PolyPid Provides Corporate Update and Reports Second Quarter 2025 Financial Results

Positive Phase 3 SHIELD II Trial Results – D-PLEX successfully met its primary efficacy endpoint and demonstrated 58% reduction in SSI

NDA submission expected in Q1 2026

Unveiled a Long-Acting GLP-1 Receptor Agonists Delivery Platform Targeting the Obesity and Diabetes Market

Successful Warrant Exercise Significantly Strengthened Balance Sheet with Cash Runway into 2026

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, Aug. 13, 2025 (GLOBE NEWSWIRE) — 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 and six months ended June 30, 2025.

Recent Corporate Highlights:

- **Positive Phase 3 Data and Additional Clinical Insights:** Reported positive top-line results from the SHIELD II Phase 3 trial of D-PLEX for the prevention of abdominal colorectal surgical site infections (SSIs). The study showed statistically significant reduction of 38% ($p<0.005$) of the primary endpoint in addition to demonstrating a robust 58% reduction in the rate of SSIs in patients treated with D-PLEX arm versus standard of care arm ($p<0.005$), including a significant reduction in deep SSIs.
- **Recently Evaluated Safety Data:** Further analysis of the Phase 3 SHIELD II trial revealed a good safety profile with no difference in serious treatment-emergent adverse events between patients treated with D-PLEX arm versus standard of care arm.
- **Regulatory Pathway Advancement:** Following the positive Phase 3 data, the Company is on track with its New Drug Application (NDA) preparation. The Company anticipates submitting the NDA to the U.S. Food and Drug Administration in early 2026, leveraging its Fast Track and Breakthrough Therapy designations to shorten regulatory review.
- **Partnership Discussions:** The Company continues to advance its commercialization preparations while simultaneously advancing strategic partnership discussions and due diligence with multiple potential partners in the United States to maximize D-PLEX 's market potential.
- **Strengthened Pipeline with Novel GLP-1 Delivery Platform:** Recently made

significant progress on the Company's GLP-1 program. This initiative leverages the Company's extensive and long-term experience and aims to deliver approximately 60 days no-burst GLP-1 for improved patient compliance and enhanced therapeutic outcomes in the rapidly growing obesity and diabetes market.

- **Appointed New Chief Medical Officer:** On August 12, 2025, the Company announced the appointment of Dr. Nurit Tweezer-Zaks, M.D., M.B.A., as Chief Medical Officer of the Company, transitioning from her role on PolyPid's Board of Directors. Dr. Tweezer-Zaks brings extensive medical, research and development (R&D), and business development expertise to this executive position, strengthening the Company's leadership team as it advances toward NDA submission and commercial preparations following the positive Phase 3 SHIELD II results.
- **Financial Position Strengthened:** Completed a warrant exercise inducement transaction significantly strengthened the Company's balance sheet, extending its cash runway well into 2026.

"The second quarter of 2025 was transformational for PolyPid with the successful completion of our SHIELD II Phase 3 trial, which demonstrated significant clinical benefits of D-PLEX in preventing SSIs in abdominal colorectal surgeries," stated Dikla Czaczkes Akselbrad, PolyPid's Chief Executive Officer. "The positive data has generated substantial interest from potential commercial partners and reinforced our conviction in D-PLEX 's potential to address a significant unmet medical need."

"Moreover, we are extremely encouraged by the enthusiastic reception from healthcare professionals who recognize the potential of D-PLEX to substantially reduce the burden of SSIs, improve patient outcomes, and generate meaningful healthcare cost savings," continued Ms. Czaczkes Akselbrad. "With our strengthened balance sheet and multiple strategic options before us, we are well-positioned to maximize the value of our innovative technology."

Financial results for three months ended June 30, 2025

- R&D expenses for the three months ended June 30, 2025, were $6.2 million, compared to $4.8 million in the same three-month period of 2024. The increase in R&D expenses was primarily due to activities related to the completion of the SHIELD II Phase 3 trial and preparation for regulatory submissions.
- General and administrative (G&A) expenses for the three months ended June 30, 2025, were $2.5 million, compared to $1.1 million for the same period of 2024. The increase was primarily due to non-cash expenses related to performance-based options (PSUs), following the successful SHIELD II Phase 3 trial, which triggered the vesting of the PSUs.
- Marketing and business development expenses for the three months ended June 30, 2025, were $0.7 million, compared to $0.3 million for the same period of 2024. The

increase was primarily due to non-cash expenses related to PSUs, following the successful SHIELD II Phase 3 trial, which triggered the vesting of the PSUs.

- For the three months ended June 30, 2025, the Company had a net loss of $10.0 million, or ($0.78) per share, compared to a net loss of $6.3 million, or ($1.25) per share, in the three-month period ended June 30, 2024.

