

PolyPid Provides Corporate Update and Reports First Quarter 2023 Financial Results

Submitted Revised Protocol for SHIELD II Phase 3 Trial to FDA to Evaluate D-PLEX₁₀₀ for Prevention of Abdominal Colorectal Surgical Site Infections; Recruitment Expected to Resume Imminently

Received Advice from the Swedish Medical Products Agency Consistent with Feedback Received from the FDA

Completed a Series of Transactions to Further Solidify Financial Position and Extend Cash Runway to Late in Q1 2024

Strengthened Board of Directors Through Appointment of Yossi BenAmram, Former SVP and President of Merck & Co.'s Europe, Russia, Africa, and Middle East Region

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, May 10, 2023 — PolyPid Ltd. (Nasdaq: PYPD) (“PolyPid” or the “Company”), a late-stage biopharma company aiming to improve surgical outcomes, today provided a corporate update and reported financial results for the three months ended March 31, 2023.

Recent Corporate Highlights:

- Submitted revised protocol to U.S. Food and Drug Administration (FDA) for SHIELD II Phase 3 trial. Based on feedback received from the FDA following a Type D meeting, the revised SHIELD II study will recruit patients undergoing colorectal resection surgery with large incisions (> 20 cm).
 - The study is expected to resume imminently with the enrollment of an estimated 550 additional patients.
 - Unblinded interim analysis is planned to be conducted once approximately 400 patients complete their 30-day follow-up.
 - Total recruitment time into the study is anticipated to be approximately 12 months and top-line results are expected in mid-2024.
- Completed a series of financial transactions to extend PolyPid’s cash runway into late Q1 2024.
 - Closed on an underwritten public offering that included the full exercise of the underwriter’s option to purchase additional Ordinary Shares and a concurrent private placement of pre-funded warrants with certain existing shareholders for total gross proceeds of approximately \$11.4 million.
 - Restructured loan agreement with Kreos Capital with over \$3 million of deferred

repayments, which will be paid from August 2024 onwards, in-line with the expected timing for the top-line results from SHIELD II.

- Received feedback in a national scientific advice meeting from the Swedish Medical Products Agency (MPA) similar to the Type D meeting feedback previously received from the FDA.
 - Swedish MPA recommended that the Company confirm the results with an additional Phase 3 study to support a Marketing Authorization Application (MAA) submission.
 - Confirmed that clinical safety data obtained to date in abdominal surgery studies is sufficient for an MAA submission.
- Appointed Yossi BenAmram, former SVP and President of Merck & Co.'s Europe, Russia, Africa, and Middle East region, as an independent Director on the Company's Board, replacing Mr. Chaim Hurvitz, a member of the Board since 2016, effective May 8, 2023.
- Announced the promotion of Jonny Missulawin, current SVP of Finance, to Chief Financial Officer.

"We are pleased with the recent progress we have achieved throughout our business," stated Dikla Czaczkes Akselbrad, PolyPid's Chief Executive Officer. "The feedback received from the FDA and the Swedish Medical Products Agency, coupled with the successful financial transactions that extended our cash runway, further solidify our clear and compelling path forward for D-PLEX₁₀₀ and the SHIELD II study, which we expect will resume patient recruitment very shortly."

"I would like to thank Mr. Hurvitz for his many years of support for PolyPid and welcome Mr. BenAmram as a new member of our Board of Directors. Mr. BenAmram's vast global experience in the pharma industry will be invaluable to PolyPid as we progress in the further advancement of D-PLEX₁₀₀ and continue our business development activities for our lead product candidate and the PLEX platform."

Financial results for three months ended March 31, 2023

- Research and development (R&D) expenses for the three months ended March 31, 2023, were \$3.8 million, compared to \$8.7 million in the same three-month period of 2022. The decrease in R&D expenses resulted primarily from the completion of the SHIELD I Phase 3 clinical trial.
- General and administrative (G&A) expenses for the three months ended March 31, 2023, were \$1.6 million, compared to \$2.5 million for the same period of 2022.
- Marketing and business development expenses for the three months ended March 31, 2023, were \$0.4 million, compared to \$0.8 million for the same period of 2022.
- For the three months ended March 31, 2023, the Company had a net loss of \$6.1

million, or (\$0.28) per share, compared to a net loss of \$11.9 million, or (\$0.63) per share, in the three-month period ended March 31, 2022.

Balance Sheet Highlights

- As of March 31, 2023, the Company had cash and cash equivalents and deposits in the amount of \$13.4 million, not including the \$6.2 million, net, received from the underwritten public offering in April 2023. PolyPid expects that its pro forma cash balance will be sufficient to fund operations into late first quarter 2024.

