

**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):
March 10, 2022**

Lucira Health, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39976
(Commission
File Number)

27-2491037
(IRS Employer
Identification No.)

1412 62nd Street
Emeryville, California
(Address of principal executive offices)

94608
(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 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On March 10, 2022, Lucira Health, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this current report.

The information in this Item 2.02 and 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 2.02 and 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 March 10, 2022.
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: March 10, 2022

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



Lucira Health Announces Fourth Quarter and Full Year 2021 Results and Reaffirms 2022 Financial Outlook

EMERYVILLE, Calif. – March 10, 2022 – Lucira Health, Inc. (Nasdaq: LHDX) (“Lucira Health,” “Lucira” or the “Company”), a medical technology company focused on the development and commercialization of transformative and innovative infectious disease test kits, today reported financial results for the fourth quarter and full year ended December 31, 2021.

Recent Highlights

- Achieved net revenue of \$61.1 million for the fourth quarter of 2021, representing approximately 300% sequential growth over the preceding quarter
- Recorded full year revenue of \$93.1 million for 2021, the Company’s first full year of commercialization
- Increased manufacturing output through the Dominican Republic-based plant resulted in positive gross profit and margin for both the fourth quarter and the full year 2021
- Secured contract with Canadian healthcare company, Switch Health, to provide more than 2 million at-home COVID-19 test kits in 2022

“Lucira’s strong fourth quarter is indicative of the inflection point the Company is experiencing in its growth,” said Erik Engelson, President and Chief Executive Officer of Lucira Health. “The strong financial performance was a result of a rise in manufacturing output against consistently high demand in the quarter. We offer consumers an easy-to-use, rapid, PCR-quality test that’s untethered from instruments or readers. It’s a revolutionary way to accurately and conveniently test for infectious disease, and we look forward to capitalizing on the market’s continued acceptance of decentralized testing in the future.”

Fourth Quarter 2021 Financial Results

The fourth quarter of 2021 represented Lucira’s first full fourth quarter of commercial activity.

Net Revenue was \$61.1 million for the fourth quarter of 2021, close to doubling the combined three prior quarters in 2021 of \$31.9 million. Net revenue growth was driven primarily by increased manufacturing output as demand continued to be strong in all four of our sales channels.

GAAP Gross Profit was approximately \$12.6 million for the fourth quarter of 2021 or 21% of revenue. Non-GAAP gross profit and non-GAAP gross margin were \$19.1 million and 31%, respectively. Increases in both gross profit and gross margin from the third quarter of 2021 were primarily due to efficiencies resulting from increased manufacturing output.

GAAP Operating Expenses were \$20.6 million in the fourth quarter of 2021, compared to \$10.9 million in the same period in 2020. Non-GAAP operating expenses were \$19.0 million in the fourth quarter of 2021, compared to \$11.6 million in the same period of 2020. The increase is primarily related to increased headcount and third-party services to facilitate commercial activities, validation of manufacturing activities, new product development, clinical studies, and public company compliance.

GAAP Net Loss was \$7.8 million in the fourth quarter of 2021, compared to \$17.2 million in the same period in 2020. Non-GAAP net income was \$0.3 million for the fourth quarter of 2021, compared to a non-GAAP net loss of \$13.1 million for the same period in 2020.

Cash Balance as of December 31, 2021 was \$106.0 million.

First Quarter and Full Year 2022 Financial Guidance

The Company anticipates first quarter revenue between \$80.0 and \$85.0 million and 2022 full year revenue in excess of \$450.0 million, in keeping with an announcement the Company previously made on January 10, 2022.

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results and provide a corporate update on Thursday, March 10, 2022, at 4:30 PM ET.

To participate in the call, please dial (833) 562-0151 (US/Canada) or (661) 567-1232 (International) and provide conference ID 9897752. A live and archived webcast of the event can be accessed through the following link ir.lucirahealth.com.

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.

Non-GAAP Financial Measures

In this press release, in order to supplement the Company's condensed financial statements presented in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"), management has disclosed certain non-GAAP financial measures for the Company's statements of operations. The Company believes that an evaluation of its ongoing operations (and comparisons of its current operations with historical and future operations) would be difficult if the disclosure of its financial results were limited to financial measures prepared in accordance with GAAP. As a result, the Company is disclosing certain non-GAAP results in order to supplement investors' and other readers' understanding and assessment of the Company's financial performance because Company management uses these measurements as aids in monitoring the Company's ongoing financial performance from quarter to quarter, and year to year, on a regular basis and for financial and operational decision-making. Non-GAAP financial measures include gross profit, gross margin, operating expenses, and net loss. Non-GAAP adjustments include stock-based compensation, depreciation and amortization, non-cash interest and other expense, preapproval inventories, a long-lived asset impairment charge and certain charges related to obsolete inventory. From time to time in the future, there may be other items that the Company may include or exclude if the Company believes that doing so is consistent with the goal of providing useful information to investors and management. The Company has provided a reconciliation of each non-GAAP financial measure used in this earnings release to the most directly comparable GAAP financial measure.

