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):
December 29, 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 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 December 29, 2021, Lucira Health, Inc. (the "Company") issued a press release commenting on its partnership with Co-Defend, Inc. and Co-Protect, LLC. 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 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 the Company, 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 December 29, 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: December 29, 2021

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

Lucira Health and Co-Defend/Co-Protect Announce Expanded Partnership for 2022

- *Lucira is the only EUA authorized at-home self-test kit that delivers PCR-quality accuracy and early detectability in a single-use test kit with results in 30 minutes*

- *Co-Defend and Co-Protect are leading providers of customized health & safety solutions, and testing & advisory services to Entertainment, Federal, State, and Local governments, Fortune 500 companies, and professional sports teams and leagues*

EMERYVILLE, CA, December 29, 2021 (GLOBE NEWSWIRE) — Lucira Health, Inc. (“Lucira”) (Nasdaq: LHDX), a medical technology company focused on the development and commercialization of transformative and innovative infectious disease test kits, announced a new distribution agreement for at least 600,000 tests in 2022 with Co-Defend, Inc. and Co-Protect, LLC, leading providers of customized health, safety, and wellness solutions.

“We want to make our first-of-its-kind test as widely available as possible so people don’t have to choose between rapid antigen tests that can’t reliably detect infection before symptoms and lab-based PCR tests that are difficult to access and take days to deliver results,” said Erik Engelson, President and Chief Executive Officer of Lucira Health. “Co-Defend and Co-Protect provides solutions to the biggest names in sports, entertainment and enterprise scaled businesses. Their extensive reach and L.A.-based distribution platform plus Lucira’s innovative on-the-spot molecular test means more Americans will have access to the peace of mind of a reliable, real-time test result before attending an event, returning to work, or gathering with family and friends.”

Adrian Cottman, President and Co-Founder of Co-Defend, and COO/EVP of Co-Protect, stated, “Rapid, point-of-care testing is a critical tool for infection prevention and should be included in every organization’s health and safety protocols to prevent the spread of the virus. Our companies minimize business disruption and get people back to living in this ‘new normal’. Lucira’s superior testing technology combined with our broad distribution channels will make an immediate positive impact on public health.”

Lucira Check-It COVID-19 test kit has emergency authorization by FDA under EUA.

LUCIRA™ Test Kits

The Lucira™ Check-It (OTC) and All-in-One (Rx) test kits are Nucleic-Acid Amplification Tests (referred to as NAAT). The tests fit in the palm of your hand, extract genetic material from the virus and amplify it, similar to PCR lab tests, to detect the presence of virus earlier and more accurately than antigen tests. The test uses an approach called reverse transcriptase loop-mediated isothermal amplification (RT-LAMP). It was designed and tested extensively for individuals to use independently and does not require a physician's prescription or supervised assistance. There is no additional equipment to purchase, such as a reader or instrument.

Each Lucira test kit contains everything needed to run one COVID-19 test. Users get the test device, two AA batteries, sample vial, swab, and simple instructions. The batteries are inserted into the device and the sample vial is placed in the test unit. The user then opens the test swab packet and rotates the swab five times in each nostril. The swab is then stirred in the sample vial, which is then gently pressed into the test unit to start the test. The "ready" light will blink until a "positive" or "negative" green light is illuminated within 30 minutes. In the US, Lucira also offers a free LUCI Pass™ digital verified test result back to a user's phone. LUCI Pass is accessed via text and does not require downloading an app. There is also an opt-in for public health reporting for users who wish to transmit their results to the relevant public health authorities.

In clinical trials, 100% of users successfully performed the test at home in about two minutes using Lucira's easy-to-use 'swab, stir and detect' Check-It test kit.

In a Community Trial setting, Lucira™ Check-It results were compared with the Hologic Panther Fusion, considered a high-sensitivity molecular test due to its low Limit of Detection ("LOD"). Lucira's accuracy was 98%, correctly detecting 385 out of 394 positive and negative samples in comparison to the Hologic Panther Fusion, excluding ten samples with very low levels of virus (those with very high PCR cycle thresholds of 37.5 or greater) that possibly no longer represented active infection. Comparative positive results agreed 97% of the time among this sample, and negative results agreed 98% of the time.

Last month, Lucira announced confirmation that its COVID-19 Check-It molecular self-test kits can detect 100% of Omicron variant genome sequences analyzed, including the "stealth variant". Lucira assays target viral sequence regions unaffected by the spike protein mutations found in Omicron, Delta and other Variants of Concern, allowing it to maintain its accuracy in the face of an evolving virus.

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.

About Co-Defend and Co-Protect

Co-Defend and Co-Protect began in 2019, providing solutions for large scale sports events and arenas who were seeking to re-start operations during COVID-19. The Los Angeles based companies specialize in customized COVID solutions for companies, governments and sports leagues; their license portfolio features NBA, MLB, MLS and several prominent Universities. As the most innovative company in protective wellness, Co-Defend and Co-Protect solutions offer an array of COVID testing, branded personal protective equipment, and a sophisticated vaccine verification and health data management platform used by millions of consumers.

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,” “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 including its variants, the extent and duration of the COVID-19 pandemic and our expectations regarding customer and user demand for our COVID-19 test kit; our ability to obtain and maintain regulatory approval for our test kits, including our existing Emergency Use Authorization for our COVID-19 test kits; the performance of, and our reliance on, third parties in connection with the commercialization of our test kits, including Jabil Inc. and our single-source suppliers; our ability to successfully continue to expand internationally; 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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