PolyPid Provides Corporate Update and Reports Second Quarter 2023 Financial Results

Reached Agreement with U.S. FDA on Design of SHIELD II Phase 3 Trial Evaluating D-PLEX$_{100}$ for the Prevention of Abdominal Colorectal Surgical Site Infections

Resumed Recruitment into SHIELD II Phase 3 Trial in Late June 2023

Total of 20 centers in U.S., Europe and Israel Expected to be Opened by End of Current Quarter

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, Aug. 09, 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 six months ended June 30, 2023.

Recent Corporate Highlights:

- Reached agreement with U.S. Food and Drug Administration ("FDA") on the design of the SHIELD II Phase 3 trial. The revised SHIELD II trial is recruiting patients undergoing open colorectal abdominal surgery with large incisions.
    - Resumed recruitment in late June 2023 with a total of 40 patients already recruited into SHIELD II trial.
    - Regulatory authorities in multiple countries have now approved the trial protocol and PolyPid expects to have 20 centers open in U.S., Europe and Israel by the end of the current quarter.
    - Unblinded interim analysis is planned to be conducted once approximately 400 patients complete their 30-day follow-up.
    - Total recruitment time into the trial is anticipated to be approximately 12 months and top-line results are expected in mid-2024.
- Published a paper highlighting the potent antibacterial activity of D-PLEX$_{100}$ and its potential as an effective prophylactic drug against the most prevalent bacteria causing surgical site infections ("SSIs"), including resistant strains, in the *European Journal of Pharmaceutical Sciences*.

"Following our agreement with the FDA on the design of the SHIELD II Phase 3 trial and the subsequent resumption of the trial, our promising lead product candidate, D-PLEX$_{100}$, is advancing as planned in the clinic," stated Dikla Czaczkes Akselbrad, PolyPid's Chief

Executive Officer. “As we expect to have 20 centers open by the end of the current quarter, we anticipate that the rate of enrollment will increase rapidly.”

“Moreover, we are beginning to see the impact of our cost containment efforts,” continued Ms. Czaczkes Akselbrad. “Despite a challenging inflationary environment, we have generated over $1 million in cost savings year-to-date, and our net cash used in operating activities decreased by 59% in the first six months of the year as compared to the first six months of 2022.”

Financial results for three months ended June 30, 2023

- Research and development (R&D) expenses, net for the three months ended June 30, 2023, were $4.0 million, compared to $8.4 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 June 30, 2023, were $1.5 million, compared to $2.2 million for the same period of 2022.
- Marketing and business development expenses for the three months ended June 30, 2023, were $0.4 million, compared to $0.9 million for the same period of 2022.
- For the three months ended June 30, 2023, the Company had a net loss of $5.8 million, or ($0.13) per share, compared to a net loss of $11.8 million, or ($0.61) per share, in the three-month period ended June 30, 2022.

Financial results for six months ended June 30, 2023

- R&D expenses, net for the six months ended June 30, 2023, were $7.8 million, compared to $17.1 million for the same six-month period of 2022. The decrease in R&D expenses resulted primarily from the completion of the SHIELD I Phase 3 clinical trial.
- G&A expenses for the six months ended June 30, 2023, were $3.1 million, compared to $4.7 million for the same period of 2022.
- Marketing and business development expenses for the six months ended June 30, 2023, were $0.7 million, compared to $1.7 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 six months of 2023.
- For the six months ended June 30, 2023, the Company had a net loss of $11.9 million, or ($0.36) per share, compared to a net loss of $23.7 million, or ($1.23) per share, in the six-month period ended June 30, 2022.

Balance Sheet Highlights

- As of June 30, 2023, the Company had cash and cash equivalents and deposits in the amount of $15.1 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, August 9, 2023
Time:	8:30 AM Eastern Time
Q&A Participants:	**https://register.vevent.com/register/BIdd3e958085d54167a5e9a8d8a59daff3**
Webcast:	**https://edge.media-server.com/mmc/p/82gmauqc**

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 surgeries with incisions greater than 20 cm. The primary endpoint of the trial is measured by the proportion of subjects with either an 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 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 its expectation to have

20 centers open in U.S., Europe and Israel by the end of the current quarter and its anticipation that the rate of enrollment will increase rapidly thereafter, the timing of the unblinded interim analysis, total recruitment time into the trial and top-line results, D-PLEX$_{100}$ ‘s potential as an effective prophylactic drug against the most prevalent bacteria causing surgical site infections and the expected benefits from cost containment efforts. 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.

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

	June 30, 2023 Unaudited	December 31, 2022 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,396	$ 8,552
Short-term deposits	11,710	4,042
Restricted deposits	503	511
Prepaid expenses and other current assets	144	1,089
Total current assets	15,753	14,194
LONG-TERM ASSETS:		
Property and equipment, net	8,529	9,247
Operating lease right-of-use assets	1,892	2,431
Other long-term assets	89	99
Total long-term assets	10,510	11,777
Total assets	$ 26,263	$ 25,971

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	June 30, 2023 Unaudited	December 31, 2022 Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt	$ 2,068	$ 4,024
Accrued expenses and other current liabilities	1,842	2,429
Trade payables	903	1,141
Current maturities of operating lease liabilities	638	959
Total current liabilities	5,451	8,553
LONG-TERM LIABILITIES:		
Long-term debt	8,538	7,574
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	933	1,173
Other liabilities	446	294
Total long-term liabilities	12,465	11,589
COMMITMENTS AND CONTINGENT LIABILITIES		

SHAREHOLDERS' EQUITY:		
Ordinary shares with no par value – Authorized: 107,800,000 and 47,800,000 shares at June 30, 2023 (unaudited) and December 31, 2022, respectively; Issued and outstanding: 49,048,703 and 19,851,833 shares at June 30, 2023 (unaudited) and December 31, 2022, respectively	–	–
Additional paid-in capital	234,696	220,273
Accumulated deficit	(226,349)	(214,444)
Total shareholders' equity	8,347	5,829
Total liabilities and shareholders' equity	$ 26,263	$ 25,971

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Six Months Ended June 30,		Three Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development, net	$ 7,754	$ 17,095	$ 3,960	$ 8,398
Marketing and business development	742	1,698	357	923
General and administrative	3,112	4,723	1,503	2,243
Operating loss	11,608	23,516	5,820	11,564
Financial expense , net	262	203	7	281
Loss before income tax	11,870	23,719	5,827	11,845
Income tax expenses	35	–	10	–
Net loss	$ 11,905	$ 23,719	$ 5,837	$ 11,845
Basic and diluted loss per ordinary share	$ 0.36	$ 1.23	$ 0.13	$ 0.61
Weighted average number of ordinary shares used in computing basic and diluted loss per share	32,910,446	19,222,423	44,383,474	19,505,246