



DIVISION OF
CORPORATION FINANCE

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

October 26, 2022

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

Re: Mangoceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted September 26, 2022
CIK No. 0001938046

Dear Jacob Cohen:

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

Coverpage

1. Please revise the Public Offering Prospectus cover page to establish the volume of shares to be offered in the Public Offering. In this regard, we note that this prospectus cover page presently indicates that the number of shares offered is based on an assumed offering price. For guidance, please refer to Compliance Disclosure Interpretations, Securities Act Rules, Question 227.02. Also, tell us why there is a "\$" located below the "Subject to Completion" legend.
2. Please revise the Resale Offering cover page located on Alt-1 to remove uncertainty regarding whether the common stock will be listed on The Nasdaq Capital Market. In this regard, we note that the sixth paragraph of this Resale cover page indicates that prior to

use of this prospectus you will have completed a 1 million share public offering, which we note is conditioned on Nasdaq listing your common stock.

Prospectus Summary, page 1

3. The first sentence of the Summary and other disclosures in the section suggest that you have a proprietary technology solution that provides you with an advantage over the competition. Accordingly, please tell us whether your technology is unique to the industry and, if so, whether it would be difficult or costly to replicate. If it is not, then please revise accordingly.
4. We note your disclosure in the second paragraph referencing the market for hair loss products. To the extent that you retain this prominent reference to hair loss products, please revise to clarify whether you have plans to develop or sell such products in the near term. Also, revise to clarify, if true, that your initial go-to-market strategy calls for sales of your Mango ED product to patients located exclusively in the state of Texas. Also, clarify if true, that you do not have immediate plans to sell third-party products via your customer portal.
5. We note your disclosure on page 1 that you are currently in the process of developing and preparing to market a new and innovative brand of ED product under the brand name “Mango.” With reference to your disclosure on page 22, revise the Overview to highlight that this product has not and will not be FDA approved.
6. On page 2 and elsewhere you make references to “our pharmacy” and “our physician network.” Please revise these references to remove any implication that you own these entities.
7. On page 3, you reference a January 2022 report published by Verified Market Research that provides a global valuation for the ED market of 3.63 billion in 2020. This same report indicates that the global market size will be 2.952 billion in 2028, de-growing at a compound annual growth rate of -3.4%. Please revise to explain the reason(s) why the market is expected to contract during this period. Also, tell us whether the global trend is applicable to the US market where you intend to market your product.
8. We refer to your disclosures on page 3 under the heading “Regulatory Environment.” Please revise to disclose whether you or your representatives have had conversations with FDA staff regarding whether the Mango ED product can be sold pursuant to Section 503A of the Federal Food, Drug, and Cosmetic Act (“FFDCA Act”).
9. We note your risk factor disclosure on page 23 that FDA will expect adequate substantiation for any efficacy claims, which would require substantial evidence derived from adequate and well-controlled clinical trials. Please revise your Regulatory Environment discussion on page 3 to disclose, if true, that you are not permitted to make efficacy claims concerning the Mango ED product because you do not have substantial

evidence derived from adequate and well-controlled clinical trials. With a view to revised disclosure, tell us in your response letter whether you will be able to market this product utilizing claims of “fast acting results” or “fast onset of action” and, in addition, tell us what basis you have to make these performance claims/predictions regarding how the proposed combination of compounds might perform in ED patients given the apparent lack of supporting data.

