# PolyPid Provides Corporate Update and Reports First Quarter 2026 Financial Results

*Initiated NDA Submission to the FDA for D-PLEX ; Completion Expected Imminently*

*U.S. Commercial Partnership Discussions in Late Stages*

*Conference Call Scheduled for Today at 8:30 AM ET*

PETACH TIKVA, Israel, May 13, 2026 (GLOBE NEWSWIRE) — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), an innovative biopharmaceutical company dedicated to improving patient outcomes by elevating treatment effectiveness, right where care begins, today provided a corporate update and reported financial results for the three months ended March 31, 2026.

**Recent Corporate Highlights:**

- **Initiated NDA Submission to the FDA under Rolling Review:**
  - On March 30, 2026, the Company initiated a New Drug Application ("NDA") submission to the U.S. Food and Drug Administration ("FDA") for D-PLEX , the Company's lead product candidate for the prevention of surgical site infections ("SSIs") in patients undergoing colorectal surgery. The first modules, including the Chemistry, Manufacturing and Controls ("CMC") and nonclinical sections, were submitted as part of the rolling review, with additional components, including the clinical section, expected to be submitted imminently, marking the completion of the NDA submission.
  - In March 2026, the FDA granted PolyPid a small business waiver of the Prescription Drug User Fee Act ("PDUFA") fee of approximately $4.3 million for the D-PLEX NDA. This meaningful waiver enables the Company to focus its resources on commercialization preparations.
- **Advancing EU Regulatory Submission:** The Company has scheduled meetings in the second quarter of 2026 with the European Medicines Agency ("EMA") Rapporteur and Co-Rapporteur, which are European regulatory authorities designated to lead the assessment of the planned Marketing Authorization Application ("MAA") for D-PLEX , to align on the content and structure of the planned submission. The MAA, which will be submitted to the EMA under the Centralized Procedure on the basis of therapeutic innovation, is currently planned for the third quarter of 2026.
- **U.S. Commercial Partnership Discussions in Late Stages:** The Company's strategic partnership discussions with potential U.S. commercial partner for D-PLEX have continued to progress and are now in what the Company believes are its late stages.
- **New SHIELD II Phase 3 Data Presented at Two Medical Congresses:** At the 45th

Annual Meeting of the Surgical Infection Society (SIS) in May 2026, an analysis of ASEPSIS[1] score data showed a 64% relative risk reduction (p=0.0103) in the proportion of patients with an ASEPSIS score greater than 20, the threshold for clinically significant wound infection, indicating that even among patients who experienced wound events in the D-PLEX arm, severity was meaningfully reduced. The results imply better clinical outcomes and the potential for lower hospital resource utilization. At the European Society of Clinical Microbiology and Infectious Diseases Global 2026 Congress in April 2026, new pharmacokinetic data provided further evidence for the sustained, controlled release of doxycycline by D-PLEX for approximately 30 days, with minimal systemic exposure.

- **Upcoming Expected Milestones:**
  - Completion of the NDA submission to the FDA for D-PLEX imminently.
  - Meetings with the EMA Rapporteur and Co-Rapporteur to discuss the planned MAA submission for D-PLEX in the second quarter of 2026.
  - Submission of the MAA to the EMA for D-PLEX under the Centralized Procedure on the basis of therapeutic innovation in the third quarter of 2026.
  - PDUFA target action date will be confirmed following NDA acceptance and planned for first quarter of 2027.

“The first quarter of 2026 marked an important transition for PolyPid, as we moved from late-stage development to the final stage prior to drug approval, the regulatory review stage, with the initiation of our NDA submission for D-PLEX ,” said Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid. “With submission completion expected shortly and our U.S. commercial partnership discussions now in late stages, we are looking forward to implementing our launch plans. At the same time, additional Phase 3 data continues to reinforce D-PLEX ‘s clinical and economic value proposition. We look forward to providing further updates as these milestones unfold.”

**Financial Results for the Three Months Ended March 31, 2026**

- Research and development expenses for the three months ended March 31, 2026, were $5.8 million, compared to $6.1 million in the same three-month period of 2025. The decrease primarily reflects the completion of the SHIELD II Phase 3 trial and the Company’s ongoing transition toward regulatory submission and commercial readiness activities.
- General and administrative expenses for the three months ended March 31, 2026, were $1.6 million, compared to $1.2 million for the same period of 2025.
- Marketing and business development expenses for the three months ended March 31, 2026, were $0.4 million, compared to $0.3 million for the same period of 2025.
- For the three months ended March 31, 2026, the Company had a net loss of $7.7 million, or ($0.35) per share, compared to a net loss of $8.3 million, or ($0.70) per share, in the three-month period ended March 31, 2025.

**Balance Sheet Highlights**

- As of March 31, 2026, the Company had cash, cash equivalents, and short-term deposits of $10.9 million, compared to $12.9 million on December 31, 2025. The modest decrease, approximately $2 million, reflects continued operating activities, partially offset by proceeds from warrant exercises during the quarter.
- In early May 2026, the Company completed the repayment of its remaining $0.8 million venture loan facility, originally entered into in April 2022. As a result, the Company has fully repaid its outstanding debt obligations and has no remaining loan-related liabilities as of the date of this press release.
- During the first quarter of 2026, long-time shareholders continued to exercise warrants, generating approximately $4.0 million in aggregate proceeds. Together with the preserved capital from the FDA's PDUFA fee waiver, these developments further strengthen the Company's financial position as it approaches key upcoming milestones.
- The Company believes its current cash resources will be sufficient to fund operations into the second half of 2026 and through several significant upcoming potential milestones.

