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): February 23, 2023

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.)**

1315 63rd Street **Emeryville, California**	**94608**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (814) 574-1546

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 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 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

As previously disclosed on February 22, 2023, Lucira Health, Inc. (the "Company") filed a voluntary petition for relief under chapter 11 of title 11 of the United States Bankruptcy Code (the "Chapter 11 Filing") in the United States Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"). The Company's chapter 11 case (the "Chapter 11 Case") is being administered under the caption, *In re: Lucira Health, Inc.*, Case No. 23-10242.

On February 23, 2023, the Company received written notice (the "Delisting Notice") from the staff of the Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that, as a result of the Chapter 11 Filing and in accordance with Nasdaq Listing Rules 5101, 5110(b) and IM-5101-1, the staff of Nasdaq had determined that the Company's common stock will be delisted from Nasdaq. In the Delisting Notice, the staff of Nasdaq referenced the Chapter 11 Filing and associated public interest concerns raised by it, concerns regarding the residual equity interest of the existing listed securities holders and concerns about the Company's ability to sustain compliance with all requirements for continued listing on Nasdaq. The Delisting Notice also indicates that the Company may appeal Nasdaq's determination pursuant to procedures set forth in Nasdaq Listing Rule 5800 Series. The Company does not intend to appeal this determination.

Trading of the Company's common stock will be suspended at the opening of business on March 6, 2023, and a Form 25-NSE will be filed with the Securities and Exchange Commission, which will remove the Company's common stock from listing and registration on Nasdaq.

On February 24, 2023, the Bankruptcy Court approved the Company's "first day" motions on an interim basis granting customary relief intended to enable the Company to continue operations in the ordinary course of business during the Chapter 11 Case.

Item 7.01 Regulation FD Disclosure.

On February 27, 2023, the Company issued a press release announcing that the U.S. Food and Drug Administration issued an emergency use authorization for the first and only combination COVID-19 & flu at-home test (the "COVID-19 & Flu Test") and commenting on its Chapter 11 Filing. The COVID-19 & Flu Test is the first over-the-counter at-home diagnostic test that can detect Influenza A and B along with SARS-CoV-2, and it provides results from self-collected nasal swab samples in roughly 30 minutes. 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.

The information in Item 7.01 and Item 9.01 (including Exhibit 99.1) to this Current Report on Form 8-K 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 Item 7.01 and Item 9.01 (including Exhibit 99.1) to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, about the Company that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Current Report on Form 8-K are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "intend," "may," or "will," or the negative of these words or other similar terms or expressions. Forward-looking statements in this Current Report on Form 8-K include, but are not limited to, the delisting of the Company's common stock on March 6, 2023, the Company's intention to not appeal Nasdaq's determination and the Company's ability to continue its ordinary course operations during the Chapter 11 Case. The forward-looking statements in this Current Report on Form 8-K are only predictions. The Company has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that it believes may affect its business, financial condition and results of operations. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause its actual results, performance or achievements to be materially different from any

future results, performance or achievements expressed or implied by the forward-looking statements, including the important factors discussed in the sections entitled “Risk Factors” of the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, and in the Company’s other filings with the Securities and Exchange Commission. The forward-looking statements in this Current Report on Form 8-K are based upon information available to the Company as of the date of this Current Report on Form 8-K, and while the Company believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and its statements should not be read to indicate that the Company has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Except as required by law, the Company assumes no obligation to update these forward-looking statements, or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated February 27, 2023.
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: February 27, 2023

By: /s/ Richard Narido

Richard Narido,
Chief Financial Officer

Exhibit 99.1

LUCIRA HEALTH ANNOUNCES FDA AUTHORIZATION OF FIRST & ONLY AT-HOME COMBINATION COVID-19 & FLU TEST AND COMMENTS ON CHAPTER 11 BANKRUPTCY FILING

Test Delivers Lab-Quality Performance with Results in 30 Minutes or Less – The First At-Home Test to Ever Include Flu

- Lab-quality results for both COVID-19 and Flu now available at home from one single test
- COVID-19 and Flu have similar symptoms but different treatments, requiring a fast, differential test to access time-sensitive prescription treatment options
- Lucira's COVID-19 & Flu Home Test demonstrated similar performance for COVID-19, Flu A and Flu B in head-to-head comparison study with highly sensitive lab-based PCR tests
- Lucira seeks a strategic or financial partner for resumption of manufacturing and development of additional home diagnostic products

EMERYVILLE, Calif., Feb. 27, 2023 — Lucira Health, Inc. (Nasdaq: LHDX) ("Lucira Health" or "Lucira"), a medical technology company, announced today that the U.S. Food and Drug Administration (FDA) granted emergency use authorization (EUA) for its Lucira COVID-19 & Flu Home Test for over the counter (OTC) use at home and other non-laboratory sites. The Lucira COVID-19 & Flu Home Test is a molecular test that demonstrated similar performance for COVID-19 and Influenza A and B compared to highly sensitive lab-based PCR tests in clinical trials. Lucira's COVID-19 & Flu Home Test represents a breakthrough in diagnostic testing as the first at-home combination COVID-19 and Flu test, and as the first Flu test for OTC use at home in the United States in history. Until today, American consumers have never before been able to self-diagnose Flu at home. The easy-to-use, all-in-one combination test delivers results in 30 minutes or less from one shallow nasal swab.

