PolyPid Provides Corporate Update and Reports Third Quarter 2023 Financial Results

Total of 20 Centers Currently Open with Approximately 40 Expected by End of 2023 in SHIELD II Phase 3 Trial Evaluating D-PLEX$_{100}$ for the Prevention of Abdominal Colorectal Surgical Site Infections

Completed Production and Release of Three Process Validation Batches of D-PLEX$_{100}$

Successful Completion of Good Manufacturing Practice Audit of Company's Manufacturing Facility

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, Nov. 08, 2023 — 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, 2023.

Recent Corporate Highlights:

- A total of 20 centers are currently open in the ongoing SHIELD II Phase 3 trial that is recruiting patients undergoing open colorectal abdominal surgery with large incisions.
  - Approximately 40 centers are expected to be open by the end of 2023.
  - Unblinded interim analysis is planned to be conducted once approximately 400 patients complete their 30-day follow-up.
  - Top-line results are expected in the second half of 2024.
- Achieved significant D-PLEX$_{100}$ manufacturing-related milestones.
  - Production and release of three process validation batches of D-PLEX$_{100.}$
  - Good Manufacturing Practice (GMP) audit of the Company's manufacturing facility completed without any critical or major findings.
- Published positive preclinical results demonstrating, for the first time, the safety profile of D-PLEX$_{100}$ and the PLEX technology platform in juvenile animals in the peer-reviewed journal, *International Journal of Toxicology*.
- Presented the results of the SHIELD I Phase 3 trial for the first time at a medical meeting, the American College of Surgeons Clinical Congress 2023.
- Appointed Nurit Tweezer-Zaks, MD, MBA, to Board of Directors following the retirement of Anat Tsour Segal.
  - Dr. Tweezer-Zaks is a biopharmaceutical industry veteran with extensive executive business development, clinical, and R&D expertise. She is an experienced sector investor and was a practicing physician for nearly 15 years.
- Regained compliance with Nasdaq's Minimum Closing Bid Price Rule.

“Our ongoing SHIELD II Phase 3 trial for our promising lead product candidate, D-PLEX$_{100}$, is progressing as anticipated,” stated Dikla Czaczkes Akselbrad, PolyPid’s Chief Executive Officer. “We currently have 20 centers open, many of which have just recently begun recruiting patients, and we expect enrollment to ramp-up shortly. We anticipate having approximately 40 centers open by the end of 2023. Importantly, we continue to expect top-line results from SHIELD II in second half of 2024.”

“While we focus on enrollment into SHIELD II, we have also recently achieved several key D-PLEX$_{100}$ manufacturing-related milestones that have helped evolve PolyPid into a fully-integrated biopharmaceutical company,” continued Ms. Czaczkes Akselbrad. “First, we successfully completed the production and release of three process validation batches of D-PLEX$_{100}$, thus completing a substantial requirement toward our planned submission of D-PLEX$_{100}$‘s New Drug Application and EU Marketing Authorization Application regulatory filings. In addition, a successful Good Manufacturing Practice audit of our manufacturing facility was completed without any critical or major findings, and the Company can now produce D-PLEX$_{100}$ at scale to meet the expected commercial demand for the product.”

As to the current situation in Israel, our immediate focus is to support our employees and their families while staying focused on running the business. As of today, there has been no material impact on our operations and business activity.

Financial results for three months ended September 30, 2023

- Research and development (R&D) expenses for the three months ended September 30, 2023, were $3.8 million, compared to $6.2 million in the same three-month period of 2022. The decrease in R&D expenses resulted primarily from the completion of the SHIELD I Phase 3 clinical trial.
- General and administrative (G&A) expenses for the three months ended September 30, 2023, were $1.2 million, compared to $1.7 million for the same period of 2022.
- Marketing and business development expenses for the three months ended September 30, 2023, were $0.3 million, compared to $0.8 million for the same period of 2022.
- For the three months ended September 30, 2023, the Company had a net loss of $5.6 million, or ($3.40) per share, compared to a net loss of $9.3 million, or ($14.19) per share, in the three-month period ended September 30, 2022.