Non-GAAP financial measures used by the Company may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies, which could reduce the usefulness of the Company's non-GAAP financial measures as tools for comparison. Investors are cautioned that there are a number of limitations associated with the use of non-GAAP financial measures as analytical tools. The Company has provided at the end of this press release, following the accompanying financial data, reconciliations of its non-GAAP measures to their most directly comparable GAAP measures. Investors are encouraged to review these reconciliations, and not to rely on any single financial measure to evaluate the Company's business. Investors and other readers are encouraged to review the related GAAP financial measures and the reconciliation of non-GAAP measures to their most directly comparable GAAP measures set forth below and should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with GAAP. Non-GAAP financial measures in this earnings release exclude the following:

Stock-based compensation expense. The Company has excluded the effect of stock-based compensation expenses in calculating the Company's non-GAAP gross profit (loss), gross (negative) margin, operating expenses and net loss measures. Although stock-based compensation is a key incentive offered to employees, consultants and board members the Company continues to evaluate its business performance excluding stock-based compensation expenses. The Company records stock-based compensation expense related to grants of time-based options and restricted stock units. Depending upon the size, timing and terms of the grants, as well as the probability of achievement of performance-based awards, this expense may vary significantly but will recur in future periods. The Company believes that excluding stock-based compensation expense better allows for comparisons from period to period.

Depreciation and amortization. The Company has excluded the effect of depreciation and amortization expense in calculating its non-GAAP gross profit (loss), gross (negative) margin, operating expenses and net loss measures. Depreciation and amortization are non-cash charges to current operations.

Non-cash interest and other expense. The Company has excluded the effect of non-cash interest and remeasurement of derivative liabilities and convertible notes in calculating its non-GAAP net loss measure.

Preapproval inventories. The Company has included the effect of preapproval inventories. Preapproval inventories were previously recorded as research and development expense during the third quarter of 2020 and subsequently sold at zero cost of product and internally consumed in research and development and sales and marketing from the fourth quarter of 2020 through the third quarter of 2021.

Long-lived asset impairment charge. The Company has excluded the impact of an impairment charge resulting from an asset with reduced fair value in calculating its non-GAAP gross profit (loss), gross (negative) margin and net loss measures.

Obsolete inventory. The Company has excluded the impact of certain obsolete inventory charges in calculating its non-GAAP gross profit (loss) gross (negative) margin and net loss measures.

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,” “aim,” “will,” “may,” “anticipates,” “expects,” 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 kit and LUCI Pass; the performance of, and our reliance on, third parties in connection with the commercialization of our test kits, including Jabil Inc. Switch Health 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 and expand our product offerings, broaden commercial activities and take advantage of growth opportunities; our ability to accurately predict continued expansion; our ability to accurately forecast revenue; our ability to bolster capital reserves and reinforce our financial health; 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.

Investor Relations

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347-620-7010

LUCIRA HEALTH, INC.
CONDENSED BALANCE SHEETS
(Unaudited)
(In thousands, except share and per share data)

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash	\$ 105,982	\$ 58,212
Accounts receivable, net	27,245	293
Inventory	50,776	4,865
Other Receivable	8,188	798
Prepaid expenses	10,274	3,496
Other current assets	3,817	229
Restricted cash equivalents	—	2,338
Total current assets	206,282	70,231
Property and equipment, net	30,974	19,408
Operating lease right-of-use assets	2,714	748
Other assets	384	2,316
Total assets	<u>\$ 240,354</u>	<u>\$ 92,703</u>
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 19,371	\$ 3,981
Accrued liabilities	29,162	4,445
Operating lease liabilities, current	1,609	431
Customer deposits	189	—
Total current liabilities	50,331	8,857
Convertible notes payable	—	24,694
Operating lease liabilities, net of current portion	1,220	380
Total liabilities	<u>51,551</u>	<u>33,931</u>
Commitments and contingencies		
Redeemable convertible preferred stock \$0.001 par value; 0 and 103,355,827 shares authorized as of December 31, 2021 and 2020, respectively; 0 and 23,978,747 shares issued and outstanding as of December 31, 2021 and 2020, respectively; aggregate liquidation preference of \$0 as of December 31, 2021	—	121,080
Stockholders' equity:		
Preferred stock \$0.001 par value; 10,000,000 and 0 shares authorized as of December 31, 2021 and 2020, respectively; 0 shares issued and outstanding as of December 31, 2021 and 2020	—	—
Common stock, \$0.001 par value; 200,000,000 and 150,000,000 shares authorized as of December 31, 2021 and 2020, respectively; 39,663,645 and 2,712,694 shares issued and outstanding as of December 31, 2021 and 2020, respectively	40	3
Additional paid-in capital	317,304	1,403
Accumulated deficit	(128,541)	(63,714)
Total stockholders' equity (deficit)	188,803	(62,308)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity	<u>\$ 240,354</u>	<u>\$ 92,703</u>