Lucira believes that a single test for both COVID-19 and Flu can be a powerful tool given how similar the two viruses appear. "COVID-19 and Flu look the same, feel the same, spread the same and, unfortunately, can still kill the same," underscored Dr. Davey Smith, Head of the Division of Infectious Disease and Global Public Health at the University of California – San Diego. "Having an at-home molecular test now available should really help people know how to keep their families safe and seek appropriate treatment when they're ill."

"Our small but experienced team at Lucira has again demonstrated the versatility of our technology platform by introducing this first-of-its-kind innovation in clinically relevant at-home diagnostics to the marketplace. The authorization of the COVID-19 & Flu Home

Test with OTC label is another example of how Lucira is helping to transform the future promise of home-based, fast, accurate diagnostics into a reality," said Erik Engelson, President and CEO of Lucira Health. "Many people are not aware that prescription antiviral medications exist for the treatment of Flu as well as for Covid. But we believe an accurate diagnosis, early in the course of infection is mandatory for effective use of such medications. Prescription and fulfillment over telehealth is convenient and safe, especially when at-home diagnoses take place using a test such as the Lucira COVID-19 & Flu Home Test."

"We regret that we had no option but to file for Chapter 11 bankruptcy and that this occurred days before we received regulatory authorization," added Mr. Engelson. "Unfortunately we were unable to bridge what became a protracted authorization cycle time within our current capital structure and it remained unclear to us when the regulatory authorization would come through, despite working closely with FDA. The Lucira COVID-19 & Flu Home Test would have been especially useful during the recent, severe respiratory season, and we had produced inventory for an anticipated autumn 2022 launch. We remain confident in the role that the new test can play in future respiratory seasons and are honored to have received the first authorization for such a home test. We appreciate the diligent work of the FDA team as they refined requirements during the review cycle."

Lucira is seeking a strategic or financial partner for the resumption of manufacturing and development of additional home diagnostic products.

The Company believes that its at-home, accurate diagnostic products are a critical third leg of the stool that also includes telehealth and home prescription delivery for the future of safe, home-based healthcare. Lucira's expectation is that as accurate home diagnostics become prevalent, suffering and disease spread can be reduced, and that all constituents, including the public health, the healthcare value chain as well as the cost of healthcare can benefit. In the end, consumers may think of visiting a healthcare office for infectious disease diagnoses and treatment as being as antiquated as going to a video rental store to get a movie to watch: as a thing of the past.

For more information on the Lucira COVID-19 & Flu Home Test, please visit www.lucirahealth.com.

About the Lucira COVID-19 & Flu Home Test

The Lucira COVID-19 & Flu Home Test is not an antigen test. It is a molecular, nucleic acid amplification (NAAT) test that utilizes the same platform and device design as both of Lucira's commercialized FDA authorized COVID-19 tests to provide independent diagnoses for COVID-19, Flu A and Flu B. The lab-quality single-use test fits in the palm of your hand, runs on 2 AA batteries, and with one shallow nasal swab provides a

positive or negative result for COVID-19, Flu A and Flu B in 30 minutes or less. Each Lucira test contains everything needed to run a single test. There is no separate reader or instrument to purchase and maintain.

About Lucira Health

Lucira is a medical technology company focused on the development and commercialization of innovative infectious disease tests to make lab-quality diagnostics more accessible. Lucira designed its test platform to provide accurate, reliable, lab-quality test results anywhere and at any time. Beyond its already commercialized molecular COVID-19 and COVID-19 & Flu tests, Lucira is working on new diagnostic tests for respiratory infections and other categories including women's health and sexually transmitted infections (STIs). 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. 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," "will," "seek," "believe," "should," "future," "look to," "continue" and similar expressions are intended to identify forward-looking statements. These forward-looking statements, including but not limited to, our belief that a single test for both COVID-19 and Flu will be a powerful tool; at-home molecular test helping people know how to keep their families safe and seek appropriate treatment when they're ill; and how OTC authorization is helping Lucira transform the future promise of home-based, fast, accurate diagnostics into a reality; the role the new test can play in future respiratory seasons; Lucira's seeking a strategic or financial partner for the resumption of manufacturing and development of additional diagnostic products and making products available in retail and online and bringing additional diagnostic products to market; Lucira's work on new diagnostic tests for respiratory infections, women's health and STIs; and Lucira's expectation that accurate home diagnostics will become prevalent and reduce suffering and disease spread, thereby benefiting all constituents, 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. These risks and uncertainties are described more fully in the "Risk Factors" section and elsewhere in Lucira's filings with the Securities and Exchange Commission and available at www.sec.gov, including in Lucira's most recent Annual Report on Form 10-K and subsequently filed reports. Any forward-looking statements that we make in this announcement speak only as of the date of this press release, and we assume 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.

Media Contact:

media@lucirahealth.com

Investor Contact:

Glenn Wiener
GW Communications (for Lucira Health)
Email: **gwiener@GWCco.com**