



DIVISION OF
CORPORATION FINANCE

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

October 29, 2021

John Trainor
President and Director
SensaSure Technologies, Inc.
505 Park Avenue 4th Floor
New York, New York 10022

Re: SensaSure Technologies, Inc.
Registration Statement on Form S-1
Filed October 4, 2021
File No. 333-260017

Dear Mr. Trainor:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Registration Statement on Form S-1 filed October 4, 2021

Cover Page

1. Please update the cover page of your registration statement to include a highlighted cross-reference to the risk factors section. Refer to Item 501(b)(5) of Regulation S-K.

Prospectus Summary

Company Overview, page 1

2. We note your disclosure in a summary risk factor on page 3 that your EB device is only sold for research purposes and is not approved or cleared for use in the United States or elsewhere. Please clarify in your Prospectus Summary - Company Overview that your EB device is being offered for research purposes only and explain briefly what this allows as

well as any uncertainties that come with obtaining regulatory approval for use of the device.

3. We note your statement on pages 1 and 2 as well as in the Business section that you have a "validated method" or "validated methodology" to collect, extract, detect and identify substances. Please revise your disclosure here to explain what you mean by "validated method" and also to clarify that you have not yet received approval from the FDA or other regulatory agency to market your EB device and you will need this approval in order to commercialize your product.
4. We note your statement here that "[y]our business model will follow a lower risk, lower capital and relatively higher margin business based upon a low risk EB collection device." Given the uncertainty of your ability to obtain regulatory approval for the commercialization of your EB device, it is inappropriate to state or imply that you have mitigated or will mitigate development risk. Accordingly, please remove the references to your business model being "lower risk" and to your EB collection device being "low risk."
5. Please disclose any material assumptions and limitations associated with your estimate of the total global device market in drug testing.
6. We note your disclosure here and in the Business section in which you make statements related to potential safety and efficacy, which are premature given the stage of development of the company's device. For example:
 - "The EB method can lead to improved overall detection accuracy."
 - "Our EB device is quicker to use and provides more predictable sample collection times[...]."
 - SensaSures' "superior" testing methodology.
 - The EB device is "an extremely sensitive, accurate and confirmatory," back-to-lab based technique.
 - Exa-Breath is "Safe - Simple - Effective."

Conclusions regarding safety and efficacy are determinations that only the FDA or a foreign government equivalent has the authority to make. Please revise your disclosure throughout your document, including but not limited to the statements noted above, to eliminate the implication that your device has been or will ultimately be determined safe and/or effective or have demonstrated safety and/or efficacy for purposes of approval by the FDA or comparable agency. Alternatively, we advise you that you may present the objective data from pre-clinical and clinical studies and trials without drawing a conclusion from the results.

Implications of Being an Emerging Growth Company, page 5

7. On the cover page, you have indicated you have elected to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. On page 5, you state you have

irrevocably elected not to avail yourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Please revise these conflicting statements here and throughout the filing.

Description of Private Placement, page 6

8. We note your disclosure here stating that you have entered into subscription agreements with investors relating to a private placement of your common stock and that the form of the subscription agreement has been filed as an exhibit to the registration statement. However, the form of the subscription agreement does not appear on the list of exhibits provided in Item 16 on page II-3. Please file the form of the subscription agreement as an exhibit.

Risk Factors, page 13

9. Please revise this section to relocate any generic risk factors you present to the end of the section under the caption "General Risk Factors." Refer to Item 105(a) of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations, page 66

10. We note your disclosure here that your EB device is being prepared for commercial deployment in Europe and North America and that "[a] 510K application will be submitted for use in the U.S." We also note your disclosure on page 68 that "[you] believe that [y]our EB device will be classified as a Class 1 medical device by the FDA. Please update your disclosure to clarify that there is no guarantee that the FDA will grant you 510(k) clearance, that you will be classified as a Class 1 medical device, or that you will be able to commercially distribute your device.

Business, page 78

11. We note your disclosure on page 9 that you have used significantly all of your assets for medical device design and research and distribution activities. Please clarify your distribution model and where your products are sold in the description of your business. See Item 101(h)(4)(ii) of Regulation S-K.

Our Products and Ongoing Development, page 80

12. We note your disclosure here that work in the field of drug testing and anti-doping has been performed through "collaborative partnerships with key industry players" and your statement on page 81 that as part of your growth strategy, you intend to "[e]xpand [your] strategic partnership engagements." We also note your disclosure in a risk factor on page 51 that you may form or seek to enter into "additional licensing arrangements." To the extent you have existing material collaborative partnerships or licensing arrangements and are substantially dependent on any of these agreements, please describe

their key terms in your Business section including, to the extent applicable, a summary of the nature and scope of any IP transferred, each parties' rights and obligations, the duration of the agreement, payment terms (including a royalty range within ten percentage points), royalty term and termination provisions. Please also file the agreements pursuant to Item 601(b)(10)(B)(ii) of Regulation S-K or explain the basis for your determination that filing them is not required.

Intellectual Property, page 81

13. Please expand your disclosure of your patent estate to include expiration dates for your pending and granted patents.

Studies and Clinical Trials, page 88

14. In your discussion of your studies and clinical trials conducted to date for the EB device, please revise your disclosure to specify for each study or trial the number of participants that participated, the primary and secondary endpoints, the results as they relate to the endpoints, any statistical analysis performed and any serious adverse events. Furthermore, to the extent known, please identify any specific study or trial that you will be relying on to support your 510(k) application with the FDA referenced on page 66.
15. We note your disclosure in risk factors on pages 21 and 51 that you work with consultants and clinical investigators in designing, monitoring and analyzing results of your clinical studies. Please expand your disclosure here to discuss the role of consultants and clinical investigators in your studies and trials. To the extent that you have material agreements with any consultant or clinical investigator on which you depend, please disclose the material terms of these agreements and file them as exhibits pursuant to Item 601(b)(10)(B)(ii) of Regulation S-K or explain the basis for your determination that filing them is not required.

Facilities, page 97

16. Please revise to provide the disclosures required by Item 102 of Regulation S-K.
17. Please expand your disclosure to discuss your sources and the availability of raw materials and include the names of any principal suppliers, or revise your disclosure as appropriate. Refer to Item 101(h)(4)(v) of Regulation S-K.

Management, page 98

18. We note your disclosure regarding the table here setting forth information regarding your executive officers and directors "as of January 31, 2019." Please clarify whether the table reflects your current executive officers and directors.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

John Trainor
SensaSure Technologies, Inc.
October 29, 2021
Page 5

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Gary Newberry at (202) 551-3761 or Lynn Dicker at (202) 551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Jessica Ansart at (202) 551-4511 or Celeste Murphy at (202) 551-3257 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: David Fleming