

PolyPid Unveils Expanded Pipeline Strategy, Introducing PD01B, a New Kynatrix™ Based Product Candidate for the Treatment of Diabetic Foot Infections

Company to host virtual Investor Day today at 11:30 AM ET, featuring key opinion leader Warren S. Joseph, DPM, FIDSA

All scheduled FDA interactions on track and aligned with D-PLEX November 28, 2026 PDUFA goal date

PolyPid introduces PD01B, a new product candidate targeting hyper-localized, controlled-release antibiotic treatment of diabetic foot infections, based on the Company's proprietary Kynatrix technology

PD01B planned to be developed as a new NDA; pre-IND meeting and first-in-human study both expected in the second half of 2027

PETACH TIKVA, Israel, Oct. 28, 2026 (GLOBE NEWSWIRE) — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), an innovative biopharmaceutical company dedicated to elevating treatment effectiveness, right where care begins, today unveiled its expanded pipeline strategy, extending its Kynatrix delivery technology from infection prevention to infection treatment, beginning with PD01B. The Company will discuss its upcoming strategy and long-term vision, including PD01B and its plans for D-PLEX , at its virtual Investor Day taking place today at 11:30 AM ET, featuring key opinion leader Warren S. Joseph, DPM, FIDSA. Details for accessing the event are provided below.

"With D-PLEX approaching its Prescription Drug User Fee Act ("PDUFA") date, a committed commercial partner in the U.S. and European rights back under our control, we are now in a position to advance other assets in our pipeline," said Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid. "PD01B is our first step in extending Kynatrix from preventing infections to treating them. While PD01B is a distinct product, with its own formulation, indication and care setting, it is built on the Kynatrix technology that was clinically validated in our Phase 3 SHIELD II trial of D-PLEX , and it leverages our established CMC and manufacturing capabilities. We believe this gives PD01B a potentially accelerated, more capital-efficient path into the clinic."

Introducing PD01B: Diabetic foot infections ("DFIs") are among the most serious and costly complications of diabetes, which affect an estimated 589 million adults worldwide.¹ Between one in five and one in three people with diabetes will develop a foot ulcer in their lifetime,² and about half of these ulcers are already infected when patients present for care. DFIs are the most frequent diabetes-related complication requiring hospitalization and the most

common event leading to lower-extremity amputation. In one large prospective study cited in the 2023 international guidelines, one year after presenting with an infected foot ulcer only 46% of patients had healed, while 17% had undergone a lower-extremity amputation and 15% had died.³

Current treatment relies on debridement and systemic antibiotics, which can struggle to achieve adequate concentrations in infected tissue with poor blood supply and, over courses that can last weeks, contribute to adverse events and antimicrobial resistance. Locally delivered antibiotics offer the potential to reach very high concentrations at the site of infection.

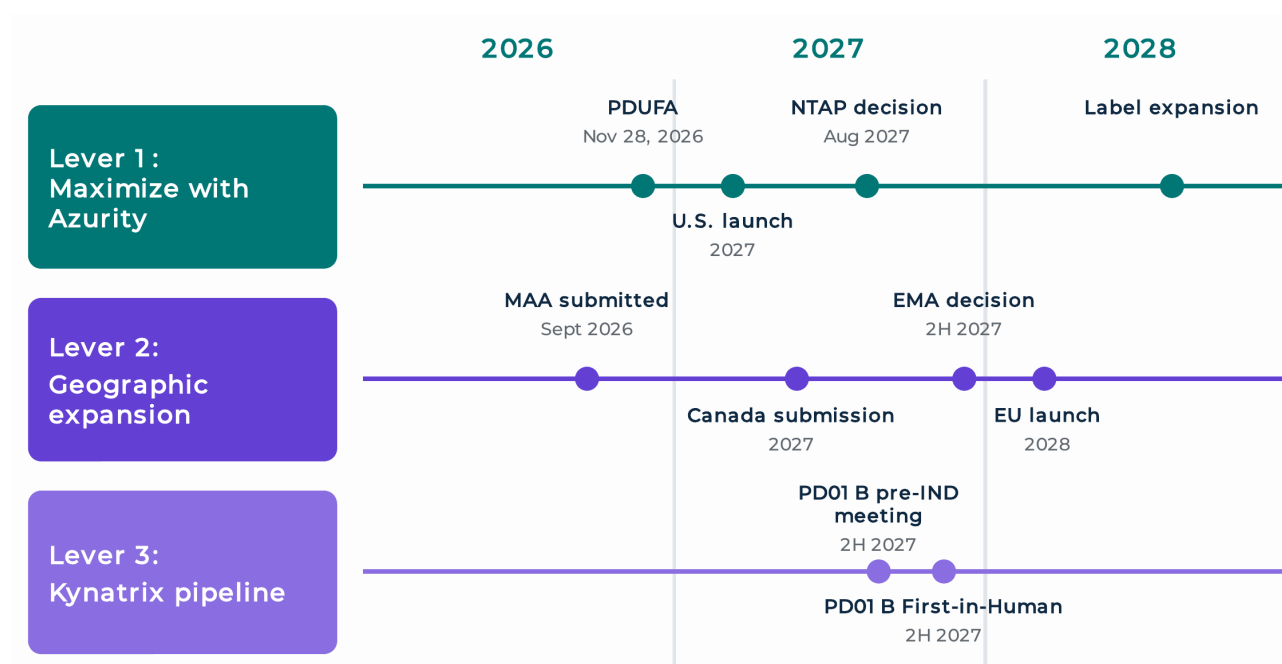
PD01B is designed to address this gap. It combines doxycycline, a well-characterized broad-spectrum antibiotic with activity against common DFI pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA),⁴ with PolyPid's Kynatrix technology. Applied directly into the wound after debridement, PD01B is designed to sustain high local doxycycline levels in the infected tissue for weeks. PD01B is being developed for patients with moderate to severe infections, the population on which U.S. Food and Drug Administration's ("FDA") guidance for DFI clinical trials focuses.⁵

