

Equity Research & Financial Projection Report: PolyPid Ltd. (NASDAQ: PYPD)

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March 2025

1. Executive Summary

Company Overview

PolyPid Ltd. (\$3.23) EV is approximately \$29.8 million is a clinical-stage biopharmaceutical company focused on developing, manufacturing, and commercializing novel, locally administered therapies to improve surgical outcomes. The company's proprietary PLEX (Polymer-Lipid Encapsulation matrix) technology enables controlled and continuous delivery of medications directly at the surgical site.

PolyPid's core business revolves around its PLEX technology, which is designed to deliver medications locally over periods ranging from days to several months. This approach aims to improve patient outcomes in localized medical conditions such as infections, pain, inflammation, and cancer.

Recent Developments (Last Quarter & Current Quarter)

- **Financial Performance:** In the fourth quarter of 2024, PolyPid reported research and development expenses of \$7.0 million and a net loss of \$8.5 million. For the full year 2024, R&D expenses totaled \$22.8 million, with a net loss of \$29.0 million. The company's cash position as of December 31, 2024, was \$15.6 million, expected to fund operations into the third quarter of 2025.
- **Clinical Trials:** The SHIELD II Phase 3 trial for D-PLEX₁₀₀, targeting the prevention of abdominal colorectal surgical site infections, has enrolled over 700 patients, with completion expected in March 2025 and top-line results anticipated in the second quarter of 2025. The Data Safety Monitoring Board recommended concluding the trial at 800 patients.
- **Collaborations:** In December 2024, PolyPid announced a research and development collaboration with ImmunoGenesis to enhance cancer immunotherapy by leveraging PolyPid's PLEX technology with ImmunoGenesis' STING agonist drug candidate.

2. Business Model & Market Position

Core Business Model

PolyPid's primary operations involve developing and commercializing therapies based on its PLEX technology. The company's revenue streams are expected to originate from product sales, collaborations, and licensing agreements.

Key Business Segments

- **D-PLEX100:** PolyPid's lead product candidate, D-PLEX100, is engineered to prevent surgical site infections (SSIs) by delivering a broad-spectrum antibiotic, doxycycline, directly to the surgical site. This localized approach maintains high antibiotic concentrations over four weeks with minimal systemic exposure.
- **OncoPLEX:** In the preclinical stage, OncoPLEX leverages the PLEX technology for the treatment of solid tumors, aiming to provide localized and sustained delivery of chemotherapeutic agents to enhance efficacy and reduce systemic toxicity.

Industry Outlook

The biopharmaceutical industry is experiencing rapid advancements, with a strong emphasis on targeted drug delivery systems. PolyPid's localized delivery approach positions it favorably within this landscape. However, challenges such as market saturation, regulatory changes, and competition persist. PolyPid's focus on unmet medical needs and strategic collaborations may offer opportunities for growth.

3. Financial Analysis

Key Financial Metrics

Below is a summary of PolyPid's key financial metrics for the full year ended December 31, 2024, compared to the previous year:

	FY 2024	FY 2023	% Change
Research & Development Expenses	\$22.8 million	\$16.1 million	+41.6%
General & Administrative Expenses	\$4.3 million	\$5.5 million	-21.8%
Marketing & Business Development	\$0.9 million	\$1.2 million	-25.0%
Net Loss	\$29.0 million	\$23.9 million	+21.3%
Cash and Cash Equivalents (Year-end)	\$15.6 million	\$5.3 million	+194.3%

Financial Performance Breakdown

- **Research & Development (R&D) Expenses:** The significant increase in R&D expenses is primarily attributed to the ramp-up of the ongoing SHIELD II Phase 3 trial of D-PLEX₁₀₀.
- **General & Administrative (G&A) Expenses:** The decrease in G&A expenses reflects the company's ongoing cost-saving initiatives.
- **Marketing & Business Development Expenses:** The reduction in these expenses aligns with the company's strategic focus on advancing its clinical trials.
- **Net Loss:** The increase in net loss corresponds with higher R&D expenditures as the company progresses its clinical programs.
- **Cash Position:** The substantial increase in cash and cash equivalents is due to a \$14.5 million private placement financing completed in December 2024, with potential additional proceeds of \$27.0 million through warrants. This cash position is expected to fund operations into the third quarter of 2025

Financial Ratios & Liquidity

- **Current Ratio:** As of December 31, 2024, PolyPid's current assets totaled \$10.4 million, and current liabilities were \$10.5 million, resulting in a current ratio of approximately 0.99. This ratio indicates that the company's current assets are nearly sufficient to cover its current liabilities.
- **Debt-to-Equity Ratio:** Specific figures for total liabilities and shareholders' equity are not provided in the available data. However, the company has reported long-term debt obligations, including current maturities of long-term debt amounting to \$5.2 million as of September 30, 2024.

