PolyPid Provides Corporate Update and Reports Third Quarter 2024 Financial Results

Last Patient Enrolled for Planned Unblinded Interim Analysis in Ongoing SHIELD II Phase 3 Trial of D-PLEX$_{100}$

Unblinded Interim Analysis Outcome Expected Later this Quarter

SHIELD II Enrollment Completion Expected in December 2024 with Top-Line Results Anticipated in First Quarter of 2025

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, Nov. 13, 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 nine months ended September 30, 2024.

Recent Corporate Highlights:

- Over 540 patients have been enrolled to date in the ongoing SHIELD II Phase 3 trial of D-PLEX$_{100}$ for the prevention of abdominal colorectal surgical site infections (SSIs).
  - Recently enrolled the last patient required (430 subjects) to conduct the planned unblinded interim analysis, which will occur during the current quarter, now that the 30-day follow-up assessment for the last patient has been completed. The unblinded interim analysis will lead to one of the following outcomes: early trial conclusion due to positive efficacy, continuation to planned patient recruitment (up to 630 subjects), sample size re-assessment, or futility.
  - Approximately 60 centers are currently open in multiple countries, including in Eastern Europe, the U.S., Germany, Ireland, Portugal and Israel.
  - Enrollment completion of up to 630 patients is expected in December 2024 and top-line results anticipated in the first quarter of 2025.
- Results from the Phase 3 SHIELD I trial, one of the largest Phase 3 studies in the prevention of SSIs in colorectal resection conducted in over a decade, were published in the *International Journal of Surgery*; manuscript available here. Key results:
  - A statistically significant reduction of the primary endpoint (a composite of incisional SSI, incisional reinterventions due to poor wound healing, or all-cause mortality) was observed in D-PLEX$_{100}$ treated patients in a pre-specified analysis of the subpopulation with large surgical incisions (greater than 20 cm; p=0.0032).
  - Analysis of the key secondary efficacy outcome, incisional SSI, also indicated a 54.6% reduction in the large surgical incision subgroup (4.4% in D-PLEX$_{100}$ vs. 9.7% in standard of care (SoC), p= 0.0410).

    - Based on the statistically significant reduction of the primary endpoint in the prespecified subgroup demonstrated in SHIELD I, and following the FDA guidance, the ongoing Phase 3 SHIELD II study focuses on patients with large surgical incisions.

“We are very encouraged by the recent significant acceleration in patient enrollment due to the opening of all 60 planned centers in the study and the increase in the volume of surgical procedures following the conclusion of the slower summer months,” stated Dikla Czaczkes Akselbrad, PolyPid’s Chief Executive Officer. “With more than 540 patients enrolled to date in SHIELD II, we look forward to the upcoming interim analysis later this quarter. Importantly, we are funded beyond this key data catalyst and, if all the warrants issued in both of our most recent private placement financings are exercised, we would be funded into 2026.”

Financial results for three months ended September 30, 2024

- Research and development (R&D) expenses for the three months ended September 30, 2024, were $6.0 million, compared to $3.8 million in the same three-month period of 2023. The increase in R&D expenses was driven by the ramp up in patient enrollment in the SHIELD II Phase 3 trial.
- General and administrative (G&A) expenses for the three months ended September 30, 2024, were $1.2 million, similar to the same period of 2023.
- Marketing and business development expenses for the three months ended September 30, 2024, were $0.2 million, compared to $0.3 million for the same period of 2023.
- For the three months ended September 30, 2024, the Company had a net loss of $7.8 million, or ($1.22) per share, compared to a net loss of $5.6 million, or ($3.40) per share, in the three-month period ended September 30, 2023.