**Conference Call Dial-In & Webcast Information:**

| | |
|---|---|
| Date: | Wednesday, May 13, 2026 |
| Time: | 8:30 AM Eastern Time |
| Conference Call: | https://register-conf.media-server.com/register/BI510ef0c33b114b5b87c2bd9d3c34e882 |
| Webcast: | https://edge.media-server.com/mmc/p/w3mvdb4o |

**About PolyPid**

PolyPid Ltd. (Nasdaq: PYPD) is an innovative biopharmaceutical company dedicated to elevating treatment effectiveness, right where care begins. The Company develops long-acting, controlled-release drugs designed to deliver therapy precisely at the site of care, addressing critical unmet medical needs across a wide and diverse pipeline spanning surgical care, metabolic diseases, and beyond. PolyPid's lead product, D-PLEX , successfully met its primary and all key secondary endpoints in the landmark Phase 3 SHIELD II trial for the prevention of surgical site infections. Guided by a commitment to precision and innovation, PolyPid is redefining how therapies perform and raise the standard of patient care. 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 the expected completion of the NDA submission, the Company's expectation to hold a Scientific Advice meeting with the EMA to discuss the planned Marketing Authorization Application submission for D-PLEX , and the expected timing thereof, the Company's expectations regarding a U.S. strategic partnership and launch plans, the Company's upcoming expected milestones, D-PLEX 's clinical and economic value proposition and the Company's expectation that its current cash resources will be sufficient to fund operations into the second half of 2026 and through several significant upcoming potential milestones. 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 25, 2026. 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 (UNAUDITED)**

**U.S. dollars in thousands**

| | March 31, 2026 | December 31, 2025 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 8,888 | $ 6,402 |
| Restricted deposits | 194 | 193 |
| Short-term deposits | 2,021 | 6,531 |
| Pre-launch inventories | 1,106 | 1,106 |
| Prepaid expenses and other current assets | 351 | 995 |
| Total current assets | 12,560 | 15,227 |
| LONG-TERM ASSETS: | | |
| Property and equipment, net | 4,805 | 5,094 |
| Operating lease right-of-use assets | 1,426 | 1,675 |
| Other long-term assets | 369 | 311 |
| Total long-term assets | 6,600 | 7,080 |
| Total assets | $ 19,160 | $ 22,307 |

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

| | March 31, 2026 | December 31, 2025 |
|---|---|---|
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| CURRENT LIABILITIES: | | |
| Trade payables | $ 1,535 | $ 2,856 |
| Accrued expenses and other current liabilities | 3,553 | 2,734 |
| Current maturities of long-term debt | 801 | 988 |
| Current maturities of operating lease liabilities | 1,159 | 1,161 |
| Total current liabilities | 7,048 | 7,739 |
| LONG-TERM LIABILITIES: | | |
| Long-term debt | – | – |
| Deferred revenues | 2,548 | 2,548 |
| Long-term operating lease liabilities | 383 | 647 |
| Other liabilities | 401 | 400 |
| Total long-term liabilities | 3,332 | 3,595 |
| COMMITMENTS AND CONTINGENT LIABILITIES | | |
| SHAREHOLDERS' EQUITY: | | |

| | | |
|---|---|---|
| Ordinary shares, no par value *) – | | |
| Authorized: 107,800,000 shares at March 31, 2026 and December 31, 2025, respectively; | | |
| Issued and outstanding: 19,174,078 and 18,204,002 shares at March 31, 2026 and December 31, 2025, respectively | – | – |
| Additional paid-in capital | 318,008 | 312,473 |
| Accumulated deficit | (309,228) | (301,500) |
| Total shareholders' equity | 8,780 | 10,973 |
| Total liabilities and shareholders' equity | $ 19,160 | $ 22,307 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2026** | **2025** |
| Operating expenses: | | |
| Research and development, net | $ 5,756 | $ 6,117 |
| Marketing and business development expenses | 414 | 289 |
| General and administrative | 1,590 | 1,173 |
| Operating loss | 7,760 | 7,579 |
| Financial expense (income), net | (32) | 678 |
| Loss before income tax | 7,728 | 8,257 |
| Income tax expense | – | 11 |
| Net loss attributable to Ordinary shares | $ 7,728 | $ 8,268 |
| Loss per share: | | |
| Basic | $ 0.35 | $ 0.70 |
| Diluted | $ 0.35 | $ 0.70 |
| Weighted average number of Ordinary shares used in computing basic and diluted loss per share | 21,924,193 | 11,754,622 |

[1] ASEPSIS is an acronym of wound assessment and treatment parameters, which provides a numerical score during an inspection of the surgical site. The final score is interpreted by the severity of wound appearance and the clinical consequences of the infection. Parameters include: serous exudate, erythema, purulent exudate, separation of deep tissue and also antibiotic therapy, drainage of pus under local/general anesthesia, isolation of pathogenic bacteria and hospital stay as inpatient.