PolyPid Provides Corporate Update and Reports Third Quarter 2022 Financial Results

- *Company Intends to Meet with U.S. and EU Regulatory Authorities to Discuss Data from SHIELD I Phase 3 Study and Regulatory Pathway for D-PLEX$_{100}$ in First Quarter of 2023*
- *Implemented a Cost Reduction Plan, Including a 20% Decrease in Headcount Across All Departments*
- *Conference Call Scheduled for Today at 8:30 AM ET*

PETACH TIKVA, Israel, Nov. 09, 2022 — 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, 2022.

Recent Corporate Highlights:

- Announced top-line results from SHIELD I (Surgical site Hospital acquired Infection prEvention with Local D-PLEX$_{100}$) study evaluating D-PLEX$_{100}$ for the prevention of abdominal soft tissue surgical site infections (SSIs).
  - PolyPid intends to discuss the SHIELD I study outcomes and potential next steps with U.S. and EU regulatory authorities in the first quarter of 2023.
- Continued data analysis of SHIELD I study showed encouraging results in certain subpopulations:
  - 54% reduction in the primary endpoint in complex surgeries with large incisions (>20cm) pre-specified subgroup (p=0.0032; n=423) compared to standard of care.
  - 34% reduction in the primary endpoint in patients with one or more personal risk factors (post hoc analysis; p=0.047; n=680) compared to standard of care.
  - SHIELD I study demonstrated a good safety profile of D-PLEX$_{100}$ with no increase in serious or severe treatment emergent adverse events compared to standard of care.
- Received confirmation from the European Medicines Agency (EMA) that D-PLEX$_{100}$ is eligible for submission of a Marketing Authorization Application under the EMA's centralized procedure in the European Union (EU).
- Positive clinical data from the previously completed Phase 2 study of D-PLEX$_{100}$ for the prevention of superficial and deep SSIs in abdominal surgery published in peer-reviewed publication, *Techniques in Coloproctology.*
- Implemented a cost reduction plan, including a 20% decrease in headcount across all departments, which is expected to extend available cash into the third quarter of 2023 in support of the Company's long-term growth strategy.

“Since the top-line results were announced, we have continued to gather and analyze additional data from SHIELD I,” stated Dikla Czaczkes Akselbrad, PolyPid’s Chief Executive Officer. “These data have been increasingly encouraging. While SHIELD I did not meet its primary endpoint, the significant reduction in SSIs in complex surgeries with large incisions and in high-risk patients, as well as the safety data, are very compelling. As such, we are in the process of preparing a comprehensive package of D-PLEX$_{100}$ data for a planned meeting with the U.S. Food and Drug Administration (FDA). We expect to meet the FDA and EU regulatory authorities regarding the regulatory pathway for D-PLEX$_{100}$ in the first quarter of 2023.”

“In parallel to preparing for these important regulatory interactions, we recently implemented a cost reduction plan, including a 20% decrease in headcount across all departments,” continued Ms. Czaczkes Akselbrad. “We expect that these significant measures will extend our cash runway into the third quarter of 2023 in support of the Company’s long-term growth strategy.”

Financial results for three months ended September 30, 2022

- Research and development, net (R&D) expenses for the three months ended September 30, 2022, were $6.2 million, compared to $7.5 million for the same three-month period of 2021, as spending decreased due to the completion of the SHIELD I Phase 3 clinical trial.
- General and administrative (G&A) expenses for the three months ended September 30, 2022, were $1.7 million, compared to $2.1 million for the same period of 2021.
- Marketing and business development expenses for the three months ended September 30, 2022, were $0.8 million, compared to $0.4 million for the same period of 2021.
- For the three months ended September 30, 2022, the Company had a net loss of $9.3 million, compared to a net loss of $9.9 million for the same three-month period ended September 30, 2021.

