PolyPid Provides Corporate Update and Reports Fourth Quarter and Full Year 2022 Financial Results

Following Positive Communication with the FDA, Regulatory Pathway Clarified for D-PLEX$_{100}$ for Prevention of Abdominal Colorectal Surgical Site Infections

Company Expects to Resume Patient Recruitment in Q2 2023 into Ongoing SHIELD II Trial, which will be Enriched with Approximately 550 Additional Patients to Complete Clinical Testing for Potential NDA

Top-line Results from SHIELD II Trial Anticipated mid-2024

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, Feb. 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 months and full year ended December 31, 2022.

Recent Corporate Highlights:

- Clarified regulatory pathway toward a potential New Drug Application (NDA) submission for D-PLEX$_{100}$ following a positive Type D meeting communication with the U.S. Food and Drug Administration (FDA) on the SHIELD I Phase 3 study data.
  - FDA acknowledged that the SHIELD I results may provide supportive evidence in patients with large surgical incisions (>20 cm) and recommended that the Company conduct an additional study to support an NDA submission.
  - FDA stated that the ongoing SHIELD II study could potentially serve as such study.
- SHIELD II patient recruitment is expected to resume in the second quarter of 2023 with the enrollment of an estimated 550 additional patients.
  - Total recruitment time into the study is anticipated to be approximately 12 months and top-line results are expected mid-2024.
  - Unblinded interim analysis is planned to be conducted once approximately 400 patients complete their 30-day follow-up.
- Announced publication of a post-hoc analysis of patients with one or more risk factors based on data from the previously completed Phase 2 study of D-PLEX$_{100}$ for the prevention of SSIs in abdominal surgery in the *American Journal of Surgery.*
- Presented Phase 2 clinical data for D-PLEX$_{100}$ at the first triennial International Orthopaedic Trauma Association meeting.

"We are thrilled to now have a clear regulatory pathway to possible approval of D-PLEX$_{100}$ in the U.S. following confirmation from the FDA that the ongoing SHIELD II trial can potentially

be used to complete our clinical testing," stated Dikla Czaczkes Akselbrad, PolyPid's Chief Executive Officer. "Importantly, the ability to leverage the SHIELD II study will significantly reduce the time and resources needed to finalize the clinical study as compared to having to initiate a new trial. We look forward to resuming patient recruitment in the second quarter."

"We view SHIELD II as a de-risked Phase 3 trial given the more focused patient population with large incisions in which we have already generated highly positive data in SHIELD I, and the fact that it will not be conducted within tight COVID-19 related restrictions," continued Ms. Czaczkes Akselbrad. "The recruitment of the additional 550 patients into SHIELD II is expected to take approximately 12 months and the top-line results are anticipated in mid-2024."

Financial results for three months ended December 31, 2022

- Research and development (R&D) expenses for the three months ended December 31, 2022 were $4.7 million, compared to $9.6 million in the same three month period of 2021. 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 December 31, 2022 were $1.6 million, compared to $2.9 million for the same period of 2021.
- Marketing and business development expenses for the three months ended December 31, 2022 were $0.4 million, compared to $1.1 million for the same period of 2021.
- For the three months ended December 31, 2022, the Company had a net loss attributable to ordinary shares of $6.5 million, or ($0.32) per share, compared to a net loss of $13.5 million, or ($0.72) per share, in the three-month period ended December 31, 2021.

Financial results for the full year ended December 31, 2022

- R&D expenses for the year ended December 31, 2022 were $28.0 million, compared to $30.6 million in 2021. The decrease in R&D expenses resulted primarily from the completion of the SHIELD I Phase 3 clinical trial.
- G&A expenses for the year ended December 31, 2022 were $8.0 million, compared to $9.6 million for 2021.
- Marketing and business development expenses for the year ended December 31, 2022 were $2.9 million, compared to $3.0 million for 2021.
- For the year ended December 31, 2022, the Company had a net loss attributable to ordinary shares of $39.5 million, or ($2.03) per share, compared to a net loss of $42.6 million, or ($2.28) per share, for 2021.

