PolyPid Provides Corporate Update and Reports Fourth Quarter and Full Year 2023 Financial Results

More Than 100 Patients Enrolled in Ongoing SHIELD II Phase 3 Trial of D-PLEX$_{100}$ for the Prevention of Abdominal Colorectal Surgical Site Infections

Unblinded Interim Analysis to be Conducted Once Approximately 400 Patients Complete Their 30-Day Follow-up; Top-line Results Expected in Second Half of 2024

New Preclinical Data Showed OncoPLEX Injected Intratumorally Reduced Tumor Volume and Improved Survival in New Animal Models

Recent Successful $16 Million Financing Extends Company's Cash Runway Through Late Third Quarter 2024 and Beyond Expected Timing of Unblinded Interim Analysis; Potential Additional $19 Million if Warrants are Exercised to Fund PolyPid to the Start of a Planned New Drug Application Submission for D-PLEX$_{100}$

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, Feb. 14, 2024 — 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 and full year ended December 31, 2023.

Recent Corporate Highlights:

- More than 100 patients have been enrolled to date in the ongoing SHIELD II Phase 3 trial that is recruiting patients undergoing colorectal abdominal surgery with large incisions.
    - Approximately 40 centers are currently open.
    - Unblinded interim analysis is planned to be conducted once a total of approximately 400 patients complete their 30-day follow-up, which is expected to occur in mid-2024.
    - Top-line results are anticipated in the second half of 2024.
- Generated new preclinical data with OncoPLEX injected intratumorally
    - OncoPLEX single intratumoral injection significantly reduced tumor growth and increased survival in two well established and commonly used tumor animal models: murine melanoma and murine colon carcinoma.
    - The intratumoral injection of the PLEX platform could be used as an interventional oncology treatment with additional chemotherapies or other types of molecules, such as monoclonal antibodies, bispecific antibodies and nucleic acids.

- Closed a private placement financing (the “PIPE”) for $16 million of gross proceeds, which extends the Company’s cash runway through late in the third quarter of 2024 and beyond the expected timing of the planned unblinded interim analysis.
    - PIPE syndicate was comprised of new and existing investors, including participation from new U.S. life sciences-focused investors, DAFNA Capital Management and Rosalind Advisors.
    - Company has the potential to secure an additional $19 million if the results of the unblinded interim analysis are positive and all warrants issued in the recent financing are exercised, which would fund PolyPid to the start of a planned New Drug Application (“NDA”) submission for D-PLEX$_{100}$.

“We are thrilled with the significant progress recently achieved throughout our business,” stated Dikla Czaczkes Akselbrad, PolyPid’s Chief Executive Officer. “As we expected, enrollment in our ongoing SHIELD II Phase 3 pivotal trial for D-PLEX$_{100}$ has begun to ramp up, and we continue to anticipate top-line results from this study in the second half of 2024. We have also generated new highly compelling preclinical data with OncoPLEX that demonstrate its potential in oncology and beyond.”

“Moreover, in order to support our robust clinical development efforts, we successfully completed a $16 million financing that included participation from multiple new U.S. life sciences-focused investors,” continued Ms. Czaczkes Akselbrad. “Importantly, we also have the potential to secure an additional $19 million if the warrants associated with this transaction are exercised, which would fund PolyPid to the start of a planned New Drug Application submission for D-PLEX$_{100}$.“

Financial results for three months ended December 31, 2023

- Research and development (R&D) expenses, net for the three months ended December 31, 2023, were $4.6 million, compared to $4.7 million in the same three-month period of 2022. R&D expenses in the most recently completed quarter were driven by the ramp up of the ongoing SHIELD II Phase 3 trial.
- General and administrative (G&A) expenses for the three months ended December 31, 2023, were $1.2 million, compared to $1.6 million for the same period of 2022.
- Marketing and business development expenses for the three months ended December 31, 2023, were $0.2 million, compared to $0.4 million for the same period of 2022.
- For the three months ended December 31, 2023, the Company had a net loss of $6.4 million, or ($3.97) per diluted share, compared to a net loss of $6.6 million, or ($9.90) per diluted share, in the three-month period ended December 31, 2022.

