

## קסניה ונצ'ר קפיטל בע"מ ("החברה")

11 בנובמבר 2021

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### מהות האירוע: פוליפייד בע"מ (להלן: "פוליפייד") – דיווח על תוצאות כספיות לרבעון השלישי לשנת 2021

החברה מתכבדת לדווח כי פוליפייד פרסמה את תוצאותיה הכספיות לרבעון השלישי של שנת 2021, ("תקופת הדוח") וכן מידע לגבי פעילותה. להלן עיקרי הנתונים:  
התוצאות הכספיות לשלושה חודשים שהסתיימו ביום 30 בספטמבר 2021:

- הפסד נקי בסך של 9.9 מיליון דולר, בהשוואה להפסד נקי בסך של 6.5 מיליון דולר בתקופה המקבילה אשתקד.
- הוצאות מו"פ בסך של 7.5 מיליון דולר, בהשוואה להוצאות מו"פ בסך של 4.2 מיליון דולר בתקופה המקבילה אשתקד. העלייה בתקופת הדוח נבעה כתוצאה מהניסויים SHILD I ו- SHILD II בפאזה השלישית.
- הוצאות הנהלה וכלליות בסך של 2.1 מיליון דולר, בהשוואה להוצאות הנהלה וכלליות בסך של 2.2 מיליון דולר בתקופה המקבילה אשתקד.

### התוצאות הכספיות לתשעה חודשים שהסתיימו ביום 30 בספטמבר 2021:

- הפסד נקי בסך של 29.1 מיליון דולר, בהשוואה להפסד נקי בסך של 31.4 מיליון דולר בתקופה המקבילה אשתקד.
- הוצאות מו"פ בסך של 20.9 מיליון דולר, בהשוואה להוצאות מו"פ בסך של 11.9 מיליון דולר בתקופה המקבילה אשתקד. העלייה בתקופת הדוח נבעה כתוצאה מהניסויים SHILD I, ו- SHILD II בפאזה השלישית.
- הוצאות הנהלה וכלליות בסך של 6.7 מיליון דולר, בהשוואה להוצאות הנהלה וכלליות בסך של 5.5 מיליון דולר בתקופה המקבילה אשתקד. העלייה בתקופה הנוכחית נבעה כתוצאה מעלויות של ביטוח דירקטורים כתוצאה מהיותה של פוליפייד חברה ציבורית.

## יתרות מזומנים:

נכון ליום 30 בספטמבר 2021 יתרת המזומנים ושווה מזומנים, פיקדונות לזמן קצר ולזמן ארוך של פוליפיד עמדה על סך של 42 מיליון דולר, בהשוואה ליתרות בסך של 67 מיליון דולר ביום 31 בדצמבר 2020.

פוליפיד מעריכה כי יתרת המזומנים שלה תאפשר את מימון הפעילות שלה עד לסוף שנת 2022.

## מידע תמציתי על פעילות פוליפיד:

- גיוס החולים בניסוי SHILD I בפאזה השלישית מתקדם כמתוכנן, ועד כה גויסו כ- 480 חולים.
- לאור הסכמת רשויות ה-FDA לכך שמחקר אחד בשלב הפאזה השלישית (SHILD I) עשוי להספיק לקבלת אישור למוצר ה-D-PLEX<sub>100</sub> למניעת זיהומים בניתוחי המעי הגס, פוליפיד מתכוונת לגייס את מספר החולים המירבי בטווח החולים שתוכנן, כ- 900 חולים.
- המטופל האחרון בניסוי SHILD צפוי להיות מגויס ברבעון השני של שנת 2022, והתוצאות אמורות להתקבל כחודשיים לאחר מכן.
- גיוס החולים בניסוי SHILD II בפאזה השלישית מתקדם כמתוכנן, ועד כה גויסו למעלה מ- 130 חולים.
- פוליפיד צפויה לקיים, במהלך החודש, שיחה מקדימה עם רשויות ה-FDA בכוונה לקדם תחילת ניסוי בפאזה ראשונה במוצר האונקולוגי שלה במהלך שנת 2022.

למיטב ידיעת החברה, פוליפיד מפתחת טכנולוגית הובלת תרופות בשם PLEX אשר מאפשרת שחרור מקומי, מושהה ומבוקר של מינוני תרופה יעילים לאורך זמן. מוצר הדגל של פוליפיד הוא D-PLEX<sub>100</sub>, אשר מאפשר שחרור מבוקר ולאורך זמן של אנטיביוטיקה, בכדי למנוע זיהומים שלאחר ניתוחי חזה ובטן. שתי האפליקציות של D-PLEX<sub>100</sub> נמצאות בשלב הפאזה השלישית של המחקר הקליני.

לפרטים נוספים אודות פוליפיד, ראו סעיף 9.3 לפרק א' לדוח התקופתי של החברה שפורסם ביום 26 במרץ 2021, מס' אסמכתא 2021-01-048501 (מידע זה מהווה הכללה על דרך ההפניה).