At the Investor Day, Dr. Joseph, a leading podiatric physician specializing in lower extremity infectious diseases and Editor-in-Chief of the Journal of the American Podiatric Medical Association, will discuss the clinical burden of DFIs, the limitations of current treatment approaches, and the potential role of locally delivered, long-acting antibiotic therapy. PolyPid's management will also review the Company's plans to maximize the value of D-PLEX, for which a New Drug Application ("NDA") is under FDA Priority Review with a PDUFA goal date of November 28, 2026, including potential label expansion beyond colorectal surgery and potential geographic expansion. A live question-and-answer session with Dr. Joseph and management will follow the formal presentations.

Upcoming Potential Milestones and Timelines

- D-PLEX PDUFA goal date: November 28, 2026
- D-PLEX U.S. launch: expected in early 2027, subject to FDA approval
- FDA communications on label expansion into additional abdominal surgeries: initiation in the fourth quarter of 2026, with potential label expansion into additional surgeries in 2028
- CMS decision on New Technology Add-on Payment ("NTAP"): expected in August 2027
- Canadian New Drug Submission for D-PLEX : 2027
- European Medicines Agency ("EMA") decision on the D-PLEX Marketing Authorization Application: second half of 2027, with a potential EU launch in 2028
- PD01B pre-investigational new drug ("IND") meeting with the FDA and first-in-human

study: second half of 2027



Investor Day Dial-In & Webcast Information:

To ensure you are connected prior to the beginning of the event, PolyPid suggests registering a minimum of 5 minutes before the start of the event. For those not planning to ask a question of management or Dr. Joseph, the Company recommends listening via the webcast.

Date: Wednesday, October 28, 2026

Time: 11:30 AM Eastern Time

Conference Call: <https://register-conf.media-server.com/register/Blb1af168335ad493c80fe51bb064f7b95>

Webcast: <https://edge.media-server.com/mmc/p/97rvqcaj>

The presentation will be available on the Events & Presentations page of the Investors section of the Company's website at investors.polypid.com. A replay of the event will be available on the same page following the event.

About PD01B

PD01B is a new product candidate being developed by PolyPid for the treatment of moderate to severe diabetic foot infections. Built on PolyPid's Kynatrix delivery technology, PD01B is designed to be applied directly into the wound after debridement and to provide controlled release of the broad-spectrum antibiotic doxycycline, resulting in hyper-localized, high concentrations of the drug at the site of infection for weeks.

About D-PLEX

D-PLEX, PolyPid's lead product candidate, is designed to provide local prolonged and

controlled anti-bacterial activity directly at the surgical site with the goal of preventing abdominal surgical site infections (“SSIs”). Following the administration of D-PLEX into the surgical site, PolyPid’s delivery technology, Kynatrix, is designed to pair with Active Pharmaceutical Ingredients, enabling a prolonged and continuous release of the broad-spectrum antibiotic doxycycline, resulting in a high local concentration of the drug for a period of 30 days for the prevention of SSIs, with additional potential to prevent SSIs caused by antibiotic-resistant bacteria at the surgical site. In the Phase 3 SHIELD II trial, D-PLEX recently demonstrated positive results in achieving its primary end point and a 60% ($p=0.0013$) relative risk reduction at the secondary end point in SSI incidence following abdominal colorectal surgery with large incisions. D-PLEX received Breakthrough Therapy Designation from the U.S. Food and Drug Administration for the prevention of SSIs in patients undergoing elective colorectal surgery.

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 its pipeline and growth strategy; the design, development plan, regulatory pathway and potential benefits of PD01B, including the anticipated timing of a pre-IND meeting and the initiation of a first-in-human study; the potential role of locally delivered, long-acting antibiotic therapy; anticipated milestones and timelines, the intended duration of local antibiotic delivery, the anticipated timing of the U.S. launch of D-PLEX, the CMS decision on NTAP, the Canadian New Drug Submission, the EMA decision on the Marketing Authorization Application and a potential EU launch; the FDA’s Priority Review of the D-PLEX NDA, the November 28, 2026 PDUFA goal date and the potential FDA approval of D-PLEX; and the potential expansion of D-PLEX into additional surgical indications and geographies. 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.

Company Contact:

PolyPid Ltd.
Ori Warshavsky
908-858-5995
IR@Polypid.com

Investor Relations Contact:

Arx Investor Relations
North American Equities Desk
polypid@arxhq.com

¹ International Diabetes Federation. IDF Diabetes Atlas, 11th edition. 2025.
<https://diabetesatlas.org/>

² Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. N Engl J Med. 2017;376(24):2367-2375. <https://doi.org/10.1056/NEJMra1615439>

³ Senneville É, Albalawi Z, van Asten SA, et al. IWGDF/IDSA Guidelines on the Diagnosis and Treatment of Diabetes-related Foot Infections (IWGDF/IDSA 2023). Clin Infect Dis. 2023. <https://doi.org/10.1093/cid/ciad527>

⁴ Senneville É, et al. IWGDF/IDSA 2023 (see note 3). <https://doi.org/10.1093/cid/ciad527>

⁵ U.S. Food and Drug Administration. Diabetic Foot Infections: Developing Drugs for Treatment. Guidance for Industry. June 2024. <https://www.fda.gov/media/173006/download>



Polypid