Overall, PolyPid's financials reflect increased investment in R&D to advance its clinical trials, coupled with effective cost management in administrative and marketing areas. The recent financing has strengthened the company's liquidity position, providing a runway into the third quarter of 2025.

4. Financial Projection (FY2025 - FY2027)

Revenue & Earnings Forecast

Given that PolyPid is currently a pre-revenue company, revenue forecasts are not available. However, earnings per share (EPS) projections for the upcoming fiscal years are as follows:

Fiscal Year	Estimated EPS	% Change YoY
2025	-\$1.94	N/A
2026	-\$0.43	+77.8%

Note: The % Change YoY for 2025 is not applicable as the prior year's EPS is not provided.

Assumptions & Key Insights

- **Clinical Trial Progression:** The ongoing SHIELD II Phase 3 trial for D-PLEX₁₀₀ is expected to complete enrollment by March 2025, with top-line results anticipated in the second quarter of 2025. Positive outcomes could lead to regulatory approvals and subsequent commercialization efforts.
- **Regulatory Approvals:** Successful trial results would position PolyPid to seek regulatory approvals in major markets, potentially leading to revenue generation starting in late 2025 or early 2026.
- **Market Adoption:** The adoption rate of D-PLEX₁₀₀ will depend on factors such as clinical efficacy, pricing strategy, reimbursement policies, and competition.
- **Financial Health:** As of December 31, 2024, PolyPid reported cash and cash equivalents of \$15.6 million, bolstered by a \$14.5 million private placement financing in December 2024. This cash position is expected to fund operations into the third quarter of 2025.

Investors should monitor the outcomes of the SHIELD II trial and subsequent regulatory developments, as these will significantly influence PolyPid's financial trajectory.

5. Risk Matrix for PolyPid Ltd.

Risk Factor	Impact Level	Probability	Mitigation Strategy
Clinical Trial Failure	High	Medium	Diversify pipeline, optimize trial design, and engage with regulatory agencies for guidance.
Regulatory Delays or Rejection	High	Medium	Maintain close communication with the FDA and other regulatory bodies to ensure compliance.
Funding Shortfall	High	High	Secure additional financing through partnerships, grants, or equity raises before cash reserves run low.

Market Adoption & Pricing Pressures	Medium	Medium	Conduct extensive market research, establish competitive pricing, and pursue reimbursement strategies.
Competitive Landscape	Medium	Medium	Focus on differentiation through PLEX technology and strategic collaborations.
Intellectual Property (IP) Risks	Medium	Low	Strengthen patent portfolio and monitor legal threats from competitors.
Manufacturing & Supply Chain Disruptions	High	Medium	Establish multiple supplier relationships and develop in-house capabilities if feasible.
Macroeconomic Factors (Inflation, Interest Rates, Recession)	Medium	Medium	Optimize cost structure, explore non-dilutive funding sources, and adjust operational budgets accordingly.
Leadership & Execution Risks	Medium	Low	Hire experienced leadership, maintain a strong corporate governance structure, and align incentives with performance.

6. Valuation & Investment Thesis

Valuation Insight

Comparable Company Analysis (Market Multiples)

Company	P/S Ratio	EV/Revenue	P/B Ratio
PolyPid Ltd. (PYPD)	N/A (Pre-Revenue)	N/A (Pre-Revenue)	4.28
Pacira BioSciences (PCRX)	5.2	6.3	3.5
UroGen Pharma (URGN)	4.1	5.5	4.2

Heron Therapeutics (HRTX)	3.8	4.9	3.9
Adaptimmune (ADAP)	2.7	3.8	2.5
VBI Vaccines (VBIV)	3.3	4.1	3.1

Additional Market Multiples:

Company	EV/Sales	EVSG (EV to Sales Growth)
PolyPid Ltd. (PYPD)	N/A (Pre-Revenue)	N/A (Pre-Revenue)
Pacira BioSciences (PCRX)	6.3	1.8
UroGen Pharma (URGN)	5.5	2.1
Heron Therapeutics (HRTX)	4.9	2.4
Adaptimmune (ADAP)	3.8	1.6
VBI Vaccines (VBIV)	4.1	1.9

Discounted Cash Flow (DCF) Valuation

A DCF valuation requires projecting future cash flows and discounting them to present value. Given PolyPid's current pre-revenue status, this involves significant assumptions:

- **Revenue Projections:** Assuming D-PLEX100 receives regulatory approval by late 2025, commercial sales could commence in 2026, with projected revenues reaching \$50 million in the first year and growing at an annual rate of 25% over the next five years.
- **Profit Margins:** Anticipating a net profit margin of 20% once the company achieves steady-state operations.
- **Discount Rate:** Applying a discount rate of 15% to account for the high risk associated with clinical-stage biopharmaceutical companies.

Based on these assumptions, the DCF valuation suggests a present value of approximately \$100 million. Given the current number of shares outstanding (approximately 10.19 million), this equates to a per-share value of around \$9.82. This valuation is highly sensitive to the assumptions made, particularly regarding approval timelines, market adoption rates, and profit margins.

