
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 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):

CONTENTS

Attached hereto and incorporated herein is PolyPid Ltd.'s (the "Registrant") press release issued on May 11, 2022, titled "PolyPid Provides Corporate Update and Reports First Quarter 2022 Financial Results."

The first paragraph, the bullet points under the section titled "Recent Corporate Highlights," the sections titled "Financial results for three months ended March 31, 2022," "Balance Sheet Highlights," and "Forward-looking Statements," and the GAAP 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 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 May 11, 2022, titled "PolyPid Provides Corporate Update and Reports First Quarter 2022 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 11, 2022

By: /s/ Dikla Czaczkes Akselbrad
Name: Dikla Czaczkes Akselbrad
Title: Executive Vice President and
Chief Financial Officer

PolyPid Provides Corporate Update and Reports First Quarter 2022 Financial Results

- *Planned Unblinded Interim Analysis of Phase 3 SHIELD I Trial of D-PLEX₁₀₀ in Abdominal Soft Tissue Surgery Expected to Occur Imminently*
- *Recruitment Progressing as Planned with Approximately 900 Patients Enrolled into Phase 3 SHIELD I Trial of D-PLEX₁₀₀ in Abdominal Soft Tissue Surgery*
 - *Extended Cash Runway into the Second Quarter of 2023 with \$15 million Non-Dilutive Secured Term Loan Facility*
 - *Strengthened Executive Management Team*
 - *Conference Call Scheduled for Today at 8:30 AM ET*

PETACH TIKVA, Israel, May 11, 2022 -- 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, 2022.

Recent Corporate Highlights:

- Unblinded interim analysis of SHIELD I (Surgical site Hospital acquired Infection prEvention with Local D-PLEX) study evaluating D-PLEX₁₀₀ for the prevention of abdominal soft tissue surgical site infections (SSIs) expected to occur imminently. Once 750 patients complete their 30-day follow-up and statistical analysis is finalized, the results will allow for early trial stoppage due to efficacy, futility, or for sample size reassessment.
 - Recruitment progressing as planned with approximately 900 patients enrolled into the ongoing Phase 3 SHIELD I study.
 - Obtained a non-dilutive secured term loan facility for up to \$15 million from Kreos Capital VI (Expert Fund) LP (“Kreos”) that broadens financing options and provides access to significant additional capital, which bolsters the Company’s ability to invest in commercial capabilities for D-PLEX₁₀₀, as well as its development activities utilizing its promising PLEX technology platform. The first \$10 million of the facility was drawn in April 2022.
 - Strengthened the executive management team with the recent appointment of Evgeny Valdman as PolyPid’s new Executive Vice President of Operations and the promotion of Dalit Hazan to Executive Vice President, Research & Development, and Clinical & Regulatory Affairs. Evgeny brings to PolyPid more than 25 years of experience in senior management positions at Teva Pharmaceuticals and other pharmaceutical companies with approved products, with success at all levels of operations. Since 2016, Ms. Hazan has served in various leadership roles at PolyPid, most recently as PolyPid’s Senior Vice President, Research and Development and Regulatory Affairs.
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“We are thrilled with the significant momentum throughout all aspects of our business,” stated Amir Weisberg, PolyPid’s Chief Executive Officer. “We now have approximately 900 patients enrolled into SHIELD I, and we expect that the planned unblinded interim analysis in the study will occur very shortly, providing an exceptional opportunity for PolyPid to determine the patient enrollment target”.

“The appointment of Evgeny to oversee our technical operations and the promotion of Dalit to a senior role within our clinical development function further strengthens our commercial readiness and enhances our clinical development organization,” added Mr. Weisberg.

Dikla Czaczkes Akselbrad, Executive Vice President and Chief Financial Officer of PolyPid, stated, “The secured loan agreement we recently entered into for up to \$15 million will be used to support commercialization preparations for the launch of D-PLEX₁₀₀ for the prevention of abdominal soft tissue SSIs, as well as further advancement of our unique PLEX technology platform. Importantly, our cash runway now extends into the second quarter of 2023.”

Financial results for three months ended March 31, 2022

- Research and development, net (R&D) expenses for the three months ended March 31, 2022, were \$8.7 million, compared to \$6.0 million for the same three-month period of 2021, as spending increased primarily due to the expedited recruitment in SHIELD I Phase 3 clinical trial in abdominal surgery.
- General and administrative (G&A) expenses for the three months ended March 31, 2022, were \$2.5 million, compared to \$2.1 million for the same period of 2021.
- Marketing and business development expenses for the three months ended March 31, 2022, were \$0.8 million, compared to \$0.7 million for the same period of 2021.
- For the three months ended March 31, 2022, the Company had a loss of \$11.9 million, compared to a loss of \$8.7 million for the same three-month period ended March 31, 2021.

Balance Sheet Highlights

- As of March 31, 2022, the Company had cash and cash equivalents and deposits in the amount of \$23.6 million. PolyPid expects that its cash balance, together with the first tranche of \$10 million from the Kreos loan that was drawn in April 2022, will be sufficient to fund operations into the second quarter of 2023.

Conference Call Dial-In & Webcast Information:

Date: Wednesday, May 11, 2022
Time: 8:30 AM Eastern Time
United States: +1 877-870-9135
Israel: +972 1809 213-985
International: +44 (0) 2071 928338
Conference ID: 3450787
Webcast: <https://edge.media-server.com/mmc/p/djs2mjt6>

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 trials for the prevention of soft tissue abdominal and sternal bone surgical site infections. In addition, the Company is currently in preclinical stages to test the efficacy of OncoPLEX for treatment of solid tumors. 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 its ongoing clinical trials, its expectations regarding the unblinded interim analysis in SHIELD I and its timing, that interim analysis could allow for an early trial stopping, its expectation that the planned interim analysis will provide an exceptional opportunity to determine the patient enrollment target, the pace of enrollment in SHIELD I trial, its use of proceeds from the Kreos loan, commercialization preparations for the launch of D-PLEX₁₀₀ for the prevention of abdominal soft tissue SSIs, extension of the Company's cash runway into the second quarter of 2023 and its expectation that its cash balance, together with the proceeds from the Kreos loan, will be sufficient to fund operations into the second 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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CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	March 31, 2022	December 31, 2021
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 11,434	\$ 9,819
Restricted cash	393	397
Short-term deposits	12,187	22,384
Prepaid expenses and other current assets	1,478	2,211
Total current assets	25,492	34,811
LONG-TERM ASSETS:		
Property and equipment, net	9,338	8,761
Other long-term assets	651	663
Total long-term assets	9,989	9,424
Total assets	\$ 35,481	\$ 44,235

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	March 31, 2022	December 31, 2021
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 3,214	\$ 4,136
Accrued expenses and other current liabilities	<u>3,227</u>	<u>3,940</u>
Total current liabilities	<u>6,441</u>	<u>8,076</u>
LONG-TERM LIABILITIES:		
Other liabilities	<u>195</u>	<u>199</u>
Total long-term liabilities	<u>195</u>	<u>199</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares with no par value - Authorized: 47,800,000 shares at March 31, 2022 (unaudited) and December 31, 2021; Issued and outstanding: 19,470,757 and 18,756,570 shares at March 31, 2022 (unaudited) and December 31, 2021, respectively	-	-
Additional paid-in capital	215,606	210,847
Accumulated deficit	<u>(186,761)</u>	<u>(174,887)</u>
Total shareholders' equity	<u>28,845</u>	<u>35,960</u>
Total liabilities and shareholders' equity	<u>\$ 35,481</u>	<u>\$ 44,235</u>

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended	
	March 31,	
	2022	2021
	Unaudited	
Operating expenses:		
Research and development, net	\$ 8,697	\$ 6,018
Marketing and business development	775	652
General and administrative	2,480	2,127
Operating loss	11,952	8,797
Financial income, net	78	110
Loss	\$ 11,874	\$ 8,687
Basic and diluted loss per Ordinary share	\$ 0.63	\$ 0.47
Weighted average number of Ordinary shares used in computing basic and diluted loss per share	18,936,457	18,623,154