

PolyPid Ltd. Provides Corporate Update and Reports Fourth Quarter and Full-Year 2020 Financial Results

- *100 Patients Enrolled into Phase 3 SHIELD I and SHIELD II Trials of D-PLEX₁₀₀ in Abdominal Surgery*
 - *Recently Initiated Phase 3 SHIELD II Trial*
- *Granted Breakthrough Therapy Designation from FDA for D-PLEX₁₀₀ for Prevention of SSIs in Patients Undergoing Elective Colorectal Surgery*
 - *Conference Call Scheduled for Today at 8:30 AM ET*

PETAH TIKVA, Israel, Feb. 10, 2021 — PolyPid Ltd. (Nasdaq: PYPD), a late-stage biopharma company aiming to improve surgical outcomes through locally administered, controlled, extended-release therapeutics, today provided a corporate update and reported financial results for the three months and full-year ended December 31, 2020.

Recent Corporate Highlights:

- Enrolled 100 patients in total into the two ongoing Phase 3 trials, SHIELD I and SHIELD II. SHIELD I (**S**urgical site **H**ospital-acquired **I**nfection **P**r**E**vention with **L**ocal **D**-plex) trial is the first of two 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.
- SHIELD II, the second of two Phase 3 clinical trials for D-PLEX₁₀₀ in abdominal surgery (soft tissue), will enroll approximately 900-1,400 patients across the same number of centers as SHIELD I, and has broader eligibility criteria, including minimally invasive surgical procedures.
- Granted Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for D-PLEX₁₀₀ for the prevention of SSIs in patients undergoing elective colorectal surgery.
- Announced positive preclinical data from the Company's new OncoPLEX intra-tumoral cancer therapy program. OncoPLEX utilizes PolyPid's PLEX technology in the intra-operative tumor resection setting to provide prolonged and controlled exposure to docetaxel within the tumor resected site, which is important to prevent the local tumor reoccurrence and the potential spreading of cancer cells. In a syngeneic mouse model for solid tumors of colon carcinoma using cancer cells highly resistant to docetaxel, a single local application of OncoPLEX at the intra-operative setting post tumor resection showed improved overall survival and significantly less tumor recurrence, and reduced systemic toxicity compared to the group treated with six subsequent cycles of systemic

docetaxel treatment with 2-4 days gap between cycles.

- Hosted a key opinion leader webinar on D-PLEX₁₀₀ for the prevention of SSIs. The webinar featured Hartzell V. Schaff, MD, Mayo Clinic, Anthony J. Senagore, MD, formerly of UTMB at Galveston, and Oded Zmora, MD, Shamir Medical Center, Israel, who discussed the burden and challenges related to SSIs post- colorectal and cardiovascular surgeries and the opportunity for D-PLEX₁₀₀ to change the current therapeutic landscape. A recording of the KOL event can be found on PolyPid's website <http://www.polypid.com>

"2020 was truly a transformative year for PolyPid," said Amir Weisberg, Chief Executive Officer. "Most importantly, our Phase 3 program for D-PLEX₁₀₀ for the prevention of SSIs is progressing as planned. We are excited to report that we have now enrolled 100 patients collectively in our two Phase 3 programs, with the vast majority of those subjects in our ongoing SHIELD I trial. We continue to anticipate top-line results from SHIELD I by year-end 2021. Moreover, our second Phase 3 trial in abdominal surgery, SHIELD II, which was recently initiated, is advancing as anticipated. We also received regulatory validation of the potential of D-PLEX₁₀₀ to demonstrate substantial improvement in the prevention of SSIs in complex surgical settings when we were granted Breakthrough Therapy Designation from the FDA for D-PLEX₁₀₀ in late 2020.

"We believe our innovative PLEX technology has potential in multiple areas of medicine where locally administered extended-release and controlled therapies are most beneficial, including oncology," continued Mr. Weisberg. "To this end, the positive preclinical data demonstrated with OncoPLEX support our belief that direct local application of this promising adjuvant therapy in the intra-operative tumor resection setting has the potential to overcome the chemotherapeutic drug resistance seen in many cancer patients across different solid tumors. We look forward to further advancing our OncoPLEX development program and potentially initiating a Phase 1 clinical trial in 2022.

"We also continue to operate from a position of significant financial strength. Our successfully completed IPO on the Nasdaq in June 2020 that generated \$62.8 million in net proceeds helped extend our cash runway into 2022. We are well-positioned to complete the SHIELD I study and conduct SHIELD II, as well as prepare for the submission of a New Drug Application to the FDA. Lastly, we are proud and delighted to update that PolyPid recently joined the ARK Israeli Innovative Technology ETF designed to track listed Israeli companies who are causing disruptive innovation in their field, including life sciences," concluded Mr. Weisberg.

Financial results for three months ended December 31, 2020

- Research and development (R&D) expenses for the three months ended December 31, 2020 were \$5.0 million, compared to \$3.3 million in the same three-month period of 2019, as spending increased due to the initiation of SHIELD I and SHIELD II Phase 3

clinical trials in abdominal surgery.

- General and administrative (G&A) expenses for the three months ended December 31, 2020 were \$2.2 million, compared to \$0.8 million for the same period of 2019, as costs increased due to being a publicly-traded company with higher D&O insurance costs, and an increase in non-cash share-based compensation.
- Marketing and Business Development expenses for the three months ended December 31, 2020 were \$0.7million, compared to \$0.3 million for the same period of 2019, as spending increased mainly due to an increase in marketing and business development personnel in our new offices in New Jersey.
- For the three months ended December 31, 2020, the Company had a net loss attributable to ordinary shares of \$7.5million, compared to a net loss of \$3.9 million, in the three-month period ended December 31, 2019.

