

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

DIVISION OF CORPORATION FINANCE

Mail Stop 3561

June 26, 2018

Dr. Julian Adams Chief Executive Officer Gamida Cell Ltd. 5 Nahum Heftsadie Street Givaat Shaul, Jerusalem 91340 Israel

Re: Gamida Cell Ltd.

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

Submitted June 1, 2018 CIK No. 0001600847

Dear Dr. Adams:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

#### General

1. 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.

# Prospectus Summary

#### Overview, page 1

- 2. You state in the first paragraph that your technology "allows for the proliferation of donor cells while maintaining the cells' functional therapeutic characteristics, providing a treatment alternative for patients." You then state on page 3 that your technology "increases engraftment efficiency in HSCT and enables engraftment and immune system reconstitution," and that NiCord thus "may serve as a universal, readily-available, reliable and effective alternative to existing sources of donor cells for HSCT." You also state on page 92 that "NiCord delivers a therapeutically effective dose of stem cells, leading to rapid engraftment and immune reconstitution." Since an efficacy determination is solely within the FDA's authority and is continuously evaluated throughout all phases of the clinical development, please remove these and all other statements or implications regarding the potential efficacy of your product candidates.
- 3. Please revise your pipeline chart here and on page 86 to specify the "hematologic malignancies" which NiCord and NAM-NK are being tested to treat. Also, given that NAM-NK is currently in a Phase 1 trial, please revise your pipeline charts to present Phase 1 and Phase 2 in separate columns or explain why you believe the current presentation is appropriate.

# NiCord as a Universal Stem Cell Graft for Allogeneic HSCT, page 3

- 4. Please revise to define the terms "neutrophil engraftment" and "platelet engraftment" as used within the context of your clinical trials. In doing so, please enhance these definitions to explain the "key indicators of clinical benefits" you discuss of "rapid engraftment and immune reconstitution."
- 5. Please revise to identify the sponsor of the completed Phase 1/2 clinical trials you describe here.

# Risk Factors

Risks Related to our Reliance on Third Parties

We rely on third parties to supply the raw materials . . . ., page 34

6. You state here that you "have a relationship with a single supplier, Miltenyi Biotec GmbH, for certain equipment (columns and beads) necessary to create [y]our product candidates." Please file your supply agreement with Miltenyi Biotech GmbH or tell

us why you do not believe you are required to do so. Refer to Item 601(b)(10)(ii)(B) of Regulation S-K.

# Use of Proceeds, page 66

7. Please expand your disclosure regarding the proceeds to be used for your product candidates to describe how far in the development process of each candidate you estimate the allocated proceeds from this offering will enable you to reach.

# Dilution, page 70

8. Reference is made to the last two bullet points on page 71. Please tell us your consideration of also disclosing that the tables and discussion exclude warrants to purchase ordinary shares upon the closing of this offering that are expected to remain outstanding at the consummation of this offering,

## Management's Discussion & Analysis

# Analysis of Results of Operations

# Comparison of the years ended December 31, 2017 and 2016, page 76

9. When you describe two or more reasons that contributed to a material change in a financial statement line item between periods, please quantify, to the extent practicable, the incremental impact of each individual reason on the overall change. For example, in your discussion of general and administrative expenses please quantify the impact of the decrease in share-based payment and the increase in salaries and professional services expenses. Please also provide an analysis of the underlying reasons for each significant change you identify.

#### Critical Accounting Policies and Estimates

#### Share-Based Compensation, page 80

- 10. We note that you determined your ordinary share value as of December 31, 2017 using the Income Approach. Please disclose the nature of the material assumptions involved. For example, disclose that this method involves estimating future cash flows and discounting those cash flows at an appropriate rate. Please also disclose the extent to which the estimates are considered highly complex and subjective.
- 11. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the ordinary shares underlying your equity issuances and

the reasons for any differences between recent valuations of your ordinary shares leading up to the IPO and the estimated offering price.

# Business, page 84

- 12. Tell us the basis for your statement "... a full match is not required for a successful transplant using cord blood."
- 13. For each of the clinical trials discussed in this section, please disclose the dosage administered to participants. In addition, if any serious adverse effects or events other than GvHD, infection, engraftment failures, or death were observed in these trials, please revise to describe their nature and prevalence. We note in that regard your related risk factor disclosure on page 22.

## NAM-Based Cell Expansion Technology, page 87

14. Please explain the significance of the p-values at the top of the charts on pages 89, 93, 94, and 97, and discuss how these values relate to the FDA's evidentiary standards of efficacy.

# NiCord is designed to Address the Limitations of HSCT, page 91

15. For the table on page 92, please provide support for your depiction of the donor source's ability to overcome the significant challenges you identify here. Also, the key you use does not appear to offer the reader a meaningful differentiation between "more favorable" and "less favorable;" if there is a reason for this, please explain why or revise to use a different depiction.

# NiCord for HSCT and Hematologic Malignancies

# NiCord: Phase 1/2 Clinical Trial Results, page 93

- 16. Explain your reference to myeloablative conditioning therapy and why it is relevant to your study.
- 17. We note your disclosure regarding additional endpoint data in the final paragraph of page 93. Please revise to include high grade acute and chronic GvHD rates and overall two-year survival rate in the historic controls. Please also specify the rate of sporadic engraftment failure in the test group and in the historic controls. We note in that regard your disclosure on page 22 regarding "a low level of sporadic engraftment failures" observed in this trial.

# NAM-NK: Our Immuno-Oncology Product Candidate, page 96

18. Clarify your description of the current phase of this product candidate as your disclosure here differs from the description provided on page 1 and elsewhere.

# NiCord for the Treatment of Non-Hematologic Disorders, page 98

19. We note your description here of Phase 1/2 clinical trials testing NiCord for treatment of SCD. Please revise to disclose the median days to initial engraftment, number of patients with long-term engraftment, and number of disease free patients in the comparison study you subsequently discuss. Please also advise us as to why you do not reflect this product use in your product pipeline charts.

# Intellectual Property, page 100

20. Please revise your discussion to disclose for each material patent and patent application the specific product(s) to which such patents or patent applications relate, the type of patent protection, patent expiration dates, and applicable jurisdictions.

You may contact Adam Phippen, Staff Accountant, at (202) 551-3336 or Donna Di Silvio, Staff Accountant, at (202) 551-3202 if you have questions regarding comments on the financial statements and related matters. Please contact Parhaum J. Hamidi, Special Counsel, at (202) 551-3421 or me at (202) 551-3720 with any other questions.

Sincerely,

/s/ Mara L. Ransom

Mara L. Ransom Assistant Director Office of Consumer Products