

PolyPid Ltd. Provides Corporate Update and Reports Third Quarter 2020 Financial Results

Over 50% of planned 60 centers for ongoing Phase 3 SHIELD I trial of D-PLEX₁₀₀ in abdominal surgery have received IRB approval

Phase 3 SHIELD II trial advanced; preparations underway to initiate by year-end 2020

Conference Call Scheduled for today at 8:30 a.m. ET

PETAH TIKVA, Israel, Nov. 11, 2020 — PolyPid Ltd. (Nasdaq: PYPD) (the “Company”), a Phase 3 clinical-stage 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 and nine months ended September 30, 2020.

Recent Corporate Highlights:

- Over 50% of planned 60 centers have received institutional review board (IRB) approval for ongoing Phase 3 SHIELD I (**S**urgical site **H**ospital-acquired **I**nfection **P**revention with **L**ocal **D**-plex) trial for D-PLEX₁₀₀ in abdominal surgery (soft tissue). This is the first of two planned Phase 3 clinical trials of D-PLEX₁₀₀, the Company’s lead product candidate for the prevention of surgical site infections (SSIs) in abdominal surgery (soft tissue). The Company plans to enroll 600 – 900 patients undergoing high priority operations in 60 centers in the United States, Europe, and Israel. Following the enrollment of approximately 500 patients, the study design provides for a blinded sample size re-estimation.
- Advanced preparations are underway to initiate SHIELD II, a second Phase 3 trial for D-PLEX₁₀₀ in abdominal surgery, by year-end 2020. This second trial will have broader eligibility criteria, including minimally invasive surgical procedures, and will enroll approximately 900 – 1,400 patients across approximately 60 centers.
- Evaluating EU commercial partnership opportunities for D-PLEX₁₀₀ as part of the Company’s stated commercial strategy.

“We are very encouraged with our strong progress to date, especially readying additional sites to enroll patients in our lead Phase 3 trial, and remain on track for our planned milestones,” said Amir Weisberg, Chief Executive Officer. “We continue to anticipate that top-line results from SHIELD I will be available in the second half of 2021. Moreover, we expect that the initiation of our second Phase 3 pivotal trial, SHIELD II, will occur in late 2020. SHIELD I and SHIELD II will serve as the basis for PolyPid’s first New Drug Application (NDA) submission and, we believe, will support a broad label for D-PLEX₁₀₀ in the prevention of

SSIs.”

“We continue to operate from a strong financial position,” continued Mr. Weisberg. “We expect that our current cash balance will be sufficient to complete SHIELD I and to initiate and conduct SHIELD II, as well as prepare for the submission of an NDA to the U.S. Food and Drug Administration.”

Financial results for three months ended September 30, 2020

- Research and development (R&D) expenses for the three months ended September 30, 2020 were \$4.2 million, compared to \$3.8 million in the same three-month period of 2019, as spending increased due to the initiation of the Phase 3 SHIELD I clinical trial and preparations for the Phase 3 SHIELD II clinical trial.
- General and administrative (G&A) expenses for the three months ended September 30, 2020 were \$2.2 million, compared to \$1.2 million for the same period of 2019, as costs increased due to becoming a publicly-traded company with higher D&O insurance costs and due to an increase in non-cash share-based compensation.
- For the three months ended September 30, 2020, the Company had a net loss attributable to ordinary shares of \$6.5 million, compared to a net loss of \$2.1 million in the three-month period ended September 30, 2019.

Financial results for nine-months ended September 30, 2020

- R&D expenses for the nine months ended September 30, 2020 were \$11.9 million, compared to \$10.8 million in the same nine-month period of 2019, as spending increased due to the initiation of the Phase 3 SHIELD I clinical trial and preparations for the Phase 3 SHIELD II clinical trial.
- G&A expenses for the nine months ended September 30, 2020 were \$5.5 million, compared to \$2.8 million for the same nine-month period of 2019, as costs increased due to becoming a publicly-traded company with higher D&O insurance costs and due to an increase in non-cash share-based compensation.
- For the nine months ended September 30, 2020, the Company had a net loss attributable to ordinary shares of \$31.4 million, compared to a net loss of \$3.0 million, for the nine-month period ended September 30, 2019.

Balance Sheet Highlights

- As of September 30, 2020, the Company had cash and cash equivalents, short-term deposits and long-term deposits in the amount of \$71.8 million, compared to \$26.6 million as of December 31, 2019. This increase reflects the completion of the Company’s IPO in June 2020, which raised net proceeds of \$62.8 million, after underwriting fees and offering expenses. PolyPid expects that this cash balance will be sufficient to fund operations into 2022.

