PolyPid Provides Corporate Update and Reports Fourth Quarter and Full-Year 2021 Financial Results

FDA Agreed to PolyPid Request for the Addition of an Unblinded Interim Analysis in SHIELD I once 750 Patients Complete their 30–day Follow-up

Recruitment Progressing as Planned with Approximately 680 Patients Enrolled into Phase 3 SHIELD I Trial of D-PLEX$_{100}$ in Abdominal Soft Tissue Surgery. Expect to Reach 750 Enrolled Patients by End of First Quarter 2022 and Have Unblinded Interim Analysis During the Second Quarter of 2022

Recently Completed Planned 500–Patient Blinded Sample Size Reassessment of SHIELD I Supports the Continuation of the Trial

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, Feb. 09, 2022 — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a Phase 3 biopharmaceutical company focused on developing targeted, locally administered, and prolonged-release therapeutics using its proprietary PLEX technology, today provided a corporate update and reported financial results for the three months and full-year ended December 31, 2021.

Recent Corporate Highlights:

- The U.S. Food and Drug Administration (the "FDA") agreed to PolyPid's request for the addition of an unblinded interim analysis in SHIELD I (Surgical site Hospital acquired Infection prEvention with Local D-PLEX) study evaluating D-PLEX$_{100}$ for the prevention of abdominal soft tissue surgical site infections (SSIs). PolyPid's request was based on the FDA's recently published guidance for pharmaceutical companies to address the impact of COVID-19 pandemic on meeting study objectives for clinical trials conducted during this period.
- The interim analysis is expected during the second quarter of 2022 once 750 patients complete their 30-day follow-up and will allow for early trial stopping due to efficacy, futility, or for sample size reassessment.
- Recruitment progressing as planned with approximately 680 patients enrolled into the ongoing Phase 3 SHIELD I study.
- Following the completion of the 30-day follow-up period for the 500th patient enrolled, the recently completed planned blinded sample size reassessment supports the continuation of SHIELD I trial.
- Patient enrollment is also advancing as anticipated in SHIELD II, the second Phase 3 clinical trial for D-PLEX$_{100}$ in abdominal surgery, with over 200 patients enrolled to date.

SHIELD II has broader eligibility criteria than SHIELD I, including minimally invasive surgical procedures.
- Successful pre-Investigational New Drug (IND) meeting with the FDA supporting a Phase 1/2 clinical trial of OncoPLEX as a potential part of first-line combination therapy for patients newly diagnosed with Glioblastoma Multiform (GBM).
- Board of Directors appointed Dikla Czaczkes Akselbrad, currently Executive Vice President and Chief Financial Officer of the Company, as PolyPid's Chief Executive Officer, effective July 1, 2022, at which time Amir Weisberg will retire from his position as Chief Executive Officer.

"Our team is achieving rapid progress in advancing our multiple development programs, as well as executing on the activities related to our commercial preparations for D-PLEX$_{100}$ for prevention of abdominal soft tissue SSIs," stated Amir Weisberg, PolyPid's Chief Executive Officer. "We are very pleased with the interim analysis in SHIELD I that will strengthen the adaptive design of the study so we can more precisely define the targeted patient enrollment range. It can also potentially allow for stopping the trial earlier than planned, if the efficacy results on SSIs are above expectations. We are also very satisfied with the study enrollment which continues at a strong pace, as we now have approximately 680 patients enrolled into the study, as compared to about 480 patients announced on our November 2021 conference call."

"We believe PolyPid is in the strongest operational position in its history, and we are well-positioned for long-term success. We continue to anticipate that our current balance sheet will be sufficient to complete the SHIELD I study and prepare for the submission of an NDA to the FDA, as well as further advancement of our OncoPLEX development platform," concluded Mr. Weisberg.

Financial results for three months ended December 31, 2021

- Research and development (R&D) expenses for the three months ended December 31, 2021 were $9.5 million, compared to $5.0 million in the same three month period of 2020, as spending increased due to the expedited recruitment in SHIELD I and initiation of SHIELD II Phase 3 clinical trials in abdominal surgery.
- General and administrative (G&A) expenses for the three months ended December 31, 2021 were $2.8 million, compared to $2.2 million for the same period of 2020.
- Marketing and business development expenses for the three months ended December 31, 2021 were $1.1 million, compared to $0.7 million for the same period of 2020, as spending increased mainly due to the initiation of pre-launch activities.
- For the three months ended December 31, 2021, the Company had a loss attributable to ordinary shares of $13.2 million, compared to a loss of $7.5 million in the three-month period ended December 31, 2020.

