
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 2024 (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 August 14, 2024, titled "PolyPid Provides Corporate Update and Reports Second Quarter 2024 Financial Results."

The bullet points under the section titled "Recent Corporate Highlights," the sections titled "Financial results for the three months ended June 30, 2024," "Financial results for the six months ended June 30, 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. [333-276826](#) and File No. [333-280658](#)) and Form S-8 (File No. [333-239517](#), File No. [333-271060](#), File No. [333-277703](#) and File No. [333-280662](#)) 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and Exchange Commission to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 August 14, 2024, titled "PolyPid Provides Corporate Update and Reports Second 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: August 14, 2024

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

PolyPid Provides Corporate Update and Reports Second Quarter 2024 Financial Results

Approximately 320 Patients Enrolled in Ongoing SHIELD II Phase 3 Trial of D-PLEX₁₀₀ for the Prevention of Abdominal Colorectal Surgical Site Infections

Unblinded Interim Analysis to be Conducted Once Approximately 400 Patients Complete Their 30-Day Follow-up, Which is Expected in Fourth Quarter of 2024; Top-Line Results Anticipated in First Quarter of 2025

Recent Successful Financing of Up to \$14 Million Extends Company's Cash Runway into Second Quarter of 2025, Beyond the Anticipated Timing for SHIELD II Top-line Results, Assuming Warrants are Fully Exercised

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, August 14, 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 and six months ended June 30, 2024.

Recent Corporate Highlights:

- Approximately 320 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.
 - Unblinded interim analysis is planned to be conducted once approximately 400 patients complete their 30-day follow-up, which is expected to occur in the fourth quarter of 2024.
 - Top-line results are anticipated in the first quarter of 2025.
 - Closed a private placement financing (“PIPE”) with existing and new investors for \$8.1 million of gross proceeds, which extends the Company’s cash runway into the first quarter of 2025, beyond expected interim analysis results and the completion of enrollment of approximately 600 patients in SHIELD II.
 - PolyPid has the potential to secure an additional \$6.1 million if the unblinded interim analysis of its SHIELD II Phase 3 trial of D-PLEX₁₀₀ results in either the stopping of the trial due to positive efficacy, or continuation to planned patient recruitment (up to 630 subjects). If all warrants issued in that financing are exercised, the Company would be funded beyond top-line results and into second quarter 2025.
 - In addition, the Company announced that it has restructured its existing secured loan agreement with Kreos Capital VI (Expert Fund) LP with over \$2 million of deferred repayments, which will be paid from April 2025 onwards, in line with the expected timing for the top-line results from the Company’s ongoing SHIELD II Phase 3 trial.
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- Hosted a Key Opinion Leader (“KOL”) event (link here) featuring Charles E. Edmiston, Ph.D., Emeritus Professor of Surgery, Division of Vascular Surgery, Medical College of Wisconsin, who discussed several key topics surrounding the prevention of Surgical Site Infections (“SSIs”). Key takeaways included:
 - The increase in SSIs to pre-COVID rates due to a rebound in elective surgeries conducted and the surgical environment normalizing to levels found prior to 2020.
 - Procedural and patient-related risk factors significantly heighten the risk of developing a SSI, and this increase in risk is compounded when patients have multiple risk factors.
 - Long-term cost to commercial payers of a single colorectal SSI event over a period of 24 months remain substantial, ranging from \$44,000 (superficial SSI) to \$64,000 (deep SSI), and the cost for Medicare ranging from \$20,000 to \$45,000, respectively.
- Promoted Ms. Dalit Hazan, Executive Vice President R&D, Clinical and Regulatory Affairs of the Company, to Deputy Chief Executive Officer, Executive Vice President R&D, Clinical and Regulatory Affairs.

“We are thrilled with the important clinical and operational progress recently achieved,” stated Dikla Czaczkes Akselbrad, PolyPid’s Chief Executive Officer. “With around 320 patients enrolled to date in SHIELD II, we look forward to the upcoming interim analysis and remain on track for the top-line data readout in the first quarter of next year. Moreover, in support of the further advancement of SHIELD II, we successfully completed a financing of up to \$14 million that included participation from multiple U.S. life sciences-focused investors,” continued Ms. Czaczkes Akselbrad.

Financial results for three months ended June 30, 2024

- Research and development (R&D) expenses for the three months ended June 30, 2024, were \$4.8 million, compared to \$4.0 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 June 30, 2024, were \$1.1 million, compared to \$1.5 million for the same period of 2023.
- Marketing and business development expenses for the three months ended June 30, 2024, were \$0.3 million, compared to \$0.4 million for the same period of 2023.
- The decreases in G&A and marketing and business development expenses were primarily due to the Company’s ongoing cost savings initiatives.
- For the three months ended June 30, 2024, the Company had a net loss of \$6.3 million, or (\$1.25) per share, compared to a net loss of \$5.8 million, or (\$3.95) per share, in the three-month period ended June 30, 2023.