Financial results for the full year ended December 31, 2023

- R&D expenses, net for the year ended December 31, 2023, were $16.1 million,

compared to $28 million in 2022. The decrease in R&D expenses resulted primarily from the completion of the SHIELD I Phase 3 clinical trial.
- G&A expenses for the year ended December 31, 2023, were $5.5 million, compared to $8.0 million for 2022.
- Marketing and business development expenses for the year ended December 31, 2023, were $1.2 million, compared to $2.9 million for 2022.
- The decreases in G&A and marketing and business development expenses were primarily due to the Company's cost reduction plan announced in October 2022 and further cost savings initiatives implemented during full year 2023.
- For the year ended December 31, 2023, the Company had a net loss of $23.9 million, or ($16.93) per diluted share, compared to a net loss of $39.6 million, or ($61.09) per diluted share, for 2022.

Balance Sheet Highlights

- As of December 31, 2023, the Company had cash and cash equivalents in the amount of $5.3 million. This does not include the net proceeds of approximately $15 million generated from the PIPE financing closed in January 2024. PolyPid expects that its pro forma cash balance will be sufficient to fund operations into late third quarter 2024.

Conference Call Dial-In & Webcast Information:

Date:	Wednesday, February 14, 2024
Time:	8:30 AM Eastern Time
Q&A Participants:	https://register.vevent.com/register/BI8900a42f492b4240a3bba8285558d15f
Webcast:	https://edge.media-server.com/mmc/p/7iigty2s

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-PLEX$_{100}$ 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 the 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 timing for top-line results from the SHIELD II trial and of the unblinded interim analysis, the planned NDA submission for D-PLEX$_{100}$, the potential impacts and uses for OncoPLEX and the PLEX platform, the Company’s expected cash runway, and the potential to receive additional funds if warrants are exercised. 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 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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CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	December 31, 2023 (Unaudited)	2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,309	$ 8,552
Restricted deposits	300	511
Short-term deposits	–	4,042
Prepaid expenses and other current assets	458	1,089
Total current assets	6,067	14,194
LONG-TERM ASSETS:		
Property and equipment, net	7,621	9,247
Operating lease right-of-use assets	1,597	2,431
Other long-term assets	87	99
Total long-term assets	9,305	11,777
Total assets	$ 15,372	$ 25,971

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

	December 31, 2023 (Unaudited)	2022
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt	$ 4,003	$ 4,024
Accrued expenses and other current liabilities	1,971	2,429
Trade payables	772	1,141
Current maturities of operating lease liabilities	540	959
Total current liabilities	7,286	8,553
LONG-TERM LIABILITIES:		
Long-term debt	6,379	7,574
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	857	1,173
Other liabilities	398	294
Total long-term liabilities	10,182	11,589
COMMITMENTS AND CONTINGENT LIABILITIES		

SHAREHOLDERS' EQUITY:		
Ordinary shares, no par value *)- Authorized: 107,800,000 and 47,800,000 shares at December 31, 2023 and 2022, respectively; Issued and outstanding: 1,653,559 and 669,605 shares at December 31, 2023 and 2022, respectively	–	–
Additional paid-in capital	236,213	220,273
Accumulated deficit	(238,309)	(214,444)
Total shareholders' equity (deficit)	(2,096)	5,829
Total liabilities and shareholders' equity (deficit)	$ 15,372	$ 25,971

*) Prior period results have been retroactively adjusted to reflect the 1-for-30 reverse share split affected on September 18, 2023.

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

	Year Ended December 31,		
	2023 (Unaudited)	**2022**	**2021**
Operating expenses:			
Research and development, net	$ 16,148	$ 27,990	$ 30,553
Marketing and business development	1,196	2,888	2,983
General and administrative	5,523	8,010	9,609
Operating loss	22,867	38,888	43,145
Financial (income) expense, net	929	540	(544)
Loss before income tax	23,796	39,428	42,601
Income tax expense	69	129	–
Net loss	$ 23,865	$ 39,557	$ 42,601
Loss per share:			
Basic	$ 16.99	$ 61.09	$ 68.27
Diluted	$ 16.93	$ 61.09	$ 68.27
Weighted-average Ordinary shares outstanding:			
Basic	1,404,368	647,556	624,051
Diluted	1,421,308	647,556	624,051

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

	Three Months Ended December 31,	
	2023 (Unaudited)	2022 (Unaudited)
Operating expenses:		
Research and development, net	$ 4,588	$ 4,655
Marketing and business development expenses	193	350
General and administrative	1,218	1,607
Operating loss	5,999	6,612
Financial expense (income), net	348	(100)
Loss before income tax	6,347	6,512
Income tax expense	9	55
Net loss	$ 6,356	$ 6,567
Loss per share:		
Basic	$ 3.84	$ 9.90
Diluted	$ 3.97	$ 9.90
Weighted average number of Ordinary shares used in computing basic and diluted loss per share	1,653,559	663,145