מצ"ב לדיווח זה, הדיווח שפרסמה פוליפיד באתר ה-NASDAQ.

בכבוד רב,

קסניה ונצ'ר קפיטל בע"מ

באמצעות: אלי סורזון, מנכ"ל וסמנכ"ל כספים

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

*Recruitment Progressing as Planned with Approximately 480 Patients Enrolled in Phase 3 SHIELD I Trial of D-PLEX<sub>100</sub> in Abdominal Surgery*

*Following FDA Agreement 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, Company Intends to Target Higher End of Patient Enrollment Range in SHIELD I to Leverage Key Clinical, Commercial and Financial Benefits*

*Company's Cash Runway Extends to Year-End 2022, ahead of Prior Forecast of Q2 2022*

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

**PETACH TIKVA, Israel, November 10, 2021** -- PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a phase 3 biopharmaceutical company focusing on developing targeted, locally administered, and prolonged-release therapeutics to improve surgical outcomes, today provided a corporate update and reported financial results for the three and nine months ended September 30, 2021.

## **Recent Corporate Highlights:**

- Recruitment progressing as planned with approximately 480 patients enrolled in the ongoing Phase 3 SHIELD I study.
- Following an agreement with the U.S. Food and Drug Administration (FDA) *that a single pivotal Phase 3 study is sufficient*, provided the study results are adequate, *for potential approval of D-PLEX<sub>100</sub>* for the prevention of SSIs in colorectal surgery, the Company determined that it is in the best interests of the development program to target the higher end of its planned patient enrollment range in SHIELD I.
- Targeting approximately 900 patients for enrollment in SHIELD I is not expected to modify D-PLEX<sub>100</sub> NDA submission timelines and will help ensure that the study is well powered and will provide additional data that will potentially be used to further demonstrate the medical and health economic benefits of D-PLEX<sub>100</sub>.
- FDA agreement *that a single pivotal Phase 3 study is sufficient for potential approval* will extend PolyPid's cash runway to year end 2022.
- Last-patient-in from SHIELD I is expected to enroll during the second quarter of 2022 with top line results 2 months thereafter.
- Patient enrollment is also advancing as anticipated in SHIELD II, the second Phase 3 clinical trials for D-PLEX<sub>100</sub> in abdominal surgery (soft tissue), with over 130 patients enrolled to date. SHIELD II has broader eligibility criteria than SHIELD I, including minimally invasive surgical procedures.

- Positive preclinical data from Company's intra-tumoral OncoPLEX cancer therapy program in two animal models of Glioblastoma Multiform (GBM) showed that single local treatment of OncoPLEX significantly inhibited tumor growth and prolonged survival. The Company will conduct a Pre-IND meeting with the FDA later this month to potentially initiate a Phase 1/2 clinical trial of OncoPLEX in GBM in 2022.

“We continue to expeditiously advance our multiple development programs, as well as our commercial preparations,” said Amir Weisberg, PolyPid’s Chief Executive Officer. “Most importantly, the pace of enrollment in the SHIELD I trial has continued to increase over the last several months and we expect an even greater acceleration in the months ahead. Having now passed the mid-point in our planned enrollment for SHIELD I, and with over 600 patients now enrolled in both SHIELD I and SHIELD II studies combined, we are well-positioned to leverage the expected clinical, commercial and financial benefits of targeting the higher end of our patient enrollment range for SHIELD I. Additionally, we are having ongoing discussions with commercialization partners in the United States, Europe and Asia, based upon the anticipated data from our Phase 3 trial in 2022.”

“We continue to be excited about the compelling preclinical data being generated by our promising OncoPLEX development platform initially targeting brain tumors. The most recent results further support our work toward the completion of a preclinical package for the filing of an Investigative New Drug application with the FDA to potentially initiate a Phase 1/2 clinical trial. We look forward to meeting with the Agency later this month to discuss the clinical and non-clinical development plan for OncoPLEX in GBM,” continued Mr. Weisberg.

“In addition, we are progressing our robust clinical development program from a position of financial strength. Our cash runway now extends to year-end 2022, a significant improvement over our prior target of the second quarter of 2022. We continue to have sufficient cash resources to complete the SHIELD I study, prepare for the submission of a New Drug Application to the FDA and further advance our OncoPLEX program,” concluded Mr. Weisberg.

#### **Financial results for the three months ended September 30, 2021**

Research and development expenses for the three months ended September 30, 2021 were \$7.5 million, compared to \$4.2 million in the same three-month period of 2020, as expenses 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 September 30, 2021 were \$0.4 million, compared to \$0.3 million for the same period in 2020, as 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 three months ended September 30, 2021 were \$2.1 million, consistent with \$2.2 million in the prior year period. The decrease was due to lower non-cash share-based compensation expenses.

For the three months ended September 30, 2021, the Company had a net loss attributable to ordinary shares of \$9.9 million, compared to a net loss of \$6.5 million in the three-month period ended September 30, 2020.