Financial results for six months ended June 30, 2024

- R&D expenses, net for the six months ended June 30, 2024, were \$9.8 million, compared to \$7.8 million for the same six-month period of 2023. The increase in R&D expenses was driven by the ramp up of the ongoing SHIELD II Phase 3 trial.
- G&A expenses for the six months ended June 30, 2024, were \$2.1 million, compared to \$3.1 million for the same period of 2023.
- Marketing and business development expenses for the six months ended June 30, 2024, were \$0.5 million, compared to \$0.7 million for the same period of 2023.
- The decreases in G&A and marketing and business development expenses were primarily due to the Company's ongoing cost savings initiatives.
- For the six months ended June 30, 2024, the Company had a net loss of \$12.7 million, or (\$2.62) per share, compared to a net loss of \$11.9 million, or (\$10.85) per share, in the six-month period ended June 30, 2023.

Balance Sheet Highlights

- As of June 30, 2024, the Company had cash and cash equivalents and short-term deposits in the amount of \$9.3 million, compared to \$5.3 million on December 31, 2023. This does not include the gross proceeds of approximately \$8.1 million generated from the PIPE financing which closed in August 2024. PolyPid expects that its pro forma cash balance will be sufficient to fund operations into the first quarter of 2025 (not including a potential additional \$6.1 million if all warrants from the recent financing are exercised).

Conference Call Dial-In & Webcast Information:

Date:	Wednesday, August 14, 2024
Time:	8:30 AM Eastern Time
Q&A Participants:	https://register.vevent.com/register/BI016c6fe17c794f8ea594d9e8bfca69f4
Webcast:	https://edge.media-server.com/mmc/p/hcwb4pob

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, and the Company's expected cash runway and the potential to secure additional funds if 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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INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	June 30, 2024	December 31, 2023
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 3,076	\$ 5,309
Restricted deposits	163	300
Short-term deposits	6,271	-
Prepaid expenses and other current assets	268	458
Total current assets	9,778	6,067
LONG-TERM ASSETS:		
Property and equipment, net	6,813	7,621
Operating lease right-of-use assets	2,679	1,597
Other long-term assets	257	87
Total long-term assets	9,749	9,305
Total assets	\$ 19,527	\$ 15,372

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	June 30, 2024	December 31, 2023
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Current maturities of long-term debt	\$ 5,437	\$ 4,003
Accrued expenses and other current liabilities	2,984	1,971
Trade payables	992	772
Current maturities of operating lease liabilities	873	540
Total current liabilities	<u>10,286</u>	<u>7,286</u>
LONG-TERM LIABILITIES:		
Long-term debt	3,127	6,379
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	1,594	857
Other liabilities	371	398
Total long-term liabilities	<u>7,640</u>	<u>10,182</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY (DEFICIT):		
Ordinary shares with no par value - Authorized: 107,800,000 shares at June 30, 2024 (unaudited) and December 31, 2023; Issued and outstanding: 4,797,252 and 1,653,559 shares at June 30, 2024 (unaudited) and December 31, 2023, respectively	-	-
Additional paid-in capital	252,652	236,213
Accumulated deficit	<u>(251,051)</u>	<u>(238,309)</u>
Total shareholders' equity (deficit)	<u>1,601</u>	<u>(2,096)</u>
Total liabilities and shareholders' equity	<u><u>19,527</u></u>	<u><u>15,372</u></u>

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Six Months Ended June 30,		Three Months Ended June 30,	
	2024	2023	2024	2023
<i>Operating expenses:</i>				
Research and development, net	\$ 9,810	\$ 7,754	\$ 4,760	\$ 3,960
Marketing and business development	501	742	265	357
General and administrative	2,111	3,112	1,096	1,503
Operating loss	12,422	11,608	6,121	5,820
Financial expense, net	311	262	171	7
Loss before income tax	12,733	11,870	6,292	5,827
Income tax expenses	9	35	2	10
Net loss	\$ 12,742	\$ 11,905	\$ 6,294	\$ 5,837
Basic and diluted loss per ordinary share *)	\$ 2.62	\$ 10.85	\$ 1.25	\$ 3.95
Weighted average number of ordinary shares used in computing basic and diluted loss per share *)	4,858,158	1,097,015	5,024,871	1,479,449

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