

PolyPid Provides Corporate Update and Reports Fourth Quarter and Full-Year 2024 Financial Results

Positive Recommendation by DSMB to Continue Enrollment of Phase 3 SHIELD II Trial of D-PLEX to 800 Patients

SHIELD II Enrolled more than 700 Patients to Date; Enrollment Completion Expected in March 2025, with Top-Line Results Anticipated in Second Quarter of 2025

Company Completed Private Placement of Up to \$41 Million; Proceeds and Exercise of Data-Triggered Warrants Expected to Extend Cash Runway Beyond Potential NDA Approval

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, Feb. 12, 2025 — 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 and full year ended December 31, 2024.

Recent Corporate Highlights:

- The independent Data Safety Monitoring Board (“DSMB”) recommended to conclude the SHIELD II Phase 3 trial of D-PLEX₁₀₀ upon enrollment of 800 patients in the study, which is the lowest sample size reassessment stop after the minimum planned number of patients.
 - The study has enrolled more than 700 patients to date and enrollment of the last patient is expected to occur in March 2025.
 - The Company anticipates reporting top-line results in the second quarter of 2025.
 - Upon potential positive Phase 3 data, PolyPid expects to submit a New Drug Application (“NDA”) with the advantages of the Fast Track and Breakthrough Therapy designations.
- Concurrent with the DSMB’s positive recommendation, as previously reported, PolyPid entered into a securities purchase agreement for a private placement financing (“PIPE”) led by existing institutional shareholders for \$14.5 million in gross proceeds.
 - Under the securities purchase agreement, the investors also received warrants which will expire upon the earlier of nine months from the date of issuance and 10 trading days following PolyPid’s announcement of top-line results from its SHIELD II Phase 3 trial. Exercise of the warrants in full would result in an additional \$27.0 million in gross proceeds to the Company.
 - The gross proceeds from the financing extend PolyPid’s cash runway into the third quarter of 2025, beyond expected top-line results from SHIELD II.

- Proceeds of all warrants issued in this transaction, if exercised, would provide the Company with capital beyond NDA approval.
- Announced a research and development collaboration with ImmunoGenesis, Inc. which focuses on the development of novel formulations utilizing PolyPid's experience with its proprietary PLEX Technology and ImmunoGenesis' potent STimulator of INterferon Genes ("STING") agonist drug candidate to potentially enhance treatment for solid tumors.
- Appointed Mr. Yitzchak Jacobovitz, CFA, to the Board of Directors, effective as of February 10, 2025. Mr. Jacobovitz is a partner and lead healthcare analyst at AIGH Capital Management and affiliates. Mr. Jacobovitz is also a board member at Myomo, Inc. He earned his MBA from Johns Hopkins University and is a Chartered Financial Analyst.

"We are thrilled with the impressive clinical and operational progress achieved in 2024 and believe that we are well-positioned for a potentially transformational year in 2025," stated Dikla Czaczkes Akselbrad, PolyPid's Chief Executive Officer. "Importantly, we remain confident that the DSMB's recent recommendation to conclude SHIELD II upon the enrollment of 800 patients is suggestive of positive efficacy signals from D-PLEX₁₀₀. Moreover, the sample size reassessment was an opportunity to 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. We continue to focus on completing the trial, while advancing our planned NDA and Marketing Authorization Application ("MAA") submissions, preparing pre-launch activities, and expediting partnership discussions in and outside of the United States. We are also excited to welcome Mr. Jacobovitz to the Board of Directors and are pleased that AIGH was the lead investor in our most recent equity offering. Mr. Jacobovitz brings extensive healthcare investment experience to our board and we look forward to his contributions."

Financial results for three months ended December 31, 2024

- Research and development ("R&D") expenses for the three months ended December 31, 2024, were \$7.0 million, compared to \$4.6 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 December 31, 2024, were \$1.0 million, compared to \$1.2 million for the same period of 2023.
- Marketing and business development expenses for the three months ended December 31, 2024, were \$0.2 million, compared to \$0.2 million for the same period of 2023.
- For the three months ended December 31, 2024, the Company had a net loss of \$8.5 million, or (\$1.13) per share, compared to a net loss of \$6.4 million, or (\$3.97) per

share, in the three-month period ended December 31, 2023.