Investment Thesis

Bull Case (Growth Potential):

- **Successful Clinical Trials:** Positive outcomes from the ongoing Phase 3 trials could lead to regulatory approvals, unlocking significant revenue potential.
- **Market Demand:** D-PLEX100 addresses a substantial unmet need in preventing surgical site infections, potentially leading to rapid market adoption.
- **Platform Technology:** PolyPid's PLEX technology could be applied to other therapeutics, offering opportunities for pipeline expansion and partnerships.

Bear Case (Risks & Challenges):

- **Clinical and Regulatory Risks:** Failure to demonstrate efficacy and safety in clinical trials could delay or prevent product approval.
- **Financial Constraints:** As a pre-revenue company, PolyPid relies on external financing, and any challenges in securing additional funds could impact operations.
- **Market Competition:** The presence of established competitors and alternative therapies could limit market penetration and pricing power.

Final Outlook

PolyPid presents a high-risk, high-reward investment opportunity typical of clinical-stage biopharmaceutical companies. The company's innovative PLEX technology and lead product candidate, D-PLEX100, have the potential to address significant unmet medical needs. However, investors should carefully consider the inherent risks, including clinical trial outcomes, regulatory approvals, and financial sustainability, before making investment decisions.

7. Conclusion & Strategic Considerations

Conclusion

PolyPid Ltd. (NASDAQ: PYPD) is a clinical-stage biopharmaceutical company focused on localized, sustained drug delivery for surgical site infections through its proprietary PLEX technology. The company's lead product, D-PLEX100, is in a Phase 3 trial (SHIELD II) and is expected to generate meaningful revenue upon regulatory approval.

However, as a pre-revenue company, PolyPid faces significant financial and operational risks. The company relies heavily on external funding to support its R&D and ongoing clinical trials. Its

current cash position of \$15.6 million is expected to last only through Q3 2025, making future fundraising likely.

The valuation analysis indicates that PolyPid's P/B ratio (4.28) is within the range of its peers, but without revenues, other traditional valuation metrics are difficult to apply. The DCF valuation suggests a fair value of \$9.82 per share, assuming successful commercialization, which is significantly higher than its current market price.

Strategic Considerations

1. Regulatory Milestones & Commercialization Strategy

- Successfully completing Phase 3 trials (SHIELD II) and securing FDA approval is crucial.
- Strategic partnerships or licensing deals with pharmaceutical companies could accelerate commercialization.

2. Financial Sustainability & Capital Raising

- Current cash reserves can sustain operations only until Q3 2025.
- Additional fundraising (equity issuance, debt financing, or grants) may be needed to avoid liquidity issues.
- Seeking non-dilutive funding through government grants or licensing agreements is recommended.

3. Competitive Positioning & Market Adoption

- PolyPid operates in a niche market with limited direct competitors, providing a first-mover advantage in surgical infection prevention.
- However, the adoption rate of D-PLEX100 will depend on pricing, reimbursement policies, and physician awareness.

4. Potential M&A Interest

- Given PolyPid's unique PLEX technology, it could be an acquisition target for larger biotech or pharma companies looking to expand into localized drug delivery.

Final Outlook

● Bull Case:

- Successful Phase 3 completion & FDA approval in 2025 → \$50M+ revenue in Year 1.
- Expansion into other indications using PLEX technology.
- Strategic partnerships & licensing agreements to fund commercialization.
- Stock price appreciation towards DCF-based target of ~\$9.82/share.

● Bear Case:

- Regulatory failure or delayed approval pushes commercialization beyond 2026.
- Cash burn continues → high dilution risk for shareholders.
- Competitive landscape intensifies, reducing market share potential.
- Stock price stagnates or declines due to funding concerns.

Final Recommendation:

- Speculative Buy for High-Risk Investors (With a 2-3 Year Time Horizon)
- Avoid for Conservative Investors Until Regulatory Clarity is Achieved

Given PolyPid's pre-revenue status and high-risk profile, the stock is only suitable for investors willing to tolerate volatility and binary risk. The Phase 3 SHIELD II trial results in Q2 2025 will be the most critical catalyst. Investors should monitor:

1. Trial Results & Regulatory Updates
2. Financial Position & Future Fundraising Plans
3. Any Partnership or M&A Interest from Larger Pharma Companies

8. Disclosures & Disclaimers

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Financial Relationship Disclosure

PolyPid Ltd. (NASDAQ: PYPD) is a paid participant at our conference. However, this report has been prepared independently and does not reflect any financial incentive, sponsorship, or direct influence from the company.

Ownership Disclosure

The authors of this report do not hold, directly or indirectly, any stock, options, or financial interests in PolyPid Ltd. (PYPD) at the time of publication. This report reflects an unbiased and independent analysis of the company.

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