Conference Call Dial-In & Webcast Information

Wednesday, November 11th at 8:30 am Eastern Time

United States: +1 877 870 9135
Israel: +972 1809 213-985
International: +44 (0) 2071 928338
Conference ID: 4557195
Webcast: <https://edge.media-server.com/mmc/p/u49mfor4>

About D-PLEX₁₀₀

PolyPid's lead product candidate, D-PLEX₁₀₀, is a novel product candidate designed to provide local prolonged anti-bacterial activity directly at the surgical site to prevent SSIs. Following the administration of D-PLEX₁₀₀ into the surgical site, the PLEX technology enables a prolonged and constant release of the broad-spectrum antibiotic doxycycline, resulting in high local concentration of the drug for a period of up to four weeks for the prevention of SSIs, with additional potential to treat antibiotic-resistant bacteria at the surgical site. D-PLEX₁₀₀ has received two Qualified Infectious Disease Product (QIDP) designations, as well as two Fast Track designations from the FDA for the prevention of post-abdominal surgery incisional infection and for the prevention of sternal wound infection post-cardiac surgery.

About PolyPid

PolyPid is a Phase 3 clinical-stage biopharmaceutical company focused on developing targeted, locally administered and prolonged-release therapeutics using its proprietary PLEX (Polymer-Lipid Encapsulation matrix) technology. PolyPid's product candidates are designed to address diseases with high unmet medical needs by pairing PLEX with drugs to deliver them directly to precise sites in the body at predetermined release rates and over durations ranging from several days to several months. PolyPid's lead product candidate, D-PLEX₁₀₀, is in Phase 3 clinical trials for the prevention of SSIs in different type of surgeries, including abdominal and open-heart surgery. PolyPid's technology and products are based on the inventions of Dr. Noam Emanuel, the Founder and the Chief Scientific Officer of the company.

For additional company information, visit www.polypid.com.

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 statements relating to its objectives, milestones, plans, and strategies, the expected timing of trials and release of the results thereof, the expected timing of an NDA and other regulatory matters, the research, development, the sufficiency of the Company's cash and use of the Company's platform technologies, technologies, products and product candidates, and all statements (other than statements of historical facts) that address activities, events, or developments that the Company intends, expects, projects, believes, or anticipates will or may occur in the future. 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 prospectus filed pursuant to Rule 424(b)(4), filed with the SEC on June 29, 2020. 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.

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	September 30, 2020 Unaudited	December 31, 2019 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 9,665	\$ 3,924
Restricted cash	378	375
Short-term deposits	34,080	22,685
Prepaid expenses and other receivables	2,504	417
<u>Total</u> current assets	46,627	27,401
LONG-TERM ASSETS:		
Property and equipment, net	6,182	6,121

Long-term deposits	28,068	-
Other long-term assets	221	230
<u>Total</u> long-term assets	34,471	6,351
<u>Total</u> assets	\$ 81,098	\$ 33,752

CONSOLIDATED BALANCE SHEETS

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

	September 30, 2020 Unaudited	December 31, 2019 Audited
LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' DEFICIENCY		
CURRENT LIABILITIES:		
Trade payables	\$ 573	\$ 1,581
Other payables and accrued expenses	1,112	998
<u>Total</u> current liabilities	1,685	2,579
LONG-TERM LIABILITIES:		
Other liabilities	180	251
Convertible preferred shares warrant liability	-	12,241
<u>Total</u> long-term liabilities	180	12,492
COMMITMENTS AND CONTINGENT LIABILITIES		
CONVERTIBLE PREFERRED SHARES:		
Preferred A, A-1, B, B-1, C-1, C-2, D-1, D-3, E and E-1 shares of NIS 0 par value - Authorized: 0 and 17,916,412 shares at September 30, 2020 (unaudited) and December 31, 2019, respectively; Issued and outstanding: 0 and 12,520,977 shares at September 30, 2020 (unaudited) and December 31, 2019, respectively	-	106,313
SHAREHOLDERS' EQUITY (DEFICIENCY):		
Share capital -		
Ordinary shares with no par value - Authorized: 47,800,000 and 22,466,000 shares at September 30, 2020 (unaudited) and December 31, 2019, respectively; Issued and outstanding: 18,494,344 and 562,748 shares at September 30, 2020 (unaudited) and December 31, 2019, respectively		
Additional paid-in capital	203,970	5,671
Accumulated deficit	(124,737)	(93,303)
<u>Total</u> shareholders' equity (deficiency)	79,233	(87,632)
<u>Total</u> liabilities, convertible preferred shares and shareholders' equity (deficiency)	\$ 81,098	\$ 33,752

CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands

	Three months ended September 30, 2020		Nine months ended September 30, 2020		2019			
	Unaudited							
Operating expenses:								
Research and development, net	\$	4,176	\$	3,789	\$	11,948	\$	10,769
Marketing and business development expenses		323		274		904		571
General and administrative		2,177		1,190		5,532		2,812
Operating loss		6,676		5,253		18,384		14,152
Financial (income) expense, net		(218)		(3,145)		10,936		(11,107)
Net loss (profit)	\$	6,458	\$	2,108	\$	29,320	\$	3,045
Deemed dividend		-		-		2,114		-
Net loss (profit) attributable to Ordinary shares	\$	6,458	\$	2,108	\$	31,434	\$	3,045
Basic and diluted net loss per Ordinary share	\$	0.35	\$	6.94	\$	4.78	\$	13.38
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share		18,415,231		562,597		6,578,969		562,354

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