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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
October 8, 2021

Lucira Health, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39976**	**27-2491037**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1412 62nd Street **Emeryville, California**	**94608**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (510) 350-8071

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**LHDX**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On October 8, 2021, Lucira Health, Inc. issued a press release commenting on the recent recall by Copan Italia SPA, or Copan, of its FLOQSwabs, or the Recalled Copan Swabs, a component of our LUCIRA COVID-19 All-In-One Test Kit and LUCIRA CHECK IT COVID-19 Test Kit, collectively the Test Kits, identified on the label as "3 Swab." According to our records, we distributed Test Kits containing the Recalled Copan Swabs from April 22, 2021 through September 22, 2021, or the Distribution Period. The Recalled Copan Swabs included in the Test Kits purchased during the Distribution Period should not be used and should be disposed. We are offering a replacement swab for customers who purchased a Test Kit containing a Recalled Copan Swab during the Distribution Period. The lot numbers of the affected Test Kits are listed in the press release. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

We expect to record expenses related to the Recalled Copan Swabs in the third quarter ended September 30, 2021. We estimate such expenses to be between $75,000 and $85,000 and intend to pass-through all related expenses, including but not limited to third party and legal costs, to Copan. The Recalled Copan Swabs had no impact on revenue recorded during the Distribution Period. In addition, although we cannot determine with certainty any additional expenses in future quarters relating to the Recalled Copan Swabs, we expect such expenses to be immaterial and we intend to pass-through such expenses to Copan. We have a sound working relationship with Copan that we intend to continue for the foreseeable future.

The information in this Item 7.01 and in the press release furnished as Exhibit 99.1 to this current report shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information contained in this Item 7.01 and in the press release furnished as Exhibit 99.1 to this current report shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Lucira Health, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release dated October 8, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Lucira Health, Inc.

Date: October 8, 2021

By: /s/ Daniel George
Daniel George
Chief Financial Officer

Exhibit 99.1

LUCIRA™ HEALTH Provides Statement on Copan's Recall of its FLOQSwabs

EMERYVILLE, CA, October 8, 2021 – Lucira Health, Inc. ("Lucira Health" or "Lucira") (NASDAQ: LHDX), a medical technology company focused on the development and commercialization of transformative and innovative infectious disease test kits, today commented on the recent recall of the FLOQSwabs by supply partner Copan Italia SPA, or Copan.

Copan, who supplies FLOQSwabs included in the LUCIRA COVID-19 All-In-One Test Kit and LUCIRA CHECK IT COVID-19 Test Kit, collectively the Test Kits, announced a recall of its FLOQSwabs. According to Lucira's records, Test Kits containing the recalled Copan swabs were distributed from April 22, 2021 through September 22, 2021. Lucira estimates expenses related to the recalled Copan swabs to be between $75,000 and $85,000 and intends to pass-through all related expenses, including but not limited to third party and legal costs, to Copan. In addition, Lucira notes the recalled Copan swabs had no impact on revenue recorded during the distribution period.

The recalled Copan swabs included in the Test Kits distributed from April 22, 2021 through September 22, 2021 should not be used and should be disposed. Lucira is offering a replacement swab for customers who purchased a Test Kit containing a recalled Copan swab. The lot numbers of the affected Test Kits are listed in the table below.

Affected Lucira Kits
REF: GLUC-2000
LOT: K07A112704214M1
LOT: K07A112704214M2
LOT: K07A112704214M3
LOT: K07A112804214M1
LOT: K07A112804214M2
REF: LUC-1000
LOT: K07A111406214M1
LOT: K07A111907214M1
LOT: K07A112005214M1
REF: LUC-2000
LOT: K07A110106214M1
LOT: K07A110505214M1
LOT: K07A110505214M2
LOT: K07A110605214M1

Affected Lucira Kits
LOT: K07A111905214M1
LOT: K07A111905214M2
LOT: K07A112105214M1
LOT: K07A112304214M1
LOT: K07A112304214M2
LOT: K07A112304214M3
LOT: K07A112404214M1
LOT: K07A112404214M2
LOT: K07A112404214M3
LOT: K07A112604214M1
LOT: K07A112604214M2
LOT: K07A112604214M3
LOT: K07A112604214M4
LOT: K07A112607214M1
LOT: K07A112607214M2

Affected Lucira Kits
LOT: K07A110605214M2
LOT: K07A110608214M1
LOT: K07A110705214M1
LOT: K07A110906214M1
LOT: K07A111006214M1
LOT: K07A111006214M2
LOT: K07A111709214M3
LOT: K07A111806214M1

Affected Lucira Kits
LOT: K07A112705214M1
LOT: K07A112805214M1
LOT: K07A113105214M1
LOT: K07A113105214M2
REF: LUC-3000
LOT: K07A111409214M1
LOT: K07A111907214M2

About Lucira Health

Lucira is a medical technology company focused on the development and commercialization of transformative and innovative infectious disease test kits. Lucira's testing platform produces lab quality molecular testing in a single-use, consumer-friendly, palm-size test kit powered by two AA batteries. Lucira designed its test kits to provide accurate, reliable, and on-the-spot molecular test results anywhere and at any time. The LUCIRA™ CHECK IT COVID-19 Test Kit (OTC) and LUCIRA™ COVID-19 All-In-One Test Kit (Rx) are designed to provide a clinically relevant COVID-19 result within 30 minutes from sample collection. For more information, visit **www.lucirahealth.com**.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, Lucira's continued development and commercialization of its transformative and innovative infectious disease test kits and ability to increase sales. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "can" "plans," "will," "may," "anticipates," "expects," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Lucira's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including our ability to increase production, streamline operations and increase product availability; the success of our test platform with COVID-19, the impact to our business of the ongoing COVID-19 pandemic; any impact on our ability to market our products; demand for our products due to deferral of procedures using our products or disruption in our supply chain; our ability to achieve or sustain profitability; our ability to gain market acceptance for our products and to accurately forecast and meet customer demand; our ability to compete successfully; our ability to enhance our product offerings; development and manufacturing problems; capacity constraints or delays in production of our products; maintenance of coverage and adequate reimbursement for procedures using our products; and product defects or failures. These and other risks and uncertainties are described more fully in the "Risk Factors" section and elsewhere in our filings with

the Securities and Exchange Commission and available at **www.sec.gov**, including in our most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. Any forward-looking statements that we make in this announcement speak only as of the date of this press release, and Lucira assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise after the date of this press release, except as required under applicable law.

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