Financial results for the full-year ended December 31, 2020

- R&D expenses for the year ended December 31, 2020 were \$17.0 million, compared to \$14.1 million in the same period of 2019, 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, 2020 were \$7.7 million, compared to \$3.6 million for the same period of 2019, as costs increased due to being a publicly-traded company with higher D&O insurance costs, and an increase in non-cash share-based compensation.
- Marketing and Business Development expenses for the year ended December 31, 2020 were \$1.6 million, compared to \$0.9 million for the same period of 2019, as spending increased due to the establishment of our new offices in New Jersey, United states, with senior marketing and business development personnel.
- For the year ended December 31, 2020, the Company had a net loss attributable to ordinary shares of \$39.0 million, or (\$4.07) per diluted share, compared to a net loss of \$6.9 million, or (\$23.69) per diluted share, for the year ended December 31, 2019.

Balance Sheet Highlights

- As of December 31, 2020, the Company had cash and cash equivalents, short-term deposits and long-term deposits in the amount of \$66.6 million, compared to \$26.6 million at December 31, 2019. This 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:

Date: Wednesday, February 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: 1468387
Webcast: <https://edge.media-server.com/mmc/p/cx5so6fj>

About D-PLEX₁₀₀

PolyPid's lead product candidate, D-PLEX₁₀₀, is a novel drug product candidate designed to provide local prolonged and controlled 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 four weeks for the prevention of SSIs, with additional potential to prevent SSIs caused by antibiotic-resistant bacteria at the surgical site. D-PLEX₁₀₀ has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX₁₀₀ has also received two Qualified Infectious Disease Product (QIDP) designations as well as two Fast Track designations for the prevention of post-abdominal surgery incisional infection and for the prevention of sternal wound infection post-cardiac surgery.

About PolyPid

PolyPid Ltd. (Nasdaq: PYPD) is a late-stage 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-PLEX₁₀₀ 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 statements relating to the expected timing of trials and release of the results thereof, the potential benefits of PLEX and OncoPLEX, the sufficiency of the Company's cash to fund future operations, 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.

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.

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	December 31,	
	2020	2019
	(Unau	(Audit
	dited)	ed)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 4,319	\$ 3,924
Restricted cash	390	375
	40,15	22,68
Short-term deposits	7	5
Prepaid expenses and other receivables	2,729	417
	47,59	27,40
<u>Total</u> current assets	5	1
Long-term assets:		
Property and equipment, net	5,890	6,121
	22,12	
Long-term deposits	0	-
Other long-term assets	242	230
	28,25	
<u>Total</u> long-term assets	2	6,351

	75,84	33,75
Total assets	\$ 7	\$ 2
CURRENT LIABILITIES:		
Trade payables	\$ 974	\$ 1,581
Other payables and accrued expenses	1,903	998
<u>Total current liabilities</u>	2,877	2,579
Long-term liabilities:		
Other liabilities	193	251
		12,24
Warrants to convertible preferred shares	-	1
		12,49
<u>Total long-term liabilities</u>	193	2
Commitments and Contingencies		
Convertible preferred shares:		
Preferred A, A-1, B, B-1, C-1, C-2, D-1, D-3, E and E-1 shares with no par value - Authorized: 0 and 17,916,412 shares at December 31, 2020 and 2019, respectively; Issued and outstanding: 0 and 12,520,977 shares at December 31, 2020 and 2019, respectively.	-	106,3 13
Shareholders' equity (deficit):		
Share capital -		
Ordinary shares with no par value - Authorized: 47,800,000 and 22,520,977 shares at December 31, 2020 and 2019, respectively; Issued and outstanding: 18,494,739 and 562,748 shares at December 31, 2020 and 2019, respectively.	-	-
	205,0	
Additional paid-in capital	63	5,671
	(132,	(93,3
Accumulated deficit	286)	03)
	72,77	(87,6
<u>Total shareholders' equity (deficit)</u>	7	32)
	75,84	33,75
Total liabilities, convertible preferred shares and shareholders' equity (deficit)	\$ 7	\$ 2

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Year ended	
	December 31,	
	2020	2019
	(Unaudited)	(Audited)
)	
Operating expenses:		
Research and development, net	\$ 16,954	\$ 14,083
Marketing and business development expenses	1,614	887
General and administrative	7,704	3,590
Operating loss	26,272	18,560
Financial (income) expense, net	10,597	(11,655)

Net loss	\$ 36,869	\$ 6,905
Deemed dividend	2,114	-
Net loss attributable to Ordinary shares	\$ 38,983	\$ 6,905
Basic and Diluted net loss per Ordinary share	\$ 4.07	\$ 23.69
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	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,	
	2020	2019
	(Unaudited)	(Unaudited)
Operating expenses:		
Research and development, net	\$ 5,006	\$ 3,314
Marketing and business development expenses	710	316
General and administrative	2,172	778
Operating loss	7,888	4,408
Financial income, net	339	548
Net loss	\$ 7,549	\$ 3,860
Deemed dividend	-	-
Net loss attributable to Ordinary shares	\$ 7,549	\$ 3,860
Basic and Diluted net loss per Ordinary share	\$ 0.41	\$ 6.86
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	18,494,773	562,748

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