



DIVISION OF
CORPORATION FINANCE

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

October 9, 2020

Shalabh Gupta, M.D.
Chief Executive Officer, President and Chairman
Unicycive Therapeutics, Inc.
5150 El Camino Real, Suite A-32
Los Altos, CA 94022

Re: Unicycive Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted September 15, 2020
CIK No. 0001766140

Dear Dr. Gupta:

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.

Draft Registration Statement on Form S-1 submitted September 15, 2020

PROSPECTUS SUMMARY

Overview, page 1

1. Please revise the Summary to explain in greater detail the development history and clinical status of UNI 218 and UNI 494. Without limitation, please discuss who developed these products and conducted the preclinical and clinical trials and discuss what clinical trial work, if any, has been conducted or will need to be conducted. In your revised disclosure, please also include the dates of the prior preclinical and clinical trials.
2. We note your use of the term "significant unmet medical need" here and elsewhere in the document. Such a term might imply that your products are eligible for fast track

designation or priority review granted by the FDA for products that treat certain serious unmet medical needs. Please remove your use of this term throughout or otherwise please explain why you believe use of this term is appropriate.

Implications of Being an Emerging Growth Company, page 2

3. 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.

RISK FACTORS

We may be adversely affected by the ongoing coronavirus pandemic, page 14

4. Please expand this risk factor to specifically describe the impact of the COVID-19 pandemic on your operations.

USE OF PROCEEDS, page 35

5. Please state the approximate amount of proceeds you intend to use for each purpose listed. See Item 504 of Regulation S-K.

BUSINESS

Background on Renazorb, page 52

6. We note your belief that Renazorb is "potent and selective." Given the stage of your product development, it appears premature to describe your product candidate as potent, which implies they are effective. Please revise or advise why this disclosure is appropriate.
7. We note your disclosure regarding the completed clinical trial where it "was concluded that Renazorb was efficacious...." As efficacy determinations are the province of the U.S. Food and Drug Administration and other comparable regulatory agencies, please remove this statement here and elsewhere in your prospectus and replace them with quantified disclosure that supports each assessment.

Clinical Trial Experience, page 53

8. The trial discussed in this section provide results without providing proper context for such results. For the clinical trial discussed in this section, please disclose the phase; the date(s) of the trial and the location; duration of treatment and dosage information (both amount and frequency); the specific endpoints established by the trial protocol; and actual results observed, including whether statistical significance was demonstrated and the p-values supporting statistical significance.

Market Potential, page 54

9. We note that the information regarding the total hyperphosphatemia market is based on a study conducted on your behalf by Syneos Health. Please tell us whether you commissioned this study for use in the registration statement, and, if so, analyze whether you are required to file a consent pursuant to Rule 436 of the Securities Act.

Clinical trials for UNI 494 in AKI, page 59

10. Please revise to clearly disclose the current development phase for UNI 494. To the extent that preclinical trials have been conducted, please disclose the date(s) of the trials and the location; duration of treatment and dosage information (both amount and frequency); the specific endpoints established by the trial protocol; and actual results observed.

Employees and Labor Relations, page 70

11. We note your disclosure that you have one full time employee. We also note that your website includes profiles of eleven individuals. Please revise or advise.

EXECUTIVE AND DIRECTOR COMPENSATION

Employment Agreements, page 75

12. Please file the employment agreement with Shalabh Gupta as an exhibit to the registration statement as required by Item 601(b)(10) of Regulation S-K.

DESCRIPTION OF CAPITAL STOCK

Exclusive Forum, page 82

13. We note that your forum selection provision identifies the State of Delaware as the exclusive forum for certain litigation, including any “derivative action.” Consistent with the risk factor disclosure on page 32, please disclose whether this provision applies to actions arising under the Securities Act or Exchange Act. Additionally, because you have identified the federal courts as the exclusive forum for Securities Act claims, please also revise your prospectus to state that there is uncertainty as to whether a court would enforce such provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

General

14. We note that the product development pipeline chart on your website appears inconsistent with information disclosed in your document as your website indicates that the FDA has approved a request to use a 505(b)(2) pathway for Renazorb. Please revise or advise.

Shalabh Gupta, M.D.
Unicycive Therapeutics, Inc.
October 9, 2020
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You may contact Ibolya Ignat at 202-551-3636 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Jeffrey Gabor at 202-551-2544 or Celeste Murphy at 202-551-3257 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Jeffrey Fessler, Esq.