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 21, 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 1.01 Entry into a Material Definitive Agreement.

On December 21, 2021, Lucira Health, Inc. (the "Company") entered into Amendment #1 to Distribution Agreement (the "Amendment") with Switch Health Solutions Inc. (the "Distributor"). The Amendment amends the Distribution Agreement, dated July 14, 2021, by and among the Company and the Distributor (the "Distribution Agreement"), to, among other things, update the forecasts of LUCIRA CHECK IT COVID-19 Test Kits (the "Test Kits") that Distributor expects to order for each of the coming 12 calendar months through December 2022 and six-month periods following December 2022 (each, a "Rolling Forecast"). In the Amendment, the Distributor agrees to purchase at least (but not less than) the quantity of Test Kits applicable to the calendar month as set forth in the Rolling Forecast. For fiscal year 2022, the Rolling Forecast is valued at approximately $100 million.

The Distribution Agreement is for a one-year term and the parties have the right to renew for successive one-year periods by providing written notice to the other party prior to the expiration of the current term. Either party may terminate the Distribution Agreement (a) immediately for material breach by the other party, (b) if the other party enters into insolvency or bankruptcy or a trustee or receiver or the equivalent is appointed for the other party or proceedings are instituted against the other party relating to dissolution, liquidation, winding up, bankruptcy, insolvency, etc. or (c) for convenience upon 30 days' notice to the other party. Additionally, either party may terminate immediately upon written notice if a regulatory or governmental agency or court takes action the result of which would prohibit or significantly restrict the sale, distribution, use or manufacture of the Test Kits in accordance with the Distribution Agreement.

If the Company fails to fulfill the quantity of Test Kits set forth in any part of the Binding Offer Period for which Distributor submits a purchase order(s), the Distributor is not required to purchase the remaining quantity of Test Kits set forth in the 12 calendar months of each Rolling Forecast (the "Binding Offer Period"). If Distributor fails to deliver a quantity of Test Kits applicable to the following calendar month as set forth in the Rolling Forecast or fails to deliver a purchase order with respect to the total, aggregate quantity of Test Kits set forth in the 12 calendar months of each Rolling Forecast (each, a "Binding Order Breach") then Distributor is liable to the Company for a low double-digit percentage of the total price applicable to the amount of Test Kits set forth in the two months following the Binding Order Breach as set forth in the Rolling Forecast.

The foregoing description of the material terms of the Amendment does not purport to be complete and is qualified in its entirety by reference to the complete text of the Amendment and the Distribution Agreement, copies of which will be filed as exhibits to the Company's Annual Report on Form 10-K for the year ending December 31, 2021.

Item 7.01 Regulation FD Disclosure.

On December 22, 2021, the Company issued a press release commenting on its expanded partnership with the Distributor. 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 22, 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 22, 2021

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

Exhibit 99.1

Lucira Health Announces Expanded Partnership with Switch Health to Increase Canadians' Access to At-Home Molecular COVID-19 Tests

- *Lucira's tests are the only available at-home self-test kits that deliver PCR-quality accuracy and early detectability in a single-use test kit with results in 30 minutes*
- *Current surge of COVID-19 cases caused by the Omicron variant highlights the need for additional at-home testing that can reliably detect early infections and deliver rapid results*

EMERYVILLE, CA, December 22, 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 agreement with Switch Health Solutions Inc. ("Switch Health") to increase Canadians' access to at-home molecular COVID-19 tests as Omicron cases surge. Lucira will provide more than 2 million at-home COVID-19 test kits in 2022 as part of the deal.

"As Omicron cases surge around the world, the need for better testing solutions has never been more apparent," said Erik Engelson, President and Chief Executive Officer of Lucira. "Only Lucira's tests provide a PCR-quality test result in 30 minutes, wherever you are, from a simple, single-use kit. Making these tests more available is critical to help slow the spread of COVID-19."

Switch Health is a Canadian healthcare company dedicated to providing better decentralized patient care. Switch Health has quickly become a leader in COVID-19 testing on-site at its Switch Health Clinics and at-home through its remote telehealth service and in-person visits.

"Switch Health's ability to be a Canadian health care leader in decentralized diagnostics is in large part due to the innovative technologies we make available to everyday Canadians," added Marc Thomson, Chief Operating Officer at Switch Health. "Lucira has been an instrumental partner in helping Switch Health achieve that in the COVID-19 era. Together, we are removing barriers to get Canadians safely back to work and reunited with their loved ones."

Last month, Lucira announced confirmation that its COVID-19 Check-It (OTC) and All-In-One (Rx) 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.

Lucira has received Interim Order authorization from Health Canada to sell and distribute its COVID-19 test kits for at-home self-testing in Canada.

LUCIRA™ CHECK IT Test Kit

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.

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. 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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