

# קסניה ונצ׳ר קפיטל בע״מ (״החברה״)

2021 בפברואר 2021

לכבוד <u>הבורסה לניירות ערך בתייא</u> www.tase.co.il

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#### מהות האירוע: פוליפיד בע"מ (להלן: "פוליפיד") – דיווח על תוצאות כספיות לרבעון הרביעי בשנת 2020 ולשנת 2020 כולה

החברה מתכבדת לדווח כי פוליפיד פרסמה את תוצאותיה הכספיות לרבעון הרביעי של שנת 2020, ולשנת 2020, וכן מידע לגבי פעילותה. להלן עיקרי הנתונים :

#### התוצאות הכספיות לשלושה חודשים שהסתיימו ביום 31 בדצמבר 2020:

- הפסד נקי בסך של 7.5 מיליון דולר בהשוואה להפסד נקי בסך של 3.9 מיליון דולר בתקופה המקבילה אשתקד.
- הוצאות מו"פ בסך של 5 מיליון דולר בהשוואה להוצאות מו"פ בסך של 3.3 מיליון דולר בתקופה המקבילה אשתקד. העלייה בתקופה הנוכחית נבעה כתוצאה מההתחלה של הניסויים SHILD II 1 בפאזה השלישית.
- הוצאות הנהלה וכלליות בסך של 2.2 מיליון דולר, בהשוואה להוצאות הנהלה וכלליות בסך של 0.8 מיליון דולר בתקופה המקבילה אשתקד. העלייה בתקופה הנוכחית נבעה כתוצאה מעלייה בעלויות ביטוח דירקטורים ונושאי משרה בעקבות ההנפקה לציבור של מניות פוליפיד, וכן מתגמול מבוסס מניות.
- הוצאות שיווק ופיתוח עסקי בסך של 0.7 מיליון דולר, בהשוואה להוצאות שיווק ופיתוח עסקי של 0.3 מיליון דולר בתקופה המקבילה אשתקד. העלייה בתקופה הנוכחית נבעה מעלויות כוח אדם של שיווק ופיתוח עסקי במשרד החדש של החברה בניו ג׳רזי.

#### התוצאות הכספיות לשנה שהסתיימה ביום 31 בדצמבר 2020 :

- הפסד נקי בסך של 39 מיליון דולר בהשוואה להפסד נקי בסך של 6.6 מיליון דולר
   אשתקד.
- הוצאות מו"פ בסך של 17 מיליון דולר בהשוואה להוצאות מו"פ בסך של 14.1 מיליון דולר בתקופה המקבילה אשתקד. העלייה בתקופה הנוכחית נבעה כתוצאה מההתחלה של הניסויים SHILD II בפאזה השלישית.
- הוצאות הנהלה וכלליות בסך של 7.7 מיליון דולר, בהשוואה להוצאות הנהלה וכלליות בסך של 3.6 בתקופה המקבילה אשתקד. העלייה בתקופה הנוכחית נבעה כתוצאה

מעלייה בעלויות ביטוח דירקטורים ונושאי משרה בעקבות ההנפקה לציבור של מניות

פוליפיד, וכן מתגמול מבוסס מניות.

• הוצאות שיווק ופיתוח עסקי בסך של 1.6 מיליון דולר, בהשוואה להוצאות שיווק ופיתוח עסקי של 0.9 מיליון דולר בתקופה המקבילה אשתקד. העלייה בתקופה הנוכחית נבעה

מעלויות כוח אדם של שיווק ופיתוח עסקי במשרד בחדש של החברה בניו גירזי.

<u>יתרות מזומנים:</u>

נכון ליום 31 בדצמבר 2020 יתרת המזומנים ושווה מזומנים, פיקדונות לזמן קצר ולזמן ארוך של

פוליפיד עומד על סך של 66.6 מיליון דולר, בהשוואה ליתרות בסך של 26.6 מיליון דולר ביום 31

בדצמבר 2019.

פוליפיד מעריכה כי יתרת המזומנים שלה תאפשר את מימון הפעילות שלה מעבר לשנת 2021.

מידע על פעילות פוליפיד:

עד היום גויסו 100 חולים בשני הניסויים  $\,$  SHILD I ו $\,$  SHILD I במסגרת הפאזה השלישית של

900 – 600 למניעת זיהומים לאחר ניתוחי בטן. פוליפיד מתכננת לגייס D-PLEX100 - מוצר ה

חולים לניסוי SHILD I, וכן לגייס 900 – 1400 חולים לניסוי SHILD II, ב – 60 מרכזים, לכל ניסוי,

בארהייב, אירופה וישראל.

