PolyPid Ltd. Reports Third Quarter 2021 Financial Results and Provides Corporate Update

Recruitment Progressing as Planned with Approximately 480 Patients Enrolled in Phase 3 SHIELD I Trial of D-PLEX$_{100}$ in Abdominal Surgery

Following FDA Agreement that a Single Pivotal Phase 3 Study is Sufficient for Potential Approval of D-PLEX$_{100}$ for the Prevention of Surgical Site Infections in Colorectal Surgery, Company Intends to Target Higher End of Patient Enrollment Range in SHIELD I to Leverage Key Clinical, Commercial and Financial Benefits

Company's Cash Runway Extends to Year-End 2022, ahead of Prior Forecast of Q2 2022

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, Nov. 10, 2021 — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a phase 3 biopharmaceutical company focusing on developing targeted, locally administered, and prolonged-release therapeutics to improve surgical outcomes, today provided a corporate update and reported financial results for the three and nine months ended September 30, 2021.

Recent Corporate Highlights:

- Recruitment progressing as planned with approximately 480 patients enrolled in the ongoing Phase 3 SHIELD I study.
- Following an agreement with the U.S. Food and Drug Administration (FDA) that a single pivotal Phase 3 study is sufficient, provided the study results are adequate, for potential approval of D-PLEX$_{100}$ for the prevention of SSIs in colorectal surgery, the Company determined that it is in the best interests of the development program to target the higher end of its planned patient enrollment range in SHIELD I.
- Targeting approximately 900 patients for enrollment in SHIELD I is not expected to modify D-PLEX$_{100}$ NDA submission timelines and will help ensure that the study is well powered and will provide additional data that will potentially be used to further demonstrate the medical and health economic benefits of D-PLEX$_{100}$.
- FDA agreement that a single pivotal Phase 3 study is sufficient for potential approval will extend PolyPid's cash runway to year end 2022.
- Last-patient-in from SHIELD I is expected to enroll during the second quarter of 2022 with top line results 2 months thereafter.
- Patient enrollment is also advancing as anticipated in SHIELD II, the second Phase 3 clinical trials for D-PLEX$_{100}$ in abdominal surgery (soft tissue), with over 130 patients enrolled to date. SHIELD II has broader eligibility criteria than SHIELD I, including

minimally invasive surgical procedures.

- Positive preclinical data from Company's intra-tumoral OncoPLEX cancer therapy program in two animal models of Glioblastoma Multiform (GBM) showed that single local treatment of OncoPLEX significantly inhibited tumor growth and prolonged survival. The Company will conduct a Pre-IND meeting with the FDA later this month to potentially initiate a Phase 1/2 clinical trial of OncoPLEX in GBM in 2022.

"We continue to expeditiously advance our multiple development programs, as well as our commercial preparations," said Amir Weisberg, PolyPid's Chief Executive Officer. "Most importantly, the pace of enrollment in the SHIELD I trial has continued to increase over the last several months and we expect an even greater acceleration in the months ahead. Having now passed the mid-point in our planned enrollment for SHIELD I, and with over 600 patients now enrolled in both SHIELD I and SHIELD II studies combined, we are well-positioned to leverage the expected clinical, commercial and financial benefits of targeting the higher end of our patient enrollment range for SHIELD I. Additionally, we are having ongoing discussions with commercialization partners in the United States, Europe and Asia, based upon the anticipated data from our Phase 3 trial in 2022."

"We continue to be excited about the compelling preclinical data being generated by our promising OncoPLEX development platform initially targeting brain tumors. The most recent results further support our work toward the completion of a preclinical package for the filing of an Investigative New Drug application with the FDA to potentially initiate a Phase 1/2 clinical trial. We look forward to meeting with the Agency later this month to discuss the clinical and non-clinical development plan for OncoPLEX in GBM," continued Mr. Weisberg.

"In addition, we are progressing our robust clinical development program from a position of financial strength. Our cash runway now extends to year-end 2022, a significant improvement over our prior target of the second quarter of 2022. We continue to have sufficient cash resources to complete the SHIELD I study, prepare for the submission of a New Drug Application to the FDA and further advance our OncoPLEX program," concluded Mr. Weisberg.

Financial results for the three months ended September 30, 2021

Research and development expenses for the three months ended September 30, 2021 were $7.5 million, compared to $4.2 million in the same three-month period of 2020, as expenses increased due to the ongoing SHIELD I and SHIELD II Phase 3 clinical trials in abdominal surgery.

Marketing and business development expenses for the three months ended September 30, 2021 were $0.4 million, compared to $0.3 million for the same period in 2020, as expenses increased primarily due to an increase in marketing and business development personnel hired in the Company's New Jersey offices.