10. With reference to your risk factor disclosed at the bottom of page 21, please revise the disclosure at the bottom of page 3 to explain how/why the compounded product you plan to market would be clinically necessary for an identified individual patient. Explain why the clinical needs of a particular patient could not be met by an FDA-approved drug product and the basis for concluding that your compounded version offers a significant difference.
11. With reference to your risk factors disclosures on pages 21 and 22, please revise the Summary on page 3 and the Business section to discuss how your plans for Mango ED satisfy the requirement that your related-party pharmacy will not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product.
12. Please revise the disclosure on page 4 concerning the corporate practice of medicine to also address fee splitting. In the Business section and, if applicable, the Risk Factor section, provide a more detailed discussion of the impact on your business from relevant laws that address the corporate practice of medicine and fee splitting.
13. We note that the disclosure on page 7 of American International Holdings Corp.’s Form 10-Q for the period ended June 30, 2022 indicates that your related-party pharmacy Epiq Scripts was formed in late January 2022. Accordingly, please revise the Summary section, where appropriate, to disclose that the pharmacy you will rely on exclusively is a new formed entity, and disclose whether to date this pharmacy has compounded any drugs that have been provided to patients. Provide risk factor disclosure that discusses risks inherent in relying exclusively on a new entity to fulfill, specialty compound, package, ship, dispense and distribute your sole drug product.
14. Please disclose in the Summary, or elsewhere as appropriate, the dosages for each of the three ingredients used in the Mango ED product.
15. With reference to your disclosure on page 4 concerning your Physician Services Agreement with Doctegrity, please revise to disclose whether this agreement addresses whether Doctegrity can prescribe ED medications other than Mango ED to its patients and use pharmacies other than Epiq Scripts to fill such orders.

Selected Risks Associated with Our Company, page 6

16. With reference to your disclosures on page 22, please revise the risk disclosure on page 6 to prominently highlight the risks that (i) (ii) the use of your planned ED product may lead

to serious patient injury in part because it has not been, and will not be, approved by the FDA and (ii) FDA may determine that the compounding of your planned products does not fall within the exemption from the FFDCA provided by Section 503A.

Our planned ED product has not been, and will not be, approved by the FDA..., page 22

17. We note your risk factor disclosure on page 22 highlighting concern that the use of Mango ED “may cause serious side effects” and “may lead to serious patient injury and death.” With a view to expanded risk factor disclosure, please tell us whether you are aware of any clinical studies involving (i) administration of Tadalafil sublingually at the doses you intend to provide patients or (ii) compounding of Tadalafil, Oxytocin and L-Arginine to treat ED. Please also revise the Overview on page 1 to discuss potential safety risks associated with the Mango ED product.

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

18. Please update this section to clearly identify your critical accounting estimates. The disclosure should supplement, not duplicate, the accounting policy description provided in the notes to the financial statements, and should provide greater insight into the quality and variability of information regarding financial condition and operating performance. Please refer to Item 303 of Regulation S-K.

Business, page 47

19. On page 48, the fourth step of the visual depiction is accompanied by the wording that a “doctor quickly reviews the information and determines if a prescription is appropriate.” With reference to your disclosure on page 4, please revise to clarify, if true, that practitioners other than licensed doctors may perform the services described.
20. We note your disclosure on page 50 and elsewhere concerning the market for ED products. Please tell us whether you commissioned any of the market or survey data that you present in the registration statement.
21. On page 57, we note that you have applied for a trademark. Please specify whether you are seeking a federal trademark or state trademark. If this is a state trademark application, please explain the differences between the benefits and rights of a federal and state trademark.

Competition and Competitive Advantages, page 50

22. Please disclose whether you face competition from third-parties that sell Tadalafil in an oral disintegrating tablet.
23. Please disclose how you will compete with respect to pricing.

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Insurance, page 53

24. Please revise to disclose whether you have insurance to cover exposure to product liability claims. To the extent that you do not, please revise your risk factor disclosure on page 20 and add a Summary risk factor disclosure on page 6, or advise.

Material Agreements, page 54

25. Please revise to discuss the indemnification obligations contained in your Physician Services Agreement with Doctegrity. Also revise to indicate whether the Master Services Agreement with Epiq Scripts addresses product liability claims.

Related Party Transactions, page 76

26. Please revise to disclose the approximate dollar value of the amount involved in each transaction. Without limitation, we note that the dollar value is not provided for the June 22, 2022 and June 30, 2022 transactions.

General

27. Please provide us with supplemental 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, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.

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