Conference Call Dial-In & Webcast Information:

Date: Wednesday, May 10, 2023
Time: 8:30 AM Eastern Time
Q&A <https://register.vevent.com/register/BI4643e991c9604c539af94f4d068227>
Participants: 4c
Webcast: <https://edge.media-server.com/mmc/p/2ymp9poq>

About SHIELD II

SHIELD II (Surgical site Hospital acquired Infection prEvention with Local D-PLEX) is a prospective, multinational, randomized, double blind Phase 3 trial designed to assess the efficacy and safety of D-PLEX₁₀₀ administered concomitantly with standard of care (SoC), which includes prophylactic systemic antibiotics, compared to SoC alone arm, in the prevention of post abdominal-surgery incisional infection in patients undergoing complex surgeries with incisions greater than 20 cm. The primary endpoint of the trial is measured by the proportion of subjects with either an SSI event as determined by a blinded and independent adjudication committee, reintervention, or mortality for any reason within 30 days post-surgery. Patient safety will be monitored for an additional 30 days. The trial will enroll patients in centers in the United States, Europe and Israel.

About PolyPid

PolyPid Ltd. (Nasdaq: PYPD) is a late-stage biopharma company aiming to improve surgical outcomes. Through locally administered, controlled, prolonged-release therapeutics, PolyPid's proprietary PLEX (Polymer-Lipid Encapsulation matrix) technology pairs with Active Pharmaceutical Ingredients (APIs), enabling precise delivery of drugs at optimal release rates over durations ranging from several days to months. PolyPid's lead product candidate D-PLEX₁₀₀ is in Phase 3 clinical trial for the prevention of abdominal colorectal surgical site infections. In addition, the Company is currently in preclinical stages to test the efficacy of OncoPLEX for treatment of solid tumors, beginning with glioblastoma.

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 the expected resumption of recruitment for the SHIELD II Phase 3 trial and the timing of top-line results therefrom, a potential MAA submission, and the Company’s expectations regarding its cash balance. 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 31, 2023. 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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INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	March 31, 2023	December 31, 2022
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 6,366	\$ 8,552
Restricted cash	504	511
Short-term deposits	7,061	4,042
Receipts on account of shares	6,206	131
Prepaid expenses and other current assets	448	958
<u>Total</u> current assets	20,585	14,194
LONG-TERM ASSETS:		
Property and equipment, net	822,8	9,247
Operating lease right-of-use assets	2,181	2,431
Other long-term assets	107	99
<u>Total</u> long-term assets	11,110	11,777
	\$	
<u>Total</u> assets	31,695	\$ 25,971

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	March 31, 2023	December 31, 2022
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt ¹	\$ 4,210	\$ 4,024
Accrued expenses and other current liabilities	1,396	2,429
Trade payables	1,083	1,141
Current maturities of operating lease liabilities	808	959
<u>Total</u> current liabilities	7,497	8,553

LONG-TERM LIABILITIES:

Long-term debt ¹	6,760	7,574
Deferred revenues	2,548	2,548
Warrant liability	2,106	-
Long-term operating lease liabilities	1,063	1,173
Other liabilities	314	294
<u>Total long-term liabilities</u>	<u>12,791</u>	<u>11,589</u>

COMMITMENTS AND CONTINGENT LIABILITIES**SHAREHOLDERS' EQUITY:**

Ordinary shares with no par value - Authorized: 47,800,000 shares at March 31, 2023 (unaudited) and December 31, 2022; Issued and outstanding: 38,694,171 and 19,851,833 shares at March 31, 2023 (unaudited) and December 31, 2022, respectively	-	-
Additional paid-in capital	231,919	220,273
Accumulated deficit	(220,512)	(214,444)
<u>Total shareholders' equity</u>	<u>11,407</u>	<u>5,829</u>
<u>Total liabilities and shareholders' equity</u>	<u>\$ 31,695</u>	<u>\$ 25,971</u>

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended March 31, 2023 2022 Unaudited	
Operating expenses:		
Research and development, net	\$ 3,794	\$ 8,697
Marketing and business development	385	775
General and administrative	1,609	2,480
Operating loss	5,788	11,952
Financial expense (income), net	255	(78)
Loss before income tax	6,043	11,874
Income tax expense	25	-
Net loss	6,068	11,874
Basic and diluted loss per Ordinary share	\$ 0.28	\$ 0.63
Weighted average number of Ordinary shares used in computing basic and diluted loss per share	21,496,651	18,936,457

¹ Not reflecting the accounting treatment of the restructured loan agreement with Kreos Capital, which was signed March 29, 2023 and will be reflected in the June 30, 2023 financial statements.

