

## **PolyPid Ltd. Reports Second Quarter 2021 Financial Results and Provides Corporate Update**

*Recruitment Progressing as Planned with Over 300 Patients Enrolled into Phase 3 SHIELD I Trial of D-PLEX<sub>100</sub> in Abdominal Surgery*

*FDA Agreed that a Single Pivotal Phase 3 Study is Sufficient for Potential Approval of D-PLEX<sub>100</sub> for the Prevention of Surgical Site Infections in Colorectal Surgery*

*Brain Tumors Selected as the Initial Indication for Company's OncoPLEX Intra-tumoral Cancer Therapy Program*

*Conference Call Scheduled for Today at 8:30 AM ET*

PETACH TIKVA, Israel, Aug. 11, 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 and six months ended June 30, 2021.

### **Recent Corporate Highlights:**

- Recruitment progressing as planned with over 300 patients enrolled into the ongoing Phase 3 SHIELD I (**S**urgical site **H**ospital-acquired **I**nfection **P**revention with **L**ocal **D**-plex) study, the first of two ongoing Phase 3 clinical trials of D-PLEX<sub>100</sub> for the prevention of surgical site infections (SSIs) in abdominal surgery (soft tissue).
- The Company plans to enroll 616-900 patients 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.
- Received written responses from the U.S. Food and Drug Administration (FDA) to a Type B meeting request submitted following receipt of Breakthrough Therapy Designation for D-PLEX<sub>100</sub>, regarding the development plan for the Company's lead product candidate, D-PLEX<sub>100</sub>. The FDA indicated that PolyPid's proposal for a single Phase 3 pivotal study, SHIELD I, provided the study results are adequate, would provide sufficient evidence of clinical efficacy and safety to support approval of D-PLEX<sub>100</sub> for the prevention of SSIs in colorectal surgery.
- Enrollment is also advancing as anticipated in SHIELD II, the second of two Phase 3 clinical trials for D-PLEX<sub>100</sub> in abdominal surgery (soft tissue). SHIELD II will enroll approximately 900-1,400 patients across 60 centers in the United States, Europe and Israel and has broader eligibility criteria than SHIELD I, including minimally invasive surgical procedures.
- The Company identified brain tumors as the initial target indication for OncoPLEX intra-

tumoral cancer therapy program. OncoPLEX utilizes PolyPid's PLEX technology in the intra-operative tumor resection setting to provide local, prolonged and controlled exposure to docetaxel within the residual tumor site, which is important to potentially reduce local tumor recurrence, the potential spreading of cancer cells to other organs and ultimately improve overall survival of the patients.

- Appointed leading colorectal surgeon, Anthony J. Senagore, M.D., as Senior Medical Director. Dr. Senagore has a long track record of academic surgery practice and significant experience in healthcare start-up companies. He will be responsible for developing PolyPid's medical infrastructure in the United States, and will contribute to the Company's NDA submission and commercial launch of D-PLEX<sub>100</sub>.

"We have recently achieved significant progress in advancing our multiple development programs, and in continuing our evolution towards becoming a commercial stage company," said Amir Weisberg, PolyPid's Chief Executive Officer. "Most importantly, the recent communication from the FDA regarding SHIELD I reduces our anticipated costs for the program, and provides us with additional financial flexibility overall. In addition, we are excited to report that we have now enrolled over 300 patients in the SHIELD I trial."

"We are also diligently working to further progress our promising OncoPLEX platform in oncology applications, which continues to advance expeditiously," continued Mr. Weisberg. "Our initial target indication for OncoPLEX will be brain tumors, the most aggressive and deadly type of cancer for which patients currently have almost no meaningful treatment options."

"Our vigorous clinical development program continues to be supported by a strong balance sheet. With a cash runway that extends into the second half of 2022, we remain well-positioned to complete the SHIELD I study, prepare for the submission of an NDA to the FDA and further advance our OncoPLEX program with our current cash resources," concluded Mr. Weisberg.

### **Financial results for three months ended June 30, 2021**

- Research and development expenses for the three months ended June 30, 2021 were \$7.4 million, compared to \$4.3 million in the same three-month period of 2020, as spending increased due to the ongoing SHIELD I and SHIELD II Phase 3 clinical trials in abdominal surgery.
- Marketing and business development expenses for the second quarter of 2021 were \$0.7 million, compared to \$0.3 million for the same period of 2020, as spending 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 second quarter of 2021 were \$2.4 million, compared to \$2.6 million in the prior year period. The decrease was due to lower non-

cash share based compensation expenses.

