

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

December 18, 2020

Erik Engelson President and Chief Executive Officer Lucira Health, Inc. 1412 62nd Street Emeryville, California 94608

Re: Lucira Health, Inc.
Draft Registration Statement on Form S-1
CIK No. 0001652724
Submitted November 23, 2020

Dear Mr. Engelson:

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

# Overview, page 1

- 1. We note that you have "conducted clinical trials that demonstrate that the molecular accuracy of our COVID-19 test kit is comparable to the Hologic, Inc. Panther Fusion SARS-CoV-2 Assay." Please provide more details on this level of accuracy, including your measurements of accuracy. Also indicate whether the trials were head-to-head. If not, please tell us on what basis you believe it is appropriate to make this comparison, or alternatively delete the comparison.
- 2. We note that "clinical trials of [your] COVID-19 test kit showed 100% of patients successfully performed self-testing at home in less than two minutes." Please provide more details on this clinical trial, including the study size, where it was performed, and

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your measure for successful performance.

## Our Solution, page 3

- 3. We note your product pipeline chart on pages 5. Please expand your disclosure in your Prospectus Summary to discuss in more detail the FDA approval process to which your products will be subjected. We note your disclosures on pages 43 and 140. Please also more prominently disclose here the information included in the footnote to your chart (i.e., in the main text of the Summary).
- 4. Please revise to disclose the basis for your statement that the limit of detection of your COVID-19 test kit is 40 to 60 times more sensitive than that of antigen tests.

## Influenza Market, page 6

5. Please discuss here whether there are other FDA approved over-the-counter testing products. Please also discuss if you have any known current of possible competitors.

#### Summary of Risk Factors, page 8

- 6. Please add a bullet point highlighting the risk discussed on pages 25-26 regarding your prior clinical trials related to the influenza indication, and the possibility that the FDA may weigh the results of the trials and the issues raised in its January 2020 additional information letter more heavily than anticipated, potentially hindering future FDA approval of your influenza test kit or your combination COVID-19 and influenza test kit.
- 7. Consider adding a summary risk factor that discusses your license from Eiken and its significance. We note your disclosure on page 30 in this regard.
- 8. We note that on page 17 that you state "that the production and widely administered use of an efficacious vaccine or other treatment for COVID-19 may reduce the demand for diagnostic tests and, as a result, the COVID-19 diagnostic testing market may not develop or substantially grow" and that "[if] the market develops in a manner that does not facilitate demand for our COVID-19 test kit, or fails to develop or grow in the manner in which we expect or at all, our business, financial condition, results of operations and cash flows may be negatively affected." Please include similar disclosures in your Summary Risk Factors.

We may be unable to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for our test kits, page 28

9. Please state explicitly whether your COVID-19 test kit currently qualifies for coverage and reimbursement from third-party payors. Please also revise your Prospectus Summary to include this information as necessary.

We depend on intellectual property licensed from Eiken Chemical Co., Ltd., or Eiken, page 30

10. We note that you are dependent on patents licensed from Eiken and that some of these

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patent licenses are non-exclusive. Please expand your risk factor to discuss whether any of these non-exclusive licenses could allow a competitor to develop a similar product and whether, to your knowledge, Eiken has granted any such licenses to other parties.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Critical Accounting Policies and Significant Management Estimates

Determination of Fair Value of Common Stock, page 104

11. 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 IPO 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.

## Clinical Performance and Data, page 127

12. Please provide a narrative to your chart that discusses what information it is presenting and why it is significant.

## <u>License Agreement with Eiken Chemical Co., Ltd., or Eiken, page 140</u>

13. Please disclose the payment terms of your of your license agreement with Eiken, including the royalty percentage (or a range not greater than ten percentage points), amounts paid to date, and payment(s) due in the future. Please also clarify the termination date by disclosing the expiration date of the last-to-expire patent underlying the license.

### Employees, page 152

14. With reference to Release No. 33-10825, please revise your disclosure to reflect the amendments to Item 101 of Regulation S-K, which became effective as of November 9, 2020, including Item 101(c)(2)(ii).

#### **Exhibits**

15. We note that your disclosures on pages 73 and 185 you state that your exclusive forum provisions do not apply to Exchange Act claims and that the federal district courts of the United States will be the exclusive forum for Securities Act claims. Please ensure that your certificate of incorporation and bylaws are consistent with your disclosures with respect to your exclusive forum provisions.

#### General

16. A number of entities recently announced their FDA approval or plans to seek FDA approval of COVID-19 vaccines. Please update your registration statement throughout to

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discuss these specific recent developments, and how they are affecting your strategies and the potential market for your products.

17. 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.

You may contact Eric Atallah at (202) 551-3663 or Angela Connell at (202) 551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Courtney Lindsay at (202) 551-7237 or Mary Beth Breslin at (202) 551-3625 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences