

PolyPid Provides Corporate Update and Reports First Quarter 2025 Financial Results

PolyPid Successfully Completed Enrollment in Phase 3 SHIELD II Trial of D-PLEX₁₀₀, with Top-Line Results Anticipated in Current Quarter

Company Continues to Advance Regulatory Submission Preparations, Commercial Launch Preparations and Partnering Discussions

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, May 14, 2025 (GLOBE NEWSWIRE) — 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, 2025.

Recent Corporate Highlights:

- **Clinical Development:** Successfully completed enrollment of 800 patients in the SHIELD II Phase 3 trial of D-PLEX₁₀₀ for the prevention of abdominal colorectal surgical site infections. This major achievement follows the independent Data Safety Monitoring Board’s (“DSMB”) recommendation to conclude the study at the lowest sample size reassessment option, potentially suggestive of positive efficacy signals from D-PLEX₁₀₀.
- **Near-term Catalyst Timeline:** Top-line results from SHIELD II remain on track and expected to be announced by the end of the current quarter (the second quarter of 2025), representing a potentially transformative milestone for the Company.
- **Regulatory Pathway:** Following potential positive Phase 3 data, PolyPid plans to leverage its Fast Track and Breakthrough Therapy designations to submit a New Drug Application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) in early 2026, with a Marketing Authorization Application (“MAA”) in the EU to follow shortly thereafter. Key regulatory components, including Chemistry, Manufacturing, and Controls (“CMC”) and non-clinical modules, are being finalized to support this timeline.
- **Commercial Strategy:** The Company continues to advance its commercialization preparations while simultaneously advancing strategic partnership discussions and due diligence with multiple potential partners in the United States to maximize D-PLEX₁₀₀’s market potential.
- **Strong Financial Position:** Upon announcement of Phase 3 top-line data, warrants from the Company’s recent financing would be eligible for exercise, potentially generating an additional \$27.0 million in capital. The Company anticipates that with such additional funding, PolyPid’s runway would be extended beyond anticipated NDA approval.

“PolyPid is on track for a transformational year in 2025. We continue to view the SHIELD II Phase 3 trial as a derisked study. This assessment has been further strengthened by the 800-patient sample size reassessment which helps ensure the study has sufficient power to conclusively confirm D-PLEX₁₀₀’s treatment benefit and we believe this increases the trial’s overall probability of success,” stated Dikla Czaczkes Akselbrad, PolyPid’s Chief Executive Officer. “As we await the top-line results from SHIELD II later this quarter, we continue to advance our preparations for NDA and MAA submissions in 2026. Moreover, we continue to progress our commercial plans, as well as engage in partnership discussions with multiple potential partners in the United States.”

Financial results for three months ended March 31, 2025

- Research and development (“R&D”) expenses for the three months ended March 31, 2025, were \$6.1 million, compared to \$5.1 million in the same three-month period of 2024. 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, 2025, were \$1.2 million, compared to \$1.0 million for the same period of 2024.
- Marketing and business development expenses for the three months ended March 31, 2025, were \$0.3 million, compared to \$0.2 million for the same period of 2024.
- For the three months ended March 31, 2025, the Company had a net loss of \$8.3 million, or (\$0.70) per share, compared to a net loss of \$6.4 million, or (\$1.37) per share, in the three-month period ended March 31, 2024.

Balance Sheet Highlights

- As of March 31, 2025, the Company had cash and cash equivalents and short-term deposits in the amount of \$8.0 million, compared to \$15.6 million on December 31, 2024. PolyPid expects that its current cash balance will be sufficient to fund operations into the third quarter of 2025.

Conference Call Dial-In & Webcast Information:

Date: Wednesday, May 14, 2025

Time: 8:30 AM Eastern Time

Conference Call: <https://register-conf.media-server.com/register/B1326905131be34ceda978c4ff2ca7a54d>

Webcast: <https://edge.media-server.com/mmc/p/bqgwfbps>

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 potential efficacy and benefits of D-PLEX₁₀₀ and the probability of success of the trial, that the current cash balance will be sufficient to fund the operations into the third quarter of 2025, the expected timing for completion of enrollment of the SHIELD II trial, the expected timing for top-line results from the SHIELD II trial, potential NDA and MAA submissions and the timing thereof, finalization of CMC and non-clinical modules, potential clinical benefits of D-PLEX₁₀₀, the potential to receive up to an additional \$27.0 million from the exercise of the warrants from the recent financing, Company's anticipation that with such additional funding, PolyPid's runway would be extended beyond anticipated NDA approval, and the Company's potential strategic partnerships. 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 February 26, 2025. 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.

Contacts:

PolyPid Ltd.
Ori Warshavsky
COO - US
908-858-5995
IR@Polypid.com

Investors:

Brian Ritchie

LifeSci Advisors
212-915-2578
britchie@lifesciadvisors.com

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	March 31, 2025 Unaudited	December 31, 2024 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 2,272	\$ 15,641
Restricted deposits	165	168
Short-term deposits	5,767	-
Prepaid expenses and other current assets	568	764
<u>Total</u> current assets	8,772	16,573
LONG-TERM ASSETS:		
Property and equipment, net	5,705	6,075
Operating lease right-of-use assets	2,088	2,295
Other long-term assets	284	277
<u>Total</u> long-term assets	8,077	8,647
<u>Total</u> assets	\$ 16,849	\$ 25,220

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands (except share and per share data)

	March 31, 2025 Unaudited	December 31, 2024 Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 2,016	\$ 2,409
Accrued expenses and other current liabilities	2,967	2,566
Current maturities of long-term debt	6,498	6,787
Current maturities of operating lease liabilities	905	919
<u>Total</u> current liabilities	12,386	12,681
LONG-TERM LIABILITIES:		
Long-term debt	381	634
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	1,044	1,277
Other liabilities	404	396

<u>Total</u> long-term liabilities	4,377	4,855
SHAREHOLDERS' EQUITY:		
Ordinary shares with no par value -		
Authorized: 107,800,000 shares at March 31, 2025 (unaudited) and December 31, 2024; Issued and outstanding: 10,190,904 shares at March 31, 2025 (unaudited) and December 31, 2024, respectively	-	-
Additional paid-in capital	275,685	275,015
Accumulated deficit	(275,599)	(267,331)
<u>Total</u> shareholders' equity	86	7,684
<u>Total</u> liabilities and shareholders' equity	\$ 16,849	\$ 25,220

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended	
	March 31,	
	2025	2024
	Unaudited	
<i>Operating expenses:</i>		
Research and development	\$ 6,117	\$ 5,050
Marketing and business development	289	236
General and administrative	1,173	1,015
Operating loss	7,579	6,301
Financial expense, net	678	140
Loss before income tax	8,257	6,441
Income tax expense	11	7
Net loss	\$ 8,268	\$ 6,448
Basic and diluted loss per ordinary share	\$ 0.70	\$ 1.37
Weighted average number of ordinary shares used in computing basic and diluted loss per share	11,751,622	4,691,445