ההערכות שלעיל הינן בגדר מידע צופה פני עתיד, כהגדרת מונח זה בחוק ניירות ערך,

התשכ"ח- 1968, המבוסס על הערכות ותחזיות של פוליפיד. אין כל וודאות להתממשות הערכות

אלו וזאת, בין היתר, בשל גורמים שאינם בשליטת פוליפיד.

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

מנוע זיהומים, בכדי אנטיביוטיקה, בכדי למנוע זיהומים, D-PLEX $_{100}$ 

נמצאות בשלב הפאזה השלישית של D-PLEX שלאחר ניתוחי חזה ובטן. שתי האפליקציות של

חקר הקליני.

לפרטים נוספים אודות פוליפיד, ראו סעיף 9.3 לפרק אי לדוח התקופתי של החברה שפורסם ביום

3 בפברואר 2020, מסי אסמכתא 2020-01-012867 (מידע זה מהווה הכללה על דרך ההפניה).

מצייב לדיווח זה, הדיווח שפרסמה פוליפיד באתר ה- NASDAQ.

בכבוד רב,

קסניה ונציר קפיטל בעיימ

באמצעות: אלי סורזון, מנכייל וסמנכייל כספים





# 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-PLEX<sub>100</sub> in Abdominal Surgery
  - Recently Initiated Phase 3 SHIELD II Trial
- Granted Breakthrough Therapy Designation from FDA for D-PLEX<sub>100</sub> for Prevention of SSIs in Patients Undergoing Elective Colorectal
   Surgery
  - Conference Call Scheduled for Today at 8:30 AM ET

**PETAH TIKVA**, Israel, February 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 (Surgical site Hospital-acquired Infection PrEvention with Local D-plex) trial is the first of two Phase 3 clinical trials of D-PLEX<sub>100</sub>, 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-PLEX<sub>100</sub> 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-PLEX<sub>100</sub> 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-PLEX<sub>100</sub> 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-PLEX<sub>100</sub> to change the current therapeutic landscape. A recording of the KOL event can be found on PolyPid's website <a href="http://www.polypid.com">http://www.polypid.com</a>

"2020 was truly a transformative year for PolyPid," said Amir Weisberg, Chief Executive Officer. "Most importantly, our Phase 3 program for D- $PLEX_{100}$  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- $PLEX_{100}$  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- $PLEX_{100}$  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 \$0.7 million, 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 \$7.5 million, 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: <a href="https://edge.media-server.com/mmc/p/cx5so6fj">https://edge.media-server.com/mmc/p/cx5so6fj</a>

#### 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 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-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 sternal and abdominal surgical site infections (SSIs).

For additional company information, please visit <a href="http://www.polypid.com">http://www.polypid.com</a> 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.

#### **Contacts:**

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#### **Investors:**

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# CONSOLIDATED BALANCE SHEETS U.S. dollars in thousands

**CURRENT LIABILITIES:** 

	2020		2019	
	(Unaudited	(k	(Audited)	
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	\$	4,319	\$	3,924
Restricted cash		390		375
Short-term deposits		40,157		22,685
Prepaid expenses and other receivables		2,729		417
Total current assets		47,595		27,401
Long-term assets:				
Property and equipment, net		5,890		6,121
Long-term deposits		22,120		-
Other long-term assets		242		230
Total long-term assets		28,252		6,351
Total assets	\$	75,847	\$	33,752

December 31,

Trade payables Other payables and accrued expenses	\$ 974 	\$ 1,581 998
<u>Total</u> current liabilities	2,877	2,579
Long-term liabilities:		
Other liabilities	193	251
Warrants to convertible preferred shares		12,241
<u>Total</u> long-term liabilities	193	12,492
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.		106,313
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.	-	-
Additional paid-in capital	205,063	5,671
Accumulated deficit	(132,286)	(93,303)
<u>Total</u> shareholders' equity (deficit)	72,777	(87,632)
Total liabilities, convertible preferred shares and shareholders' equity (deficit)	\$ 75,847	\$ 33,752

#### **CONSOLIDATED STATEMENTS OF OPERATIONS**

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

	(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	

#### **Three Months Ended** December 31, 2020 2019

Year ended December 31,

2019

2020

	(Unaudited)	(Unaudited)	
Operating expenses: Research and development, net Marketing and business development expenses General and administrative	\$ 5,006 710 2,172	\$ 3,314 316 778	
Operating loss Financial income, net	7,888 	4,408 548	
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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