Financial results for the full year ended December 31, 2024

- R&D expenses, net for the twelve months ended December 31, 2024, were \$22.8 million, compared to \$16.1 million for the same twelve-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 twelve months ended December 31, 2024, were \$4.3 million, compared to \$5.5 million for the same period of 2023.
- Marketing and business development expenses for the twelve months ended December 31, 2024, were \$0.9 million, compared to \$1.2 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 twelve months ended December 31, 2024, the Company had a net loss of \$29.0 million, or (\$4.91) per diluted share, compared to a net loss of \$23.9 million, or (\$16.93) per diluted share, in the twelve-month period ended December 31, 2023.

Balance Sheet Highlights

- As of December 31, 2024, the Company had cash and cash equivalents in the amount of \$15.6 million, compared to \$5.3 million on December 31, 2023. 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, February 12, 2025
Time: 8:30 AM Eastern Time
Conference Call: <https://register.vevent.com/register/BI4e72dfffa5a7b4167a28a33a6b3097df3>
Webcast: <https://edge.media-server.com/mmc/p/7uzqoye3>

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, Fast Track and Qualified Infectious Disease Product (QIDP) Designations 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 completion of enrollment of the SHIELD II trial, expected timing for top-line results from the SHIELD II trial, potential NDA and MAA submissions, potential clinical benefits of D-PLEX₁₀₀, including safety and efficacy, and potential success of the trial, pre-launch activities and partnership discussions, that the gross proceeds from the financing extend the Company's

cash runway into the third quarter of 2025, that proceeds from the exercise of all warrants issued in the financing transaction would provide the Company with capital beyond NDA approval, that the Company is well-positioned for a potentially transformational year in 2025, the potential of the Company's collaboration with ImmunoGenesis to enhance treatment for solid tumors, and the expectation that the Company's current cash balance will be sufficient to fund operations into the third quarter of 2025. 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

	December 31,	
	2024	2023
	(Unaudited)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 15,641	\$ 5,309
Restricted deposits	168	300
Prepaid expenses and other current assets	764	458
<u>Total</u> current assets	16,573	6,067
LONG-TERM ASSETS:		
Property and equipment, net	6,075	7,621
Operating lease right-of-use assets	2,295	1,597
Other long-term assets	277	87
<u>Total</u> long-term assets	8,647	9,305
<u>Total</u> assets	\$ 25,220	\$ 15,372

CONSOLIDATED BALANCE SHEETS

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

	December 31,	
	2024	2023
	(Unaudited)	
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Trade payables	\$ 2,409	\$ 772
Accrued expenses and other current liabilities	2,566	1,971
Current maturities of long-term debt	6,787	4,003
Current maturities of operating lease liabilities	919	540
<u>Total</u> current liabilities	12,681	7,286
LONG-TERM LIABILITIES:		
Long-term debt	634	6,379
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	1,277	857
Other liabilities	396	398
<u>Total</u> long-term liabilities	4,855	10,182
COMMITMENTS AND CONTINGENT LIABILITIES (NOTE 8)		
SHAREHOLDERS' EQUITY (DEFICIT):		

Ordinary shares, no par value –

Authorized: 107,800,000 shares at December 31, 2024 and 2023, respectively; Issued and outstanding: 10,190,904 and 1,653,559 shares at December 31, 2024 and 2023, respectively

	–	–
Additional paid-in capital	275,015	236,213
Accumulated deficit	(267,331)	(238,309)
<u>Total</u> shareholders' equity (deficit)	7,684	(2,096)
<u>Total</u> liabilities and shareholders' equity (deficit)	\$ 25,220	\$ 15,372

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Year Ended December 31,		
	2024	2023	2022
	(Unaudited)		
<i>Operating expenses:</i>			
Research and development, net	\$ 22,811	\$ 16,148	\$ 27,990
Marketing and business development	945	1,196	2,888
General and administrative	4,273	5,523	8,010
Operating loss	28,029	22,867	38,888
Financial expense, net	951	929	540
Loss before income tax	28,980	23,796	39,428
Income tax expense	42	69	129
Net loss	\$ 29,022	\$ 23,865	\$ 39,557
<i>Loss per share *):</i>			
Basic	\$ 4.91	\$ 16.99	\$ 61.09
Diluted	\$ 4.91	\$ 16.93	\$ 61.09
<i>Weighted-average Ordinary shares outstanding *):</i>			
Basic	5,912,890	1,404,368	647,556
Diluted	5,912,890	1,421,308	647,556

*) Results for the year ended December 31, 2022, have been retroactively adjusted to reflect the 1-for-30 reverse share split affected on September 18, 2023.

