PolyPid Provides Corporate Update and Reports Third Quarter 2025 Financial Results

Face-to-Face Pre-NDA Meeting with the FDA Scheduled for Early December; NDA Submission for D-PLEX On Track for Early 2026

Advancements in Discussions with Potential U.S. Partners Following Positive Phase 3 Trial Results

Company Continues to Advance Towards Commercial Manufacturing Readiness with Successful Completion of IMOH GMP Inspection

Conference Call Scheduled for Today at 8:30 AM ET

PETACH TIKVA, Israel, Nov. 12, 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 nine months ended September 30, 2025.

Recent Corporate Highlights:

- **Regulatory Pathway Advancement:** The Company continues to make progress in its regulatory strategy with a face-to-face pre- New Drug Application ("NDA") meeting with the U.S. Food and Drug Administration ("FDA") scheduled for early December and remains on track to submit an NDA for D-PLEX in the prevention of abdominal colorectal surgical site infections ("SSIs") in early 2026, leveraging its Fast Track and Breakthrough Therapy designations.
- **Advancing U.S. Partnership Discussions:** The Company is engaged in strategic partnership discussions with potential partners in the United States for D-PLEX . These discussions have progressed in the recent quarter following the Company's positive Phase 3 SHIELD II trial results, announced in the second quarter.
- **Commercial Readiness:**
  - The Company successfully completed the Israeli Ministry of Health ("IMOH") Good Manufacturing Practice ("GMP") inspection, an important milestone in preparing PolyPid toward commercial manufacturing readiness for D-PLEX . The positive outcome of this inspection marks the fourth consecutive successful GMP inspection of PolyPid's manufacturing facility and further strengthens the Company's regulatory submission preparation.
  - The Company recently completed a U.S. market access research that included input from surgeons, hospital administrators and payers and reinforced the substantial value proposition of D-PLEX in reducing the significant clinical and economic burden of SSIs.

    - The Company presented the topline results of the SHIELD II Phase 3 trial at the American College of Surgeons Clinical Congress 2025.

“This past quarter was significant for PolyPid as we continue to progress toward bringing D-PLEX to market,” said Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid. “With our upcoming pre-NDA meeting with the FDA and our NDA submission on track for early 2026, we continue to execute on our regulatory strategy while in parallel, advancing discussions with potential U.S. partners.”

Financial results for three months ended September 30, 2025

- Research and development (R&D) expenses for the three months ended September 30, 2025, were $5.3 million, compared to $6.0 million in the same three-month period of 2024 and a decrease from $6.2 million in the previous quarter (Q2 2025). This decrease reflects the successful completion of the SHIELD II Phase 3 trial.
- General and administrative (G&A) expenses for the three months ended September 30, 2025, were $1.8 million, compared to $1.2 million for the same period of 2024.
- Marketing and business development expenses for the three months ended September 30, 2025, were $0.4 million, compared to $0.2 million for the same period of 2024.
- For the three months ended September 30, 2025, the Company had a net loss of $7.5 million, or ($0.37) per share, compared to a net loss of $7.8 million, or ($1.22) per share, in the three-month period ended September 30, 2024.

Financial results for nine months ended September 30, 2025

- R&D expenses, net for the nine months ended September 30, 2025, were $17.6 million, compared to $15.8 million for the same nine-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 nine months ended September 30, 2025, were $5.4 million, compared to $3.3 million for the same period of 2024.
- Marketing and business development expenses for the nine months ended September 30, 2025, were $1.4 million, compared to $0.7 million for the same period of 2024.
- For the nine months ended September 30, 2025, the Company had a net loss of $25.7 million, or ($1.72) per share, compared to a net loss of $20.5 million, or ($3.82) per share, in the nine-month period ended September 30, 2024.

Balance Sheet Highlights

- As of September 30, 2025, the Company had cash, cash equivalents, and short-term deposits in the amount of $18.8 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. Notably, during the quarter, we made significant progress reducing our

debt by decreasing current maturities of long-term debt from $6.5 million as of June 30, 2025 to $2.4 million as of September 30, 2025.

Conference Call Dial-In & Webcast Information:

Date:	Wednesday, November 12, 2025
Time:	8:30 AM Eastern Time
Conference Call:	https://register-conf.media-server.com/register/BIc1123c3d1ebf446fb8b5342dae528d37
Webcast:	https://edge.media-server.com/mmc/p/hgt6udvi

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 its regulatory strategy and timeline for its pre-NDA meeting and NDA submission, ongoing partnership discussions with potential U.S. partners, benefits, value proposition and advantages of D-PLEX$_{100}$ and the Company's ability to bring D-PLEX to market, readiness for commercialization and its ability to fund operations 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

	September 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 9,669	$ 15,641
Restricted deposits	186	168
Short-term deposits	9,120	–
Prepaid expenses and other current assets	609	764
Total current assets	19,584	16,573
LONG-TERM ASSETS:		
Property and equipment, net	$ 5,120	6,075
Operating lease right-of-use assets	1,833	2,295
Other long-term assets	304	277
Total long-term assets	7,257	8,647
Total assets	$ 26,841	$ 25,220

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

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

	September 30, 2025	December 31, 2024
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt	$ 2,416	$ 6,787
Accrued expenses and other current liabilities	2,207	2,566
Trade payables	1,908	2,409
Current maturities of operating lease liabilities	1,092	919
Total current liabilities	7,623	12,681
LONG-TERM LIABILITIES:		
Long-term debt	–	634
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	829	1,277
Other liabilities	476	396
Total long-term liabilities	3,853	4,855
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY :		
Ordinary shares with no par value – Authorized: 107,800,000 shares at September 30, 2025 and December 31, 2024, respectively; Issued and outstanding: 16,634,790 and 10,190,904 shares at September 30, 2025 and December 31, 2024, respectively.	–	–
Additional paid-in capital	308,392	275,015
Accumulated deficit	(293,027)	(267,331)
Total shareholders' equity	15,365	7,684
Total liabilities and shareholders' equity	$ 26,841	$ 25,220

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

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

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 17,589	$ 15,784	$ 5,257	$ 5,974
Marketing and business development	1,421	747	432	246
General and administrative	5,427	3,277	1,766	1,166
Operating loss	24,437	19,808	7,455	7,386
Loss on extinguishment of debt	512	–	–	–
Financial expense (income), net	661	665	(26)	354

Loss before income tax	25,610	20,473	7,429	7,740
Income tax expenses	86	29	22	20
Net loss	$ 25,696	$ 20,502	$ 7,451	$ 7,760
Basic and diluted loss per ordinary share	$ 1.72	$ 3.82	$ 0.37	$ 1.22
Weighted average number of ordinary shares used in computing basic and diluted loss per share	14,920,521	5,362,858	20,054,071	6,361,286