

Divakar Gupta +1 212 479 6474 dgupta@cooley.com

June 5, 2020

U.S. Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, DC 20549

Attn: Christie Wong

Daniel Gordon Chris Edwards Tim Buchmiller

Re: PolyPid Ltd.

**Draft Registration Statement on Form F-1** 

Submitted February 24, 2020

CIK No. 0001611842

## Ladies and Gentlemen:

On behalf of PolyPid Ltd. (the "Company"), we are providing this letter in response to the comments of the staff of the U.S. Securities and Exchange Commission's Division of Corporation Finance (the "Staff") contained in its letter, dated March 19, 2020 (the "Comment Letter"), relating to the Company's Draft Registration Statement on Form F-1, confidentially submitted on February 24, 2020 (the "Draft Registration Statement"). In response to the Comment Letter, the Company has revised the Draft Registration Statement and is publicly filing via EDGAR a revised Registration Statement on Form F-1 (the "Registration Statement") with this response letter. The numbering of the paragraphs below corresponds to the numbering of the comments contained in the Comment Letter, which for your convenience we have incorporated into this response letter in italics. Capitalized terms used in this letter but not otherwise defined in this letter shall have the meanings set forth in the Registration Statement.

**Draft Registration Statement on Form F-1** 

# Company Overview, page 1

1. Please clarify in the summary that the FDA's abbreviated approval pathway may not lead to a faster development process or regulatory review and does not increase the likelihood that a product candidate will receive approval.

Cooley LLP 55 Hudson Yards New York, NY 10001 t: (212) 479-6000 f: (212) 479-6275 cooley.com VIA EDGAR

RESPONSE: In response to the Staff's comment, the Company has revised the disclosure on pages 2 and 93 of the Registration Statement.

Risks Associated With Our Business, page 4

2. Please revise the final bullet point on page 4 to highlight briefly the adverse tax consequences that you reference, such as the three consequences identified in the final full paragraph on page 57. Also, highlight the annual IRS filing requirements that you reference on page 162. Please also revise the final sentence of the bullet point to clarify your present intention to not provide the information necessary for holders to make the QEF election. In this regard, we refer to your disclosure on page 162.

<u>RESPONSE</u>: In response to the Staff's comment, the Company has revised the disclosure on page 5 of the Registration Statement.

# Use of Proceeds, page 66

3. Please revise your disclosure in this section to indicate how far you expect the proceeds from the offering will allow you to proceed in the separate Phase 3 clinical trials for DPLEX<sub>100</sub> after abdominal surgery and after cardiac surgery. If the anticipated proceeds from your offering will not be sufficient to complete those trials, please disclose the amount and sources of other funds needed. Also, if any of the expenses identified in the bullet points on page 74 will be a principal intended use of your net proceeds, please expand your disclosure as appropriate.

RESPONSE: The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on page 69 of the Registration Statement.

## Dilution, page 70

4. Please tell us how you computed historical and pro forma net tangible book value and net tangible book value per share amount as of 12/31/2019. Reconcile the amounts used in your calculation to the historical and pro forma balance sheet as of December 31, 2019, and tell us how your calculation appropriately considers the Redeemable Preferred Shares.

<u>RESPONSE</u>: The Company acknowledges the Staff's comment and respectfully advises the Staff that, after re-examination of the calculation, the Company has adjusted the dilution calculation and revised the disclosure on page 73 of the Registration Statement.

The process by which the Company computed historical net tangible book value as of December 31, 2019 was by subtracting total liabilities (\$15.1 million) from total assets (\$33.8 million). The process by which the Company computed pro forma net tangible book value as of December 31, 2019 was by subtracting pro forma total liabilities (\$2.8 million) from pro forma total assets (\$33.8 million). The Company did not have any intangible assets on its balance sheet as of December 31, 2019.

The Company calculated historical net tangible book value per share for the same period by dividing such historical net tangible book value as of December 31, 2019 by the total number of outstanding ordinary shares as of December 31, 2019 (588,650). The Company also calculated pro forma net tangible book value per share for the same period by dividing such pro forma net tangible book value as of December 31, 2019 by the total number of outstanding ordinary shares after giving effect to the automatic conversion of all outstanding preferred shares into 13,097,218 ordinary shares upon the closing of this offering and the exercise of warrants to purchase 56,250 Series A preferred shares, and the automatic conversion thereof into 56,250 ordinary shares, as of December 31, 2019 (13,742,118).