Financial results for nine months ended September 30, 2023

- R&D expenses, net for the nine months ended September 30, 2023, were $11.6 million, compared to $23.3 million for the same nine-month period of 2022.
- G&A expenses for the nine months ended September 30, 2023, were $4.3 million, compared to $6.4 million for the same period of 2022.
- Marketing and business development expenses for the nine months ended September

30, 2023, were $1.0 million, compared to $2.5 million for the same period of 2022.
- The decreases in G&A and marketing and business development expenses were primarily due to the Company's cost reduction plan announced in October 2022 and further cost savings initiatives implemented during the first nine months of 2023.
- For the nine months ended September 30, 2023, the Company had a net loss of $17.5 million, or ($13.59) per share, compared to a net loss of $33.0 million, or ($51.15) per share, in the nine-month period ended September 30, 2022.

Balance Sheet Highlights

- As of September 30, 2023, the Company had cash and cash equivalents and deposits in the amount of $10.2 million. PolyPid expects that this cash balance will be sufficient to fund operations into late first quarter of 2024.

Conference Call Dial-In & Webcast Information:

Date:	Wednesday, November 8, 2023
Time:	8:30 AM Eastern Time
Q&A Participants:	**https://register.vevent.com/register/BIbd0a9baa57b1427e809302152ba58bd3**
Webcast:	**https://edge.media-server.com/mmc/p/r9ot5d24**

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 surgical site infections (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 open abdominal colorectal surgery with large incisions (>20cm).

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 number of centers expected to open by the end of 2023, the expected timing of top-line data, the planned submission of a New Drug Application and EU Marketing Authorization Application regulatory filings, potential commercial demand for D-$PLEX_{100}$ and the expected sufficiency of the Company's cash balance. 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 March 31, 2023. 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

	September 30, 2023 Unaudited	December 31, 2022 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,353	$ 8,552
Short-term deposits	8,801	4,042
Restricted cash	495	511
Prepaid expenses and other current assets	473	1,089
Total current assets	11,122	14,194
LONG-TERM ASSETS:		
Property and equipment, net	8,077	9,247
Operating lease right-of-use assets	1,632	2,431
Other long-term assets	101	99
Total long-term assets	9,810	11,777
Total assets	$ 20,932	$ 25,971

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

	September 30, 2023 Unaudited	December 31, 2022 Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt	$ 2,859	$ 4,024
Accrued expenses and other current liabilities	2,024	2,429

Trade payables	529	1,141
Current maturities of operating lease liabilities	486	959
Total current liabilities	5,898	8,553
LONG-TERM LIABILITIES:		
Long-term debt	7,665	7,574
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	832	1,173
Other liabilities	451	294
Total long-term liabilities	11,496	11,589
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares with no par value – Authorized: 107,800,000 and 47,800,000 shares at September 30, 2023 (unaudited) and December 31, 2022, respectively; Issued and outstanding: 1,653,559 and 669,605 shares at September 30, 2023 (unaudited) and December 31, 2022, respectively *)	–	–
Additional paid-in capital	235,491	220,273
Accumulated deficit	(231,953)	(214,444)
Total shareholders' equity	3,538	5,829
Total liabilities and shareholders' equity	$ 20,932	$ 25,971

*) On September 18, 2023, the Company affected a 1-for-30 reverse share split (the "Reverse Share Split")

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

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development, net	$ 11,560	$ 23,335	$ 3,806	$ 6,240
Marketing and business development	1,003	2,538	261	840
General and administrative	4,305	6,403	1,193	1,680
Operating loss	16,868	32,276	5,260	8,760
Financial expense, net	581	640	319	437
Loss before income tax	17,449	32,916	5,579	9,197
Income tax expenses	60	74	25	74
Net loss	$ 17,509	$ 32,990	$ 5,604	$ 9,271
Basic and diluted loss per ordinary share *)	$ 13.59	$ 51.15	$ 3.40	$ 14.19

Weighted average number of ordinary shares used in computing basic and diluted loss per share	1,288,678	644,958	1,650,259	653,240

*) On September 18, 2023, the Company affected a 1-for-30 reverse share split (the “Reverse Share Split”)