

PolyPid Ltd. Reports First Quarter 2021 Financial Results and Provides Corporate Update

Recruitment Progressing as Planned with Nearly 200 Patients Enrolled into Phase 3 SHIELD I Trial of D-PLEX₁₀₀ in Abdominal Surgery

Recruitment Rate in SHIELD I trial Doubled in the Last Three Weeks

Manufacturing Facility Now Fully Scaled Up and Capable of Supporting at Least First 30 Months of Anticipated Commercial Demand for D-PLEX₁₀₀

Conference Call Scheduled for Today at 8:30 AM ET

PETAH TIKVA, Israel, May 12, 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 ended March 31, 2021.

Recent Corporate Highlights:

- Recruitment progressing as planned with nearly 200 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 the Company's lead product candidate D-PLEX₁₀₀, for the prevention of surgical site infections (SSIs) in abdominal surgery (soft tissue).
- The Company plans to enroll 616-900 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.
- Enrollment is also advancing as anticipated in SHIELD II, the second of two Phase 3 clinical trials for D-PLEX₁₀₀ 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, including minimally invasive surgical procedures.
- Manufacturing facility is now fully scaled up and capable of producing the first 30 months of anticipated commercial demand for D-PLEX₁₀₀.
- Continued to generate compelling 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 local tumor recurrence and the potential spreading of cancer cells.

“We have made significant progress advancing our promising development programs and continuing our evolution towards successful commercialization,” said Amir Weisberg, PolyPid’s Chief Executive Officer. “Our robust Phase 3 trials for D-PLEX₁₀₀ for the prevention of SSIs, SHIELD I and SHIELD II, continue to enroll patients at the expected rate. To this end, we are thrilled to report that the recruitment rate in SHIELD I trial doubled in the last three weeks and that we have now enrolled nearly 200 patients in the trial. We continue to anticipate the availability of top-line results for SHIELD I by year-end 2021 and top-line results from SHIELD II by the end of next year.”

“We also continue to generate additional compelling preclinical data with OncoPLEX, including positive safety data in a promising solid tumor indication,” continued Mr. Weisberg. “We are excited to further progress our OncoPLEX development program and potentially initiate a first-in-man Phase 1 clinical trial in 2022.”

“Our strong balance sheet continues to drive our robust clinical development program. Our cash runway extends into 2022 and we remain 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 with cash on hand,” concluded Mr. Weisberg.

Financial results for three months ended March 31, 2021

- Research and development expenses for the three months ended March 31, 2021 were \$6.0 million, compared to \$3.4 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 three months ended March 31, 2021 were \$0.7 million, compared to \$0.3 million for the same period of 2020, as spending increased primarily due to additional marketing and business development personnel hired in the Company’s New Jersey offices.
- General and administrative expenses for the three months ended March 31, 2021 were \$2.1 million, compared to \$0.7 million for the same period of 2020. This increase was due to the increase in costs due to the Company’s status as a publicly traded company with higher D&O insurance costs and an increase in non-cash share-based compensation.
- For the three months ended March 31, 2021, the Company had a net loss attributable to ordinary shares of \$8.7 million, compared to a net loss of \$5.9 million, in the three-month period ended March 31, 2020.
- As of March 31, 2021, the Company had cash and cash equivalents, short-term deposits and long-term deposits in the amount of \$61.4 million, compared to \$66.6 million at December 31, 2020. PolyPid continues to expect that this cash balance will be sufficient to fund operations into 2022.

Conference Call Dial-In & Webcast Information:

Date: Wednesday, May 12, 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: 7258907
Webcast: <https://edge.media-server.com/mmc/p/j63c5h43>

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 recruitment for trials, timing of trials and release of the results thereof, the

capacity of the Company's manufacturing facility, 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.

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CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

| March 31, | December |
|----------------------------------|-----------------|
| 2021 | 31, |
| Unaudited | 2020 |
| Audited | |
| U.S. dollars in thousands | |

| ASSETS | | | |
|--|----|--------|----------|
| CURRENT ASSETS: | | | |
| Cash and cash equivalents | \$ | 5,993 | \$ 4,319 |
| Restricted cash | | 385 | 390 |
| Short-term deposits | | 43,279 | 40,157 |
| Prepaid expenses and other receivables | | 1,286 | 2,334 |
| <u>Total</u> current assets | | 50,943 | 47,200 |
| LONG-TERM ASSETS: | | | |
| Property and equipment, net | | 6,023 | 5,890 |
| Long-term deposits | | 12,100 | 22,120 |
| Other long-term assets | | 773 | 637 |
| <u>Total</u> long-term assets | | 18,896 | 28,647 |
| Total assets | | 69,839 | 75,847 |

CONSOLIDATED BALANCE SHEETS

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

| | March 31, | December 31, |
|---|----------------------------------|---------------------|
| | 2021 | 2020 |
| | Unaudited | Audited |
| | U.S. dollars in thousands | |
| LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Trade payables | \$ 1,468 | \$ 974 |
| Other payables and accrued expenses | 2,038 | 1,903 |
| <u>Total</u> current liabilities | 3,506 | 2,877 |
| Long-term liabilities: | | |
| Other liabilities | 186 | 193 |
| <u>Total</u> long-term liabilities | 186 | 193 |
| Commitments and Contingencies | | |
| Shareholders' equity: | | |
| Share capital - | | |

Ordinary shares with no par value – Authorized:
47,800,000 shares at March 31, 2021 (unaudited) and
December 31, 2020; Issued and outstanding:
18,745,142 and 18,494,739 shares at March 31, 2021
(unaudited) and December 31, 2020, respectively.

| | | |
|---|-----------|-----------|
| | - | - |
| Additional paid-in capital | 207,120 | 205,063 |
| Accumulated deficit | (140,973) | (132,286) |
| <u>Total shareholders' equity</u> | 66,147 | 72,777 |
| Total liabilities, convertible preferred shares and shareholders' equity | \$ 69,839 | \$ 75,847 |

CONSOLIDATED STATEMENTS OF OPERATIONS

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

**Three months ended
March 31,**

2021 2020

Unaudited

U.S. dollars in thousands

Operating expenses:

| | | |
|-------------------------------|----------|----------|
| Research and development, net | \$ 6,018 | \$ 3,433 |
|-------------------------------|----------|----------|

| | | |
|---|-----|-----|
| Marketing and business development expenses | 652 | 276 |
|---|-----|-----|

| | | |
|----------------------------|-------|-----|
| General and administrative | 2,127 | 727 |
|----------------------------|-------|-----|

| | | |
|----------------|-------|-------|
| Operating loss | 8,797 | 4,436 |
|----------------|-------|-------|

| | | |
|---------------------------------|-------|-------|
| Financial expense (income), net | (110) | 1,433 |
|---------------------------------|-------|-------|

| | | |
|----------|----------|----------|
| Net loss | \$ 8,687 | \$ 5,869 |
|----------|----------|----------|

| | | |
|--|----------|----------|
| Net loss attributable to Ordinary shares | \$ 8,687 | \$ 5,869 |
|--|----------|----------|

| | | |
|---|---------|----------|
| Basic and diluted net loss per Ordinary share | \$ 0.47 | \$ 13.90 |
|---|---------|----------|

| | | |
|--|------------|---------|
| Weighted average number of Ordinary shares used in computing basic and diluted net loss per share | 18,623,154 | 562,748 |
|--|------------|---------|