As of September 30, 2021, the Company had cash, cash equivalents, short-term deposits, and long-term deposits in the amount of \$42.0 million, compared to \$67.0 million at December 31, 2020. PolyPid expects that its cash on hand will be sufficient to fund operations until the end of 2022.

### **Financial results for the nine months ended September 30, 2021**

Research and development expenses for the nine months ended September 30, 2021 were \$20.9 million, compared to \$11.9 million in the same nine-month period of 2020, as expenses increased due to the ongoing SHIELD I and SHIELD II Phase 3 clinical trials in abdominal surgery.

Marketing and business development expenses for the nine months ended September 30, 2021 were \$1.8 million, compared to \$0.9 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 nine months ended September 30, 2021 were \$6.7 million, compared to \$5.5 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 nine months ended September 30, 2021, the Company had a net loss attributable to ordinary shares of \$29.1 million, as compared to a net loss of \$31.4 million in the nine months ended September 30, 2020.

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

Date:	Wednesday, November 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: 4585862  
Webcast: <https://edge.media-server.com/mmc/p/5rbkqsbe>

## **About PolyPid**

[PolyPid Ltd.](#) (Nasdaq: [PYPD](#)) is a phase 3 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 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 its cash runway and sufficiency of its cash resources, ongoing clinical trials, plans to use the guidance provided by the FDA to progress with its SHIELD I program, the pace of enrollment in the SHIELD I trial, the timing of last-patient-in or of top-line results of the SHIELD I trial, the size and design of the SHIELD I trial, potential initiation of Phase 1/2 clinical trial of OncoPLEX in GBM in 2022 and D-PLEX<sub>100</sub> NDA submission timelines. 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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**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**U.S. dollars in thousands**

	<b>September 30, 2021</b>	<b>December 31, 2020</b>
	<b>Unaudited</b>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 9,217	\$ 4,319
Restricted cash	390	390
Short-term deposits	32,375	40,157
Prepaid expenses and other current assets	<u>3,335</u>	<u>2,334</u>
Total current assets	<u>45,317</u>	<u>47,200</u>
<b>LONG-TERM ASSETS:</b>		
Property and equipment, net	5,717	5,890
Long-term deposits	-	22,120
Other long-term assets	<u>2,425</u>	<u>637</u>
Total long-term assets	<u>8,142</u>	<u>28,647</u>
Total assets	<u>\$ 53,459</u>	<u>\$ 75,847</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Trade payables	\$ 1,656	\$ 974
Other payables and accrued expenses	<u>3,488</u>	<u>1,903</u>
Total current liabilities	<u>5,144</u>	<u>2,877</u>



**LONG-TERM LIABILITIES:**

Other long-term liabilities	<u>192</u>	<u>193</u>
Total long-term liabilities	<u>192</u>	<u>193</u>

**COMMITMENTS AND CONTINGENCIES****SHAREHOLDERS' EQUITY:**

Share capital -		
Ordinary shares with no par value - Authorized: 47,800,000 shares at September 30, 2021 and December 31, 2020; Issued and outstanding: 18,756,570 and 18,494,739 shares at September 30, 2021 and December 31, 2020, respectively	-	-
Additional paid-in capital	209,508	205,063
Accumulated deficit	<u>(161,385)</u>	<u>(132,286)</u>
Total shareholders' equity	<u>48,123</u>	<u>72,777</u>
Total liabilities and shareholders' equity	<u>\$ 53,459</u>	<u>\$ 75,847</u>

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

<b>Nine months ended</b>		<b>Three months ended</b>	
<b>September 30,</b>		<b>September 30,</b>	
<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>

	<b>Unaudited</b>			
Operating expenses:				
Research and development, net	\$ 20,936	\$ 11,948	\$ 7,476	\$ 4,176
Marketing and business development expenses	1,836	904	445	323
General and administrative	<u>6,719</u>	<u>5,532</u>	<u>2,143</u>	<u>2,177</u>
Operating loss	29,491	18,384	10,064	6,676
Financial (income) expense, net	<u>(392)</u>	<u>10,936</u>	<u>(129)</u>	<u>(218)</u>
Net loss	<u>\$ 29,099</u>	<u>\$ 29,320</u>	<u>\$ 9,935</u>	<u>\$ 6,458</u>
Deemed dividend	<u>-</u>	<u>2,114</u>	<u>-</u>	<u>-</u>
Net loss attributable to Ordinary shares	<u>\$ 29,099</u>	<u>\$ 31,434</u>	<u>\$ 9,935</u>	<u>\$ 6,458</u>
Basic and diluted net loss per Ordinary share	<u>\$ 1.56</u>	<u>\$ 4.78</u>	<u>\$ 0.53</u>	<u>\$ 0.35</u>
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	<u>18,709,719</u>	<u>6,578,969</u>	<u>18,756,570</u>	<u>18,415,231</u>