Additionally, the Company does not believe the Redeemable Preferred Shares should be included in its calculation of historical net tangible book value per ordinary share, as the Redeemable Preferred Shares were not ordinary shares as of the historical date. The Company included the Redeemable Preferred Shares in its calculation of the pro forma net tangible book value per share, as such number gives effect to the automatic conversion of all Redeemable Preferred Shares into ordinary shares upon the closing of the offering.

#### Components of Results of Operations

## Research and Development, Net, page 75

5. We note that you included certain expenses related to regulatory activities, filing fees paid to regulatory agencies and other costs incurred in seeking regulatory approval as part of Research and Development ("R&D") expenses. Tell us the nature of such regulatory filing and approval fees and your consideration of ASC 730-10-55-1 through 55-2.

<u>RESPONSE</u>: In response to the Staff's comment, the Company has reviewed all such regulatory expenses classified as R&D expenses for the years ended December 31, 2018 and 2019. The Company respectfully notes that the regulatory expenses classified as R&D expenses during these periods directly supported and advanced the Company's clinical trials and ongoing clinical development of D-PLEX<sub>100</sub>, including the preparation and submission of

regulatory briefing packages, applications and other submissions to the United States Food and Drug Administration, European Medicines Agency and comparable foreign regulatory authorities. Such activities were required for the initiation and conduct of the trials of D-PLEX<sub>100</sub> and the continued development of this product candidate. All such work was performed by the Company's employees and consultants in the R&D function, each of whom have advanced scientific backgrounds. Accordingly, the Company believes that such regulatory activities are properly classified as R&D expenses because they meet the definition of "Research and Development" set forth in ASC 730-10-20, as these regulatory activities were critical elements of the Company's efforts to conduct clinical trials and advance D-PLEX<sub>100</sub>. These regulatory activities represented 5% and 4% of the Company's total research and development, net expenses for the years ended December 31, 2018 and 2019, respectively. The Company further notes that the regulatory activities conducted during these periods did not include any of the types of activities referenced in ASC 730-10-55-2.

Phase 2 Clinical Trial for D-PLEX100 in the Prevention of SSIs after Abdominal Surgery, page 100

6. Please identify the eight treatment emergent adverse events.

RESPONSE: In response to the Staff's comment, the Company has revised the disclosure on page 106 of the Registration Statement.

# Additional Clinical Data in Support of D-PLEX100, page 103

7. Please disclose the number of patients in the two pilot clinical trials for D-PLE $X_{1000}$ .

<u>RESPONSE</u>: In response to the Staff's comment, the Company has revised the disclosure on page 108 of the Registration Statement.

# Principal Shareholders, page 142

8. Please ensure that you identify the natural persons who are the beneficial owners of the shares held by the 5% or greater shareholders identified in your table.

RESPONSE: The Company has revised the disclosure on pages 148 to 150 of the Registration Statement.

Notes to Consolidated Financial Statements
Note 2: Significant Accounting Policies

b. Consolidated financial statements in U.S. dollars, page F-8

You indicated that the functional and reporting currency of the Company is the U.S. dollar. However, we note on page F-20 and F-25 that
certain preferred shares exercise prices and ordinary share par value are presented in New Israeli Shekel (NIS). Please revise accordingly.

<u>RESPONSE</u>: In response to the Staff's comment, the Company respectfully notes that, while its functional and reporting currency is the U.S. dollar, the Company is an Israeli corporation and pursuant to the Israeli Companies Law and regulations promulgated thereunder, the par value for the Company's shares must be denominated in NIS. With respect to the exercise price of the Company's Series A preferred shares, the Company has revised the disclosure on pages F-19 and F-20 of the Registration Statement.

## General

10. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

RESPONSE: The Company acknowledges the Staff's comment and respectfully advises the Staff that it has commenced "testing the waters" meetings with potential investors. Accordingly, the Company will supplementally provide to the Staff a copy of the presentation that the Company uses in such meetings with qualified institutional buyers or institutional accredited investors. The Company further advises the Staff that it will supplementally provide the Staff with copies of any additional written communications of the type referenced in the Staff's comment.

\* \* \* \*

Please contact me at (212) 479-6474 with any questions or further comments regarding our responses to the Staff's comments.

Sincerely,

/s/ Divakar Gupta

Divakar Gupta

cc: Amir Weisberg, PolyPid Ltd.
Dikla Czaczkes Akselbrad, PolyPid Ltd
Oded Har-Even, Zysman, Aharoni, Gayer & Co.
Nathan Ajiashvili, Latham & Watkins LLP
Barry P. Levenfeld, Yigal Arnon & Co.