- For the three months ended June 30, 2021, the Company had a net loss attributable to ordinary shares of \$10.5 million, compared to a net loss of \$19.1 million in the three-month period ended June 30, 2020.
- As of June 30, 2021, the Company had cash, cash equivalents, short-term deposits, and long-term deposits in the amount of \$52.9 million, compared to \$66.6 million at December 31, 2020. PolyPid continues to expect that its cash on hand will be sufficient to fund operations into the second half of 2022.

### **Financial results for the six months ended June 30, 2021**

- Research and development expenses for the six months ended June 30, 2021 were \$13.5 million, compared to \$7.8 million in the same six-month period of 2020, as spending increased due to the ongoing SHIELD I and SHIELD II Phase 3 clinical trials in abdominal surgery.
- Marketing and business development expenses for the six months ended June 30, 2021 were \$1.4 million, compared to \$0.6 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 six months ended June 30, 2021 were \$4.6 million, compared to \$3.4 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 six months ended June 30, 2021, the Company had a net loss attributable to ordinary shares of \$19.2 million, as compared to a net loss of \$25.0 million in the six months ended June 30, 2020.

### **Conference Call Dial-In & Webcast Information:**

Date: Wednesday, August 11, 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: 1663949  
Webcast: <https://edge.media-server.com/mmc/p/2eu7k7nj>

### **About D-PLEX<sub>100</sub>**

PolyPid's lead product candidate, D-PLEX<sub>100</sub>, 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-PLEX<sub>100</sub> into the surgical site, the PLEX

technology enables a prolonged and continuous 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-PLEX<sub>100</sub> 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-PLEX<sub>100</sub> 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-PLEX<sub>100</sub> 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](http://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 recruitment for trials, 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 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.

**Contacts:**

PolyPid, Ltd.

Dikla Czaczkes Akselbrad

EVP & CFO

Tel: +972-747195700

**Investors:**

Bob Yedid

LifeSci Advisors

646-597-6989

Bob@LifeSciAdvisors.com

**Media :**

Nechama Feuerstein

551-444-0784

Nechama.Feuerstein@finnpartners.com

**CONSOLIDATED BALANCE SHEETS**

**U.S. dollars in thousands**

	<b>June 30,</b>	<b>December</b>
	<b>2021</b>	<b>31,</b>
	<b>Unaudited</b>	<b>2020</b>
		<b>Audited</b>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 7,448	\$ 4,319
Restricted cash	388	390
Short-term deposits	40,399	40,157
Prepaid expenses and other current assets	937	2,334
Total current assets	49,172	47,200

<b>LONG-TERM ASSETS:</b>			
Property and equipment, net		5,734	5,890
Long-term deposits		5,059	22,120
Other long-term assets		1,431	637
Total long-term assets		12,224	28,647
Total assets		\$ 61,396	\$ 75,847
		<b>June 30,</b>	<b>December 31,</b>
		<b>2021</b>	<b>2020</b>
		<b>Unaudited</b>	<b>Audited</b>

**LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY**

<b>CURRENT LIABILITIES:</b>			
Trade payables		\$ 1,756	\$ 974
Other payables and accrued expenses		2,565	1,903
Total current liabilities		4,321	2,877
<b>LONG-TERM LIABILITIES:</b>			
Other liabilities		190	193
Total long-term liabilities		190	193
<b>COMMITMENTS AND CONTINGENCIES</b>			
<b>SHAREHOLDERS' EQUITY:</b>			
Share capital -			
Ordinary shares with no par value - Authorized: 47,800,000 shares at June 30, 2021 (unaudited) and December 31, 2020; Issued and outstanding: 18,756,570 and 18,494,739 shares at June 30, 2021 (unaudited) and December 31, 2020, respectively		-	-
Additional paid-in capital		208,335	205,063
Accumulated deficit		(151,450)	(132,286)
Total shareholders' equity		56,885	72,777
Total liabilities and shareholders' equity		\$ 61,396	\$ 75,847

**CONSOLIDATED STATEMENTS OF OPERATIONS**

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

	<b>Six months ended June 30,</b>		<b>Three months ended June 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
	<b>Unaudited</b>			
<b>Operating expenses:</b>				
Research and development, net	\$ 13,460	\$ 7,772	\$ 7,442	\$ 4,339
Marketing and business development expenses	1,391	581	739	305
General and administrative	4,576	355,3	2,449	2,628
Operating loss	19,427	11,708	10,630	7,272

Financial (income) expense, net	(263)	11,154	(153)	9,721
Net loss	19,164	22,862	10,477	16,993
Deemed dividend	-	114,2	-	114,2
Net loss attributable to Ordinary shares	\$ 19,164	\$ 24,976	\$ 10,477	\$ 19,107
Basic and diluted net loss per Ordinary share	\$ 1.03	\$ 37.87	\$ 0.56	\$ 25.30
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	18,685,906	659,551	18,747,967	755,289

