



DIVISION OF
CORPORATION FINANCE

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

December 8, 2022

Jacob Cohen
Chief Executive Officer
Mangoceuticals, Inc.
4131 N. Central Expressway, Suite 900
Dallas, TX 75204

Re: Mangoceuticals, Inc.
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted November 18, 2022
CIK No. 0001938046

Dear Jacob Cohen:

We have reviewed your amended 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.

Amendment No. 1 to Draft Registration Statement on Form S-1

Overview, page 1

1. We note your revised disclosures in response to prior comment 3. Please remove statements on page 1 and elsewhere concerning the expectation that your formulation may deliver “fast acting results,” that it may have a “fast onset of action” and that it is not “expected to have any material side effects.” In this regard, efficacy and safety determinations are within the purview of FDA and furthermore, based on your disclosures, there is no clinical trial data involving your formulation nor any indication that a person has ever taken this formulation. You may indicate that the planned product employs a sublingual delivery mechanism because such mechanisms generally allow for a faster rate of drug absorption without indicating that your planned drug has or may have

the designed effect. Also, remove or revise the statement on page 4 that claims such as “fast acting results” and “fast onset of action” are not efficacy claims.

2. Your disclosure highlighting that Mango ED features ingredients contained in “FDA-approved drugs” suggests that this formulation is safe. To the extent that you highlight that your formulation contains ingredients found in FDA-approved drugs, please revise to provide equally prominent disclosure that these approvals do not mean that these ingredients will prove safe when combined into a single formulation to treat ED.

Competition and Competitive Advantages, page 3

3. On page 3 you state that you are competing with companies which seek to sell Tadalafil in an oral disintegrating tablet. Please clarify whether other companies are currently selling oral disintegrating tables for ED, including ones containing Tadalafil. Additionally, please disclose whether your product formulation could be replicated by other companies.

Regulatory Environment, page 3

4. On page 4, as well as page 51, you broadly cite “scientific literature” and “previous clinical studies” to support the performance of the planned Mango ED product. Please revise your Business section to identify and discuss the literature and clinical studies that you highlight in your Summary.
5. We refer to your disclosure on page 4 concerning FDA objection to any promotional activities, including those involving testimonials and surrogates, absent substantial evidence derived from adequate and well-controlled clinical trials. Accordingly, please revise to clarify whether you will be able to legally conduct any promotional activities for Mango ED, including activities involving the use of testimonials and surrogates.
6. Please explain your basis for stating that sublingual sildenafil “typically functions in a similar way as tadalafil” which is the primary ingredient in your planned Mango ED product.

Selected Risks Associated with Our Company, page 6

7. We note your revisions in response to prior comment 16 and refer to your website at <https://www.mangorx.com/>. Please tell us whether the testimonials and the performance claims listed below concerning your planned product meet the Section 503A conditions under which compounded human drug products are exempt from the FFDCA Act sections on FDA approval. We refer to the statements that Mango ED:
 - is “a fast-acting ED treatment;”
 - has “fast acting performance;”
 - “lasts up to 36 hours” and
 - “typically begins working in as little as 10 minutes.”

Managements Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Estimates, page 46

8. We acknowledge your response to prior comment 18, and your revised disclosures. Please further expand your disclosure to clarify your accounting policy for warrants issued as part of a unit. For example, warrants may be treated as equity classified instruments, or liability classified instruments that do not qualify for equity classification. You disclose throughout your document that you issued restricted common stock to certain managers and other related parties. Revise your critical accounting policy disclosure to address how you accounted for these shares, including how you determined their fair values. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features. Please discuss with the staff how to submit your response.

Business, page 47

9. On page 48, you provide a visual depiction of the evaluation and purchasing process. In the fifth step, you note that “the prescription is sent to our TX based partner pharmacy, Epiq Scripts, where it is filled and shipped.” On page 2, you state that “we initially plan to focus our sales in the 21 states where our related party pharmacy is licensed and *where it is located*, with the goal of eventually undertaking sales across all 50 states, pending licensing approvals of our related party pharmacy” (emphasis added). Please clarify whether Epiq Scripts is solely located in Texas, or whether it is located in each state or territory in which it receives licensure.

Unaudited Financial Statements, page F-13

10. Please tell us why you believe that the labels “Issuance of Common Stock for Cash” presented in your Statement of Changes in Stockholders’ deficit, and "Sales of common stock for cash" presented in your Statement of Cash Flows are appropriate, given that the transaction the amounts were raised in was a private placement unit offering. Please revise as appropriate.

Jacob Cohen
Mangoceuticals, Inc.
December 8, 2022
Page 4

You may contact Ibolya Ignat at (202) 551-3636 or Terence O'Brien at (202) 551-3355 if you have questions regarding comments on the financial statements and related matters. Please contact Jimmy McNamara at (202) 551-7349 or Joe McCann at (202) 551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Industrial Applications and
Services

cc: David Loev