Financial results for the full-year ended December 31, 2021

- R&D expenses for the year ended December 31, 2021 were $30.4 million, compared to $17.0 million in 2020, as spending increased due to the initiation of SHIELD I and SHIELD II Phase 3 clinical trials in abdominal surgery.
- G&A expenses for the year ended December 31, 2021 were $9.5 million, compared to $7.7 million for 2020, as costs increased due to the Company's status as a publicly-traded company with higher directors and officers insurance costs.
- Marketing and business development expenses for the year ended December 31, 2021 were $3.0 million, compared to $1.6 million for 2020, as spending increased due to the initiation of pre-launch activities and the establishment of the Company's new offices in New Jersey, with senior marketing and business development personnel.
- For the year ended December 31, 2021, the Company had a loss attributable to ordinary shares of $42.3 million, or ($2.26) per share, compared to a loss of $39.0 million, or ($4.48) per share, for 2020.

Balance Sheet Highlights

- As of December 31, 2021, the Company had cash and cash equivalents and deposits in the amount of $32.2 million, compared to $66.6 million at December 31, 2020. PolyPid expects that this cash balance will be sufficient to fund operations through the end of 2022.

Conference Call Dial-In & Webcast Information:

Date:	Wednesday, February 9, 2022
Time:	8:30 AM Eastern Time
United States:	+1 877-870-9135
Israel:	+972 1809 213-985
International:	+44 (0) 2071 928338
Conference ID:	6092321
Webcast:	https://edge.media-server.com/mmc/p/fxz7727t

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 pre-determined 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 and sternal surgical site infections (SSIs).
For additional company information, please visit 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, its expectations regarding the interim analysis and its timing, that interim analysis could potentially allow for an early trial stopping if the efficacy results on SSIs exceed the expectations, the pace of enrollment in SHIELD I and SHIELD II trials, the timing of top-line results of the SHIELD I trial, the IND meeting with the FDA supporting a Phase 1/2 clinical trial of OncoPLEX as a potential part of first-line combination therapy for patients newly diagnosed with Glioblastoma Multiform (GBM), the potential of OncoPLEX to help treat brain tumors and have substantial commercial benefit, the Company’s belief that PolyPid is in the strongest operational position in its history, its anticipation that its current balance sheet will be sufficient to complete the SHIELD I study and prepare for the submission of an NDA to the FDA, as well as further advance its OncoPLEX development platform and fund operations through the end of 2022. 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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CONSOLIDATED BALANCE SHEETS

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

	December 31, 2021 (Unaudited)	December 31, 2020 (Audited)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 9,819	$ 4,319
Restricted cash	397	390
Short-term deposits	22,384	40,157
Prepaid expenses and other current assets	2,211	2,334
Total current assets	34,811	47,200
LONG-TERM ASSETS:		
Property and equipment, net	8,761	5,890
Long-term deposits	–	22,120
Other long-term assets	663	637
Total long-term assets	9,424	28,647
Total assets	$ 44,235	$ 75,847

	December 31, 2021 (Unaudited)	December 31, 2020 (Audited)
LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY		

CURRENT LIABILITIES:		
Trade payables	$ 4,136	$ 974
Other payables and accrued expenses	3,670	1,903
Total current liabilities	7,806	2,877
LONG-TERM LIABILITIES:		
Other liabilities	199	193
Total long-term liabilities	199	193
Commitments and Contingencies		
Shareholders' equity (deficit):		
Share capital –		
Ordinary shares with no par value – Authorized: 47,800,000 shares at December 31, 2021 and 2020; Issued and outstanding: 18,756,570 and 18,494,739 shares at December 31, 2021 and 2020, respectively	–	–
Additional paid-in capital	210,847	205,063
Accumulated deficit	(174,617)	(132,286)
Total shareholders' equity	36,230	72,777
Total liabilities shareholders' equity	$ 44,235	$ 75,847

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Year ended December 31,		
	2021 (Unaudited)	**2020 (Audited)**	**2019 (Audited)**
Operating expenses:			
Research and development, net	$ 30,423	$ 16,954	$ 14,083
Marketing and business development	2,973	1,614	887
General and administrative	9,479	7,704	3,590
Operating loss	42,875	26,272	18,560
Financial (income) expense, net	(544)	10,597	(11,655)
Loss	$ 42,331	$ 36,869	$ 6,905
Deemed dividend	–	2,114	–
Loss attributable to Ordinary shares	$ 42,331	$ 38,983	$ 6,905
Basic and diluted loss per Ordinary share	$ 2.26	$ 4.48	$ 23.69
Weighted average number of Ordinary shares used in computing basic and diluted loss per share	18,721,528	9,582,405	562,451

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended December 31,	
	2021 (Unaudited)	**2020 (Unaudited)**
Operating expenses:		
Research and development, net	$ 9,487	$ 5,006
Marketing and business development expenses	1,137	710
General and administrative	2,760	2,172
Operating loss	13,384	7,888
Financial income, net	152	339
Loss	$ 13,232	$ 7,549
Loss attributable to Ordinary shares	$ 1232,3	$ 7,549
Basic and Diluted loss per Ordinary share	$ 0.71	$ 0.41
Weighted average number of Ordinary shares used in computing basic and diluted loss per share	18,756,570	18,494,773