General and administrative expenses for the three months ended September 30, 2021 were $2.1 million, consistent with $2.2 million in the prior year period. The decrease was due to lower non-cash share-based compensation expenses.

For the three months ended September 30, 2021, the Company had a net loss attributable to ordinary shares of $9.9 million, compared to a net loss of $6.5 million in the three-month period ended September 30, 2020.

As of September 30, 2021, the Company had cash, cash equivalents, short-term deposits, and long-term deposits in the amount of $42.0 million, compared to $67.0 million at December 31, 2020. PolyPid expects that its cash on hand will be sufficient to fund operations until the end of 2022.

Financial results for the nine months ended September 30, 2021

Research and development expenses for the nine months ended September 30, 2021 were $20.9 million, compared to $11.9 million in the same nine-month period of 2020, as expenses increased due to the ongoing SHIELD I and SHIELD II Phase 3 clinical trials in abdominal surgery.

Marketing and business development expenses for the nine months ended September 30, 2021 were $1.8 million, compared to $0.9 million for the same period of 2020. These expenses increased primarily due to an increase in marketing and business development personnel hired in the Company's New Jersey offices.

General and administrative expenses for the nine months ended September 30, 2021 were $6.7 million, compared to $5.5 million in the prior year period. The increase in general and administrative expenses was due to the increase in costs associated with the Company's status as a publicly traded company with higher D&O insurance costs.

For the nine months ended September 30, 2021, the Company had a net loss attributable to ordinary shares of $29.1 million, as compared to a net loss of $31.4 million in the nine months ended September 30, 2020.

Conference Call Dial-In & Webcast Information:

Date:	Wednesday, November 10, 2021
Time:	8:30 AM Eastern Time
United States:	+1 877 870 9135
Israel:	+972 1809 213-985
International:	+44 (0) 2071 928338
Conference ID:	4585862
Webcast:	https://edge.media-server.com/mmc/p/5rbkqsbe

About PolyPid

PolyPid Ltd. (Nasdaq: PYPD) is a phase 3 biopharma company aiming to improve surgical outcomes through locally administered, controlled, extended-release therapeutics. PolyPid's proprietary PLEX (Polymer-Lipid Encapsulation matriX) technology pairs with medications, enables precise delivery of drugs at effective 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 sternal and abdominal surgical site infections (SSIs).

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 cash runway and sufficiency of its cash resources, ongoing clinical trials, plans to use the guidance provided by the FDA to progress with its SHIELD I program, the pace of enrollment in the SHIELD I trial, the timing of last-patient-in or of top-line results of the SHIELD I trial, the size and design of the SHIELD I trial, potential initiation of Phase 1/2 clinical trial of OncoPLEX in GBM in 2022 and D-PLEX$_{100}$ NDA submission timelines. 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 5, 2021. 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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CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	September 30, 2021 Unaudited	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 9,217	$ 4,319
Restricted cash	390	390
Short-term deposits	32,375	40,157
Prepaid expenses and other current assets	3,335	2,334
Total current assets	45,317	47,200
LONG-TERM ASSETS:		
Property and equipment, net	5,717	5,890
Long-term deposits	–	22,120
Other long-term assets	2,425	637
Total long-term assets	8,142	28,647
Total assets	$ 53,459	$ 75,847

LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 1,656	$ 974
Other payables and accrued expenses	3,488	1,903
Total current liabilities	5,144	2,877
LONG-TERM LIABILITIES:		
Other long-term liabilities	192	193
Total long-term liabilities	192	193
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital –		
Ordinary shares with no par value – Authorized: 47,800,000 shares at September 30, 2021 and December 31, 2020; Issued and outstanding: 18,756,570 and 18,494,739 shares at September 30, 2021 and December 31, 2020, respectively	–	–
Additional paid-in capital	209,508	205,063
Accumulated deficit	(161,385)	(132,286)
Total shareholders' equity	48,123	72,777
Total liabilities and shareholders' equity	$ 53,459	$ 75,847

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,	
	2021	2020	2021	2020
	Unaudited			
Operating expenses:				
Research and development, net	$ 20,936	$ 11,948	$ 7,476	$ 4,176
Marketing and business development expenses	1,836	904	445	323
General and administrative	6,719	5,532	2,143	2,177
Operating loss	29,491	18,384	10,064	6,676
Financial (income) expense, net	(392)	10,936	(129)	(218)
Net loss	$ 29,099	$ 29,320	$ 9,935	$ 6,458
Deemed dividend	–	2,114	–	–
Net loss attributable to Ordinary shares	$ 29,099	$ 31,434	$ 9,935	$ 6,458
Basic and diluted net loss per Ordinary share	$ 1.56	$ 4.78	$ 0.53	$ 0.35
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	18,709,719	6,578,969	18,756,570	18,415,231


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