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

Initiated Phase 3 SHIELD I Trial for D-PLEX$_{100}$ in Abdominal Surgery and Received Fast Track Designation for D-PLEX$_{100}$ from FDA

Presented Positive Phase 2 Results of D-PLEX$_{100}$ for Prevention of Surgical Site Infections in Abdominal Surgery at ASCRS Meeting

Completed Initial Public Offering in U.S., Raising Net Proceeds of $62.8 Million

Conference Call scheduled for Wednesday, August 19 at 8:30 AM Eastern Time

PETAH TIKVA, Israel, Aug. 19, 2020 — PolyPid Ltd. (Nasdaq: PYPD), 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 six months ended June 30, 2020.

Recent Corporate Highlights:

- Enrolled and randomized the first patient in the Phase 3 SHIELD I (**S**urgical site **H**ospital-acquired **I**nfection Pr**E**vention with **L**ocal **D**-plex) trial. This is the first of two planned Phase 3 clinical trials of the Company's lead product candidate, D-PLEX$_{100}$, for the prevention of surgical site infections (SSIs) post-abdominal surgery (soft tissue). The Company plans to enroll 600-900 patients among 60 centers in the U.S., Europe and Israel. Following the enrollment of the first 500 patients, the study design provides for a blinded sample size re-estimation. The second Phase 3 clinical trial in the same indication, SHIELD II, is expected to begin in late 2020.

- Received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for D-PLEX$_{100}$ for the prevention of post abdominal surgery incisional infection.

- Presented positive Phase 2 clinical trial data of D-PLEX$_{100}$ for the prevention of SSIs in abdominal surgery at the American Society of Colon and Rectal Surgeons (ASCRS) 2020 Annual Scientific Conference Recorded Sessions. The data were presented via a video session based on the accepted abstract entitled, "*Local Constant Prolonged Release of an Antibiotic for the Prevention of Surgical Site Infections (SSI) Post Colorectal Resection Abdominal Surgeries*."

- Completed an initial public offering (IPO) on the Nasdaq Global Market through which the Company sold 4,312,500 ordinary shares at a price to the public of $16.00 per share, raising $62.8 million of net proceeds.

“We have recently completed a truly transformational period in PolyPid’s corporate evolution,” said Amir Weisberg, Chief Executive Officer. “We made significant progress in advancing our promising clinical development program for D-PLEX$_{100}$ as highlighted by the initiation of our first Phase 3 clinical trial in abdominal surgery. This key milestone represented a significant step toward furthering our U.S. regulatory approval strategy and our objective to provide a novel solution for surgeons and their patients as expeditiously as possible. Moreover, we were excited to recently receive Fast Track Designation for D-PLEX$_{100}$, an important regulatory validation of our innovative PLEX technology and the high clinical unmet need that currently exists in preventing surgical site infections in complex surgical settings, such as abdominal surgeries.”

Mr. Weisberg added, “We were also proud to complete our IPO on the Nasdaq Global Market in June, successfully raising $62.8 million of net proceeds. Our IPO and listing increase our visibility in the U.S. capital markets, and provides us with critical growth capital to continue the clinical development of D-PLEX$_{100}$ through both Phase 3 trials in abdominal surgery, begin our rolling New Drug Application submission and initiate our commercial preparations for this compelling asset.”

Financial results for three months ended June 30, 2020

- For the three months ended June 30, 2020, the Company had a net loss of $17 million, compared to a net profit of $0.3 million in the three-month period ended June 30, 2019.
- Research and development (R&D) expenses for the three months ended June 30, 2020 were $4.3 million, compared to $3.5 million in the same three-month period of 2019, as spending increased due to the preparation of the Phase 3 SHIELD I clinical trial of D-PLEX$_{100}$ for the prevention of SSIs in abdominal surgery.
- General and administrative (G&A) expenses for the three months ended June 30, 2020 were $2.9 million, compared to $1.2 million for the same period of 2019, as costs increased due to the Company’s IPO and an increase in non-cash share-based compensation.
- GAAP net loss attributable to ordinary shares for the three months ended June 30, 2020 was $19.1 million, compared to GAAP net profit of $0.3 million for the three months ended June 30, 2019.
- Non-GAAP net loss attributable to ordinary shares for the three months ended June 30, 2020 was $4.8 million compared to non-GAAP net loss of $4.3 million in the prior year period. A reconciliation between GAAP net loss and non-GAAP net loss for the three-month periods ended June 30, 2020 and 2019 is provided in the financial results that are part of this news release. The difference between GAAP to non-GAAP net loss attributable to ordinary shares is mainly due to the revaluation of our convertible