Balance Sheet Highlights

- As of December 31, 2022, the Company had cash and cash equivalents and deposits in

the amount of $12.6 million, compared to $32.2 million at December 31, 2021. PolyPid expects that this cash balance will be sufficient to fund operations well into the third quarter of this year.

Conference Call Dial-In & Webcast Information:

Date:	Wednesday, February 8, 2023
Time:	8:30 AM Eastern Time
Q&A Participants:	**https://register.vevent.com/register/BIdad8bd318dec4d3cb9437ab9c40bd263**
Webcast:	**https://edge.media-server.com/mmc/p/rak4fxxm**

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), 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 trials 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 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 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 regulatory pathway for the potential NDA submission for D-PLEX$_{100}$, including the potential of the SHIELD I results and SHIELD II study to provide support, the timing of resumption, completion of patient recruitment and top-line results of the revised SHIELD II study, and the timing of the unblinded analysis thereof, and the Company's expectations regarding its 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 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.

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CONSOLIDATED BALANCE SHEETS

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

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 8,552	$ 9,819
Restricted cash	511	397
Short-term deposits	4,042	22,384
Prepaid expenses and other current assets	1,089	2,211
Total current assets	14,194	34,811
LONG-TERM ASSETS:		
Property and equipment, net	9,247	8,761
Operating lease right-of-use assets	2,431	–
Other long-term assets	99	663
Total long-term assets	11,777	9,424
Total assets	$ 25,971	$ 44,235

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

CONSOLIDATED BALANCE SHEETS

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

	December 31, 2022	December 31, 2021
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt	$ 4,024	$ –
Accrued expenses and other current liabilities	2,517	3,940
Trade payables	1,141	4,136
Current maturities of operating lease liabilities	959	–
Total current liabilities	8,641	8,076
LONG-TERM LIABILITIES:		
Long-term debt	7,574	–
Deferred revenues	2,548	–
Long-term operating lease liabilities	1,173	–
Other liabilities	174	199
Total long-term liabilities	11,469	199
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		

Ordinary shares with no par value – Authorized: 47,800,000 shares at December 31, 2022 and 2021; Issued and outstanding: 19,851,833 and 18,756,570 shares at December 31, 2022 and 2021, respectively	–	–
Additional paid-in capital	220,273	210,847
Accumulated deficit	(214,412)	(174,887)
Total shareholders' equity	5,861	35,960
Total liabilities and shareholders' equity	$ 25,971	$ 44,235

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

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Year Ended December 31,		
	2022	2021	2020
Operating expenses:			
Research and development, net	$ 27,990	$ 30,553	$ 16,954
Marketing and business development	2,888	2,983	1,614
General and administrative	8,010	9,609	7,704
Operating loss	38,888	43,145	26,272
Financial (income) expense, net	540	(544)	10,597
Loss before income tax	39,428	42,601	36,869
Income tax expense	97	–	–
Net loss	39,525	42,601	36,869
Deemed dividend	–	–	2,114
Net loss attributable to Ordinary shares	$ 39,525	$ 42,601	$ 38,983
Basic and diluted net loss per Ordinary share	$ 2.03	$ 2.28	$ 4.48
Weighted average number of Ordinary shares used in computing basic and diluted loss per share	19,426,692	18,721,528	9,582,405

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

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended December 31,	
	2022 (Unaudited)	2021 (Unaudited)

Operating expenses:		
Research and development, net	$ 4,655	$ 9,617
Marketing and business development expenses	350	1,147
General and administrative	1,607	2,890
Operating loss	6,612	13,654
Financial income, net	100	152
Loss before income tax	6,512	13,502
Income tax expense	23	–
Net loss attributable to Ordinary shares	$ 6,535	$ 13,502
Basic and Diluted loss per Ordinary share	$ 0.32	$ 0.72
Weighted average number of Ordinary shares used in computing basic and diluted loss per share	19,658,048	18,756,570