing SHIELD II Phase 3 trial that is recruiting patients undergoing colorectal abdominal surgery with large incisions.
 - Approximately 50 centers are currently open in multiple countries, including the U.S., Germany, Italy, Ireland, Portugal, Hungary and Israel.
 - Unblinded interim analysis is planned to be conducted once approximately 400 patients complete their 30-day follow up, which is expected to occur in mid-2024.
 - Top-line results are anticipated in the second half of 2024.
 - To date, the median age, male/female split and percentage of enrolled cancer patients in SHIELD II are similar to the patient population in the SHIELD I large incision pre-specified subgroup. Observing similar demographics between the two studies in this more focused patient population in which D-PLEX₁₀₀ has already generated highly positive data in SHIELD I could be an important de-risking factor for SHIELD II.
- Closed a private placement financing (“PIPE”) for \$16 million of gross proceeds. The Company’s cash runway now extends into the fourth quarter of 2024 and beyond the expected timing of the planned unblinded interim analysis.
 - PolyPid has the potential to secure an additional \$19 million if the results of the unblinded interim analysis are positive and all of the warrants issued in the PIPE are exercised, which would fund PolyPid to the start of a planned New Drug Application (“NDA”) submission for D-PLEX₁₀₀.

“We are excited about the substantial momentum throughout our business, most importantly as it relates to enrollment in our ongoing SHIELD II pivotal Phase 3 trial for D-PLEX₁₀₀,” stated Dikla Czaczkes Akselbrad, PolyPid’s Chief Executive Officer. “With more than 200 patients, the SHIELD II study is now more than half enrolled for the interim analysis, which is planned to be conducted in mid-2024. We expect to continue enrollment at a pace of 1.5 patients per recruiting center per month. There are approximately 50 centers currently open in multiple countries and approximately 10 more centers are anticipated to open over the next couple of months.”

Financial results for three months ended March 31, 2024

- Research and development (R&D) expenses for the three months ended March 31, 2024, were \$5.1 million, compared to \$3.8 million in the same three-month period of 2023. The increase in R&D expenses in the most recently completed quarter was driven by the ramp up of the ongoing SHIELD II Phase 3 trial.
- General and administrative (G&A) expenses for the three months ended March 31, 2024, were \$1.0 million, compared to \$1.6 million for the same period of 2023.
- Marketing and business development expenses for the three months ended March 31, 2024, were \$0.2 million, compared to \$0.4 million for the same period of 2023.
- For the three months ended March 31, 2024, the Company had a net loss of \$6.4 million, or (\$1.37) per diluted share, compared to a net loss of \$6.1 million, or (\$8.47) per diluted share, in the three-month period ended March 31, 2023.

Balance Sheet Highlights

- As of March 31, 2024, the Company had cash and cash equivalents and short-term deposits in the amount of \$14.5 million, compared to \$5.3 million on December 31, 2023. This includes the net proceeds of approximately \$15 million generated from the PIPE financing closed in January 2024. PolyPid expects that its pro forma cash balance will be sufficient to fund operations into the fourth quarter of 2024.

Conference Call Dial-In & Webcast Information:

Date: Wednesday, May 8, 2024
Time: 8:30 AM Eastern Time
Q&A Participants: <https://register.vevent.com/register/BI6c0218de1fe64ed5b4d221783eb70bba>
Webcast: <https://edge.media-server.com/mmc/p/34fyspqn>

About SHIELD II

SHIELD II (Surgical site Hospital acquired Infection prEvention with Local 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 SoC alone arm, in the prevention of post abdominal-surgery incisional infection in patients undergoing abdominal colorectal surgeries with large incisions. The primary endpoint of the trial is measured by the proportion of subjects with either a surgical site infection (“SSI”) event as determined by a blinded and independent adjudication committee, reintervention, or mortality for any reason within 30 days post-surgery. Patient safety will be monitored for an additional 30 days. The trial will enroll patients in centers in the United States, Europe and Israel.

About D-PLEX₁₀₀

D-PLEX₁₀₀, 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-PLEX₁₀₀ 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 a 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-PLEX₁₀₀ received Breakthrough Therapy Designation from the U.S. Food and Drug Administration for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX₁₀₀ is currently in Phase 3 SHIELD II trial for the prevention of surgical site infections in patients undergoing abdominal colorectal surgery with large incisions.

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-PLEX₁₀₀ is in Phase 3 clinical trial for the prevention of abdominal colorectal surgical site infections. In addition, the Company is currently in preclinical stages to test the efficacy of OncoPLEX for the 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 the expected timing for top-line results from the SHIELD II trial and of the unblinded interim analysis, that observing similar demographics between SHIELD I and SHIELD II in large incision pre-specified subgroup could be an important de-risking factor for SHIELD II, the expected enrollment pace, the expectation to add approximately 10 more centers over the next couple of months, the planned NDA submission for D-PLEX₁₀₀, the Company's expected cash runway and the potential to receive additional funds if the results of the unblinded interim analysis are positive and all of the warrants issued through the PIPE are exercised. 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, including, but not limited to, the risks detailed in the Company's Annual Report on Form 20-F filed on March 6, 2024. 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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CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	March 31, 2024	December 31, 2023
	(Unaudited)	(Audited)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 3,844	\$ 5,309
Restricted cash	166	300
Short-term deposits	10,612	-
Prepaid expenses and other current assets	471	458
Total current assets	15,093	6,067
LONG-TERM ASSETS:		
Property and equipment, net	7,201	7,621
Operating lease right-of-use assets	2,883	1,597
Other long-term assets	218	87
Total long-term assets	10,302	9,305
Total assets	\$ 25,395	\$ 15,372

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share and per share data)

	March 31, 2024	December 31, 2023
	(Unaudited)	(Audited)
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Current maturities of long-term debt	\$ 4,436	\$ 4,003
Accrued expenses and other current liabilities	2,609	1,971
Trade payables	1,288	772
Current maturities of operating lease liabilities	862	540
Total current liabilities	9,195	7,286
LONG-TERM LIABILITIES:		
Long-term debt	4,288	6,379
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	1,816	857
Other liabilities	403	398
Total long-term liabilities	9,055	10,182
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY (DEFICIT):		
Ordinary shares, no par value *) - Authorized: 107,800,000 shares at March 31, 2024 (Unaudited) and December 31, 2023; Issued and outstanding: 4,797,252 and 1,653,559 shares at March 31, 2024 (Unaudited) and December 31, 2023, respectively	-	-
Additional paid-in capital	251,902	236,213
Accumulated deficit	(244,757)	(238,309)
Total shareholders' equity (deficit)	7,145	(2,096)
Total liabilities and shareholders' equity (deficit)	\$ 25,395	\$ 15,372

*) Prior period results have been retroactively adjusted to reflect the 1-for-30 reverse share split affected on September 18, 2023.

CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands (except share and per share data)

	Three Months Ended March 31,	
	2024 (Unaudited)	2023 (Unaudited)
Operating expenses:		
Research and development, net	\$ 5,050	\$ 3,794
Marketing and business development expenses	236	385
General and administrative	1,015	1,609
Operating loss	6,301	5,788
Financial expense, net	140	255
Loss before income tax	6,441	6,043
Income tax expense	7	25
Net loss	\$ 6,448	\$ 6,068
Basic and Diluted loss per Ordinary share *)	\$ 1.37	\$ 8.47
Weighted average number of Ordinary shares used in computing basic and diluted loss per share *)	4,691,445	716,555

*) Prior period results have been retroactively adjusted to reflect the 1-for-30 reverse share split affected on September 18, 2023.