preferred share warrant liability following the increase in fair value due to the IPO price.

Financial results for six months ended June 30, 2020

- For the six months ended June 30, 2020, the Company had a net loss of $22.9 million, compared to a net loss of $0.9 million for the six-month period ended June 30, 2019.
- R&D expenses for the six months ended June 30, 2020 were $7.8 million, compared to $7.0 million in the same six-month period of 2019, as spending increased due to the preparation of the Phase 3 SHIELD I clinical trial.
- G&A expenses for the six months ended June 30, 2020 were $3.9 million, compared to $1.9 million for the same six-month period of 2019, as costs increased due to the Company's IPO and an increase in non-cash share-based compensation.
- GAAP net loss attributable to ordinary shares for the six months ended June 30, 2020 was $25.0 million, compared to GAAP net loss of $0.9 million for the six months ended June 30, 2019.
- Non-GAAP net loss attributable to ordinary shares for the six months ended June 30, 2020 was $8.7 million compared to non-GAAP net loss of $8.1 million in the prior year period. A reconciliation between GAAP net loss and non-GAAP net loss for the six-month periods ended June 30, 2020 and 2019 is provided in the financial results that are part of this release. The difference between GAAP to non-GAAP net loss attributable to ordinary shares is mainly due to the revaluation of our convertible preferred share warrant liability following the increase in fair value due to the IPO price.

Balance Sheet Highlights

- As of June 30, 2020, the Company had cash and cash equivalents, restricted cash and short-term deposits in amount of $81.7 million, compared to $27.0 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 this cash balance is sufficient to fund operations through the second half of 2022.

Conference Call & Webcast
Wednesday, August 19 @ 8:30 am Eastern Time
Domestic: 877-870-9135
International: 44 (0) 2071 928338
Passcode: 6389197
Webcast: https://edge.media-server.com/mmc/p/v669bncn

About D-PLEX$_{100}$

PolyPid's lead product candidate, D-PLEX$_{100}$, 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-PLEX$_{100}$ 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-PLEX$_{100}$ has received two Qualified Infectious Disease Product (QIDP) 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-PLEX$_{100}$, is in Phase 3 clinical trials for the prevention of sternal SSIs and abdominal SSIs. 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**.

CONSOLIDATED BALNCE SHEET
(U.S. dollars in thousands)

	June 30, 2020 Unaudited	December 31, 2019 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 69,282	$ 3,924
Restricted cash	376	375
Short-term deposits	12,054	22,685
Prepaid expenses and other receivables	430	417
Total current assets	82,142	27,401
LONG-TERM ASSETS:		
Property and equipment, net	6,231	6,121
Other long-term assets	227	230
Total long-term assets	6,458	6,351

Total assets	$ 88,600	$ 33,752
LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIENCY)		
CURRENT LIABILITIES:		
Trade payables	$ 630	$ 1,581
Other payables and accrued expenses	3,312	998
Total current liabilities	3,942	2,579
LONG-TERM LIABILITIES:		
Other liabilities	179	251
Convertible preferred shares warrant liability	–	12,241
Total long-term liabilities	179	12,492
COMMITMENTS AND CONTINGENT LIABILITIES		
CONVERTIBLE PREFERRED SHARES:	–	106,313
SHAREHOLDERS' EQUITY (DEFICIENCY):		
Share capital	–	–
Additional paid-in capital	202,758	5,671
Accumulated deficit	(118,279)	(93,303)
Total shareholders' equity (deficiency)	84,479	(87,632)
Total liabilities, convertible preferred shares and shareholders' equity (deficiency)	$ 88,600	$ 33,752

CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands (except share and per share data))

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
	Unaudited			
Operating expenses:				
Research and development, net	$ 4,339	$ 3,503	$ 7,772	$ 6,980
General and administrative	2,933	1,199	3,936	1,919
Operating loss	7,272	4,702	11,708	8,899
Financial (income) expense, net	9,721	(4,995)	11,154	(7,962)
Net loss (profit)	$ 16,993	$ (293)	$ 22,862	$ 937
Deemed dividend	2,114	–	2,114	–
Net loss (profit) attributable to Ordinary shares	$ 19,107	$ (293)	$ 24,976	$ 937
Basic profit (net loss) per Ordinary share	(25.30)	0.52	(37.87)	(6.43)

Diluted net loss per Ordinary share	(25.30)	(1.10)	(37.87)	(6.43)
Weighted average number of Ordinary shares used in computing basic net loss per share	755,289	562,270	659,551	562,229
Weighted average number of Ordinary shares used in computing diluted net loss per share	755,289	614,515	659,551	562,229

RECONCILIATION OF GAAP TO NON-GAAP NET LOSS (INCOME) AND NET LOSS (INCOME) PER SHARE
(U.S. dollars in thousands (except per share data))

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
	Unaudited			
GAAP net loss (profit) attributable to Ordinary shares:	$ 19,107	$ (293)	$ 24,976	$ 937
Add:				
Deemed dividend	2,114	–	2,114	–
Depreciation and amortization	254	208	498	398
Share-based compensation	2,068	204	2,257	391
Warrants change in fair value	9,861	(4,991)	11,373	(7,933)
Non-GAAP net loss attributable to Ordinary shares	$ 4,810	$ 4,286	$ 8,734	$ 8,081
Basic and diluted net loss per Ordinary share	6.37	7.62	13.24	14.37
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	755,289	562,270	659,551	562,229

Use of Non-GAAP Financial Results

In addition to disclosing financial results calculated in accordance with United States generally accepted accounting principles (GAAP), this press release contains non-GAAP financial measures of net loss for the period that excludes the effect of stock-based compensation expenses, change in fair value of warrant liability, deemed dividend and depreciation and amortization. The company’s management believes the non-GAAP financial information provided in this release is useful to investors’ understanding and assessment of the company’s ongoing operations. Management also uses both GAAP and non-GAAP information in evaluating and operating business internally and as such deemed it important to provide all this information to investors. The non-GAAP financial measures disclosed by the company should not be considered in isolation or as a substitute for, or superior to, financial measures calculated in accordance with GAAP, and the financial results calculated in

accordance with GAAP and reconciliations to those financial statements should be carefully evaluated.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995 and other Federal 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, PolyPid is using forward-looking statements in this press release when it discusses the expected timing of Phase 3 trials, potential of D-PLEX$_{100}$ to prevent SSIs, furthering U.S. regulatory approval strategy, ability to provide a novel solution for surgeons and their patients as expeditiously as possible, sufficiency of capital to continue the clinical development of D-PLEX$_{100}$ through both Phase 3 trials and through the second half of 2022, to begin a rolling New Drug Application submission and advance commercial preparations. Because such statements deal with future events and are based on PolyPid’s current expectations, they are subject to various risks and uncertainties. Also, while PolyPid has received Fast Track Designation for D-PLEX$_{100}$ for the prevention of SSIs, it cannot guarantee that it will be able to maintain such designation due to reasons within our outside of its control. Actual results, performance or achievements of PolyPid could differ materially from those described in or implied by the statements in this press release. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, including those discussed under the heading “Risk Factors” in PolyPid’s final prospectus dated June 25, 2020, filed pursuant to Rule 424(b)(4) with the Securities and Exchange Commission (“SEC”), and in any subsequent filings with the SEC. Except as otherwise required by law, PolyPid undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. 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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