Financial results for six months ended June 30, 2025

- R&D expenses for the six months ended June 30, 2025, were $12.3 million, compared to $9.8 million for the same six-month period of 2024. The increase in R&D expenses was primarily due to activities related to the completion of the SHIELD II Phase 3 trial and preparation for regulatory submissions.
- G&A expenses for the six months ended June 30, 2025, were $3.7 million, compared to $2.1 million for the same period of 2024. The increase was primarily due to non-cash expenses related to PSUs, following the successful SHIELD II Phase 3 trial, which triggered the vesting of the PSUs.
- Marketing and business development expenses for the six months ended June 30, 2025, were $1.0 million, compared to $0.5 million for the same period of 2024. The increase was primarily due to non-cash expenses related to PSUs, following the successful SHIELD II Phase 3 trial, which triggered the vesting of the PSUs.
- For the six months ended June 30, 2025, the Company had a net loss of $18.2 million, or ($1.48) per share, compared to a net loss of $12.7 million, or ($2.62) per share, in the six-month period ended June 30, 2024.

Balance Sheet Highlights

- As of June 30, 2025, the Company had cash and cash equivalents and short-term deposits in the amount of $29.5 million, compared to $15.6 million on December 31, 2024. PolyPid expects that its current cash balance will be sufficient to fund operations well into 2026.

Conference Call Dial-In & Webcast Information:

Date:	Wednesday, August 13, 2025
Time:	8:30 AM Eastern Time
Conference Call:	https://register-conf.media-server.com/register/BI24f4e2ebaf86432084ad872a4496f74d
Webcast:	https://edge.media-server.com/mmc/p/aqeywg9m

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. Following positive phase 3 results, New Drug Application (NDA) submission of D-PLEX , PolyPid's lead product candidate, for the prevention of abdominal colorectal surgical site infections, is expected in early 2026. In addition, the Company has an innovative pipeline in oncology, obesity and diabetes.

For additional Company information, please visit http://www.polypid.com and follow us on Twitter (X) 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 D-PLEX 's potential clinical benefits, the expected NDA submission and its timing, its commercialization preparations and strategic partnership discussions to maximize D-PLEX 's market potential, the aims of GLP-1 program, the Company's potential commercial partners, D-PLEX 's potential to address a significant unmet medical need, the Company's ability to maximize the value of its innovative technology and the Company's expectation that its current cash runway will be sufficient well into 2026. 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, including, but not limited to, the risks detailed in the Company's Annual Report on Form 20-F filed on February 26, 2025. 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 (UNAUDITED)
U.S. dollars in thousands

	June 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 17,448	$ 15,641
Restricted deposits	182	168
Short-term deposits	12,007	–
Prepaid expenses and other current assets	351	764
Total current assets	29,988	16,573
LONG-TERM ASSETS:		
Property and equipment, net	5,339	6,075
Operating lease right-of-use assets	2,062	2,295
Other long-term assets	298	277
Total long-term assets	7,699	8,647
Total assets	$ 37,687	$ 25,220

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

	June 30, 2025	December 31, 2024
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 2,572	$ 2,409
Accrued expenses and other current liabilities	2,967	2,566

Current maturities of long-term debt	6,548	6,787
Current maturities of operating lease liabilities	1,068	919
Total current liabilities	13,155	12,681
LONG-TERM LIABILITIES:		
Long-term debt	–	634
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	1,054	1,277
Other liabilities	454	396
Total long-term liabilities	4,056	4,855
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares with no par value – Authorized: 107,800,000 shares at June 30, 2025 and December 31, 2024; Issued and outstanding: 15,654,129 and 10,190,904 shares at June 30, 2025 and December 31, 2024, respectively		
Additional paid-in capital	306,052	275,015
Accumulated deficit	(285,576)	(267,331)
Total shareholders' equity	20,476	7,684
Total liabilities and shareholders' equity	$ 37,687	$ 25,220

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

	Six Months Ended June 30,		Three Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 12,332	$ 9,810	$ 6,215	$ 4,760
Marketing and business development	989	501	700	265
General and administrative	3,661	2,111	2,488	1,096
Operating loss	16,982	12,422	9,403	6,121
Loss on extinguishment of debt	512	–	–	–
Financial expenses, net	687	311	521	171
Loss before income tax	18,181	12,733	9,924	6,292
Income tax expenses	64	9	53	2
Net loss	$ 18,245	$ 12,742	$ 9,977	$ 6,294
Loss per share:				
Basic and diluted	$ 1.48	$ 2.62	$ 0.78	$ 1.25
Weighted-average Ordinary shares outstanding:				
Basic and diluted	12,298,113	4,858,158	12,841,621	5,024,871


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