Financial results for nine months ended September 30, 2022

- R&D expenses, net for the nine months ended September 30, 2022, were $23.3 million, compared to $20.9 million for the same nine-month period of 2021. The increase in spending was due to the accelerated recruitment of the final patients in the SHIELD I Phase 3 clinical trial in abdominal surgery.
- G&A expenses for the nine months ended September 30, 2022, were $6.4 million, compared to $6.7 million for the same period of 2021.
- Marketing and business development expenses for the nine months ended September 30, 2022, were $2.5 million, compared to $1.8 million for the same period of 2021.
- For the nine months ended September 30, 2022, the Company had a net loss of $33.0 million, compared to a net loss of $29.1 million for the same nine-month period ended

September 30, 2021.

Balance Sheet Highlights

- As of September 30, 2022, the Company had cash and cash equivalents and deposits in the amount of $18.1 million, including the $2.6 million upfront payment from ADVANZ PHARMA received during the third quarter. Following the recently announced cost reduction plan, PolyPid expects that its current cash balance will be sufficient to fund operations into the third quarter of 2023.

Conference Call Dial-In & Webcast Information:

Date:	Wednesday, November 9, 2022
Time:	8:30 AM Eastern Time
Q&A Participants:	**https://register.vevent.com/register/BI5e06285152a24249a0330f025cefc01e**
Webcast:	**https://edge.media-server.com/mmc/p/c6nr79zi**

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 trials for the prevention of soft tissue abdominal surgical site infections. In addition, the Company is currently in preclinical stages to test the efficacy of OncoPLEX for 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 ongoing clinical trials and the increasing encouragement from data analysis of the SHIELD I study outcome, its expectation to extend the Company's available cash into the third quarter of 2023, its intention to *meet with U.S. and EU regulatory authorities to discuss data from SHIELD I Phase 3* study *and regulatory pathway for D-PLEX$_{100}$ in first quarter of 2023 and the potential safety and efficacy of D-PLEX$_{100}$*. 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 February 28, 2022. 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, 2022 Unaudited	December 31, 2021 Audited
ASSETS		

CURRENT ASSETS:		
Cash and cash equivalents	$ 16,108	$ 9,819
Restricted cash	394	397
Short-term deposits	2,003	22,384
Prepaid expenses and other current assets	1,297	2,211
Total current assets	19,802	34,811
LONG-TERM ASSETS:		
Property and equipment, net	8,976	8,761
Other long-term assets	603	663
Total long-term assets	9,579	9,424
Total assets	$ 29,381	$ 44,235

The accompanying notes are an integral part of the interim condensed consolidated financial statements.

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

	September 30, 2022 Unaudited	**December 31, 2021 Audited**
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt	$ 3,132	$ –
Trade payables	1,031	4,136
Accrued expenses and other current liabilities	2,722	3,940
Total current liabilities	6,885	8,076
LONG-TERM LIABILITIES:		
Long-term debt	8,354	–
Deferred revenues	2,548	–
Other liabilities	91	199
Total long-term liabilities	10,993	199
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares with no par value – Authorized: 47,800,000 shares at September 30, 2022 (unaudited) and December 31, 2021 (audited); Issued and outstanding: 19,655,608 and 18,756,570 shares at September 30, 2022 (unaudited) and December 31, 2021 (audited), respectively	–	–
Additional paid-in capital	219,380	210,847
Accumulated deficit	(207,877)	(174,887)

Total shareholders' equity	11,503	35,960
Total liabilities and shareholders' equity	$ 29,381	$ 44,235

The accompanying notes are an integral part of the interim condensed consolidated financial statements.

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

	Nine Months Ended September30,		Three Months Ended September30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development, net	$ 23,335	$ 20,936	$ 6,240	$ 7,476
Marketing and business development	2,538	1,836	840	445
General and administrative	6,403	6,719	1,680	2,143
Operating loss	32,276	29,491	8,760	10,064
Financial expense (income), net	640	(392)	437	(129)
Net loss before income tax	32,916	29,099	9,197	9,935
Income tax expense	74	–	74	–
Net loss	$ 32,990	$ 29,099	$ 9,271	$ 9,935
Basic and diluted loss per Ordinary share	$ 1.71	$ 1.56	$ 0.48	$ 0.53
Weighted average number of Ordinary shares used in computing basic and diluted loss per share	19,348,725	18,709,719	19,597,212	18,756,570

The accompanying notes are an integral part of the interim condensed consolidated financial statements.