Financial results for nine months ended September 30, 2024

- R&D expenses, net for the nine months ended September 30, 2024, were $15.8 million, compared to $11.6 million for the same nine-month period of 2023. The increase in R&D expenses was driven by the ramp up in patient enrollment in the SHIELD II Phase 3 trial.
- G&A expenses for the nine months ended September 30, 2024, were $3.3 million, compared to $4.3 million for the same period of 2023.
- Marketing and business development expenses for the nine months ended September 30, 2024, were $0.7 million, compared to $1.0 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 nine months ended September 30, 2024, the Company had a net loss of $20.5 million, or ($3.82) per share, compared to a net loss of $17.5 million, or ($13.59) per share, in the nine-month period ended September 30, 2023.

Balance Sheet Highlights

- As of September 30, 2024, the Company had cash, cash equivalents, and short-term deposits in the amount of $9.5 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 first quarter of 2025. If all warrants issued in both of the Company's most recent private placement financings are exercised, the Company would be funded into 2026.

Conference Call Dial-In & Webcast Information:

Date:	Wednesday, November 13, 2024
Time:	8:30 AM Eastern Time
Conference Call:	https://register.vevent.com/register/BI198de55d5c06495994d35cbb213655eb
Webcast:	https://edge.media-server.com/mmc/p/j6bnvt8c

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-PLEX$_{100}$ 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-PLEX$_{100}$

D-PLEX$_{100,}$ 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-PLEX$_{100}$ 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-PLEX$_{100}$ received Breakthrough Therapy Designation from the U.S. Food and Drug Administration for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX$_{100}$ 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-PLEX$_{100}$ 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 enrollment pace, the expected timing for top-line results from the SHIELD II trial and of the unblinded interim analysis, the Company's expected cash runway and that if all warrants issued in both of Company's most recent private placement financings are exercised, the Company would be funded into 2026. 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.

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

	September 30, 2024	December 31, 2023
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,804	$ 5,309
Restricted deposits	165	300
Short-term bank deposits	4,728	–
Prepaid expenses and other current assets	750	458
Total current assets	10,447	6,067
LONG-TERM ASSETS:		
Property and equipment, net	6,414	7,621
Operating lease right-of-use assets	2,464	1,597
Other long-term assets	269	87
Total long-term assets	9,147	9,305
Total assets	$ 19,594	$ 15,372

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

	September 30, 2024	December 31, 2023

	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt	$ 5,178	$ 4,003
Accrued expenses and other current liabilities	2,770	1,971
Trade payables	1,641	772
Current maturities of operating lease liabilities	888	540
Total current liabilities	10,477	7,286
LONG-TERM LIABILITIES:		
Long-term debt	2,529	6,379
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	1,421	857
Other liabilities	461	398
Total long-term liabilities	6,959	10,182
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY (DEFICIT):		
Ordinary shares with no par value – Authorized: 107,800,000 and 107,800,000 shares at September 30, 2024 (unaudited) and December 31, 2023, respectively; Issued and outstanding: 6,803,478 and 1,653,559 shares at September 30, 2024 (unaudited) and December 31, 2023, respectively.	–	–
Additional paid-in capital	260,969	236,213
Accumulated deficit	(258,811)	(238,309)
Total shareholders' equity (deficit)	2,158	(2,096)
Total liabilities and shareholders' equity (deficit)	$ 19,594	$ 15,372

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
U.S. dollars in thousands (except share and per share data)

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development, net	$ 15,784	$ 11,560	$ 5,974	$ 3,806
Marketing and business development	747	1,003	246	261
General and administrative	3,277	4,305	1,166	1,193
Operating loss	19,808	16,868	7,386	5,260
Financial expense, net	665	581	354	319
Loss before income tax	20,473	17,449	7,740	5,579
Income tax expenses	29	60	20	25
Net loss	$ 20,502	$ 17,509	$ 7,760	$ 5,604
Basic and diluted loss per ordinary share	$ 3.82	$ 13.59	$ 1.22	$ 3.40
Weighted average number of ordinary shares used in computing basic and				

diluted loss per share	5,362,858	1,288,678	6,361,286	1,650,259