LUCIRA HEALTH, INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share and per share data)

	<u>Three Months Ended December 31,</u>		<u>Twelve Months Ended December 31,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net sales	\$ 61,124	\$ 269	\$ 93,055	\$ 269
Cost of products sold	48,682	1,941	81,392	1,941
Impairment of long-lived assets	(183)	—	1,439	—
Gross profit (loss)	<u>12,625</u>	<u>(1,672)</u>	<u>10,224</u>	<u>(1,672)</u>
Operating expenses:				
Research and development	9,099	8,512	39,840	24,620
Selling, general and administrative	11,550	2,412	35,538	5,633
Total operating expenses	<u>20,649</u>	<u>10,924</u>	<u>75,378</u>	<u>30,253</u>
Loss from operations	<u>(8,024)</u>	<u>(12,596)</u>	<u>(65,154)</u>	<u>(31,925)</u>
Other income (expense), net:				
Grant income	204	138	597	2,145
Interest income (expense), net	5	(9)	11	(53)
Remeasurement of derivative liabilities and convertible notes	—	(4,720)	(281)	(7,515)
Total other income (expense), net	<u>209</u>	<u>(4,591)</u>	<u>327</u>	<u>(5,423)</u>
Net loss	<u>\$ (7,815)</u>	<u>\$ (17,187)</u>	<u>\$ (64,827)</u>	<u>\$ (37,348)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.20)</u>	<u>\$ (6.70)</u>	<u>\$ (1.86)</u>	<u>\$ (15.58)</u>
Weighted-average number of shares used in net loss per share of common stock, basic and diluted	<u>39,029,856</u>	<u>2,565,252</u>	<u>34,768,542</u>	<u>2,396,798</u>

Reconciliation of GAAP to Non-GAAP Financial Measures

The following table represents the reconciliation of non-GAAP financial measures to the most directly comparable GAAP financial measures:

(In thousands)
(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Reconciliation of GAAP to non-GAAP Gross Profit (Loss):				
GAAP Gross Profit (Loss)	\$ 12,625	\$ (1,672)	\$ 10,224	\$ (1,672)
Stock-based compensation expense	385	17	736	17
Depreciation and amortization	1,082	87	2,259	87
Impairment of long-lived assets	(183)	—	1,439	—
Inventory obsolescence charge	5,223	—	6,507	—
Preapproval inventories	—	(60)	(1,089)	(60)
Non-GAAP Gross profit (loss)	<u>\$ 19,132</u>	<u>\$ (1,628)</u>	<u>\$ 20,076</u>	<u>\$ (1,628)</u>
Reconciliation of GAAP to non-GAAP Gross margin				
GAAP Gross (negative) margin	21%	(622%)	11%	(622%)
Stock-based compensation expense	1%	6%	1%	6%
Depreciation and amortization	2%	32%	2%	32%
Impairment of long-lived assets	0%	0%	2%	0%
Inventory obsolescence charge	9%	0%	7%	0%
Preapproval inventories	0%	(22%)	(1%)	(22%)
Non-GAAP Gross (negative) margin	<u>31%</u>	<u>(605%)</u>	<u>22%</u>	<u>(605%)</u>
Reconciliation of GAAP to non-GAAP Operating expenses:				
GAAP Operating expenses	\$ 20,649	\$ 10,924	\$ 75,378	\$ 30,253
Stock-based compensation expense	(1,220)	(185)	(7,369)	(420)
Depreciation and amortization	(431)	(40)	(1,412)	(193)
Preapproval inventories	—	893	305	893
Non-GAAP Operating expenses	<u>\$ 18,998</u>	<u>\$ 11,592</u>	<u>\$ 66,902</u>	<u>\$ 30,533</u>
Reconciliation of GAAP to non-GAAP Net loss:				
GAAP Net loss	\$ (7,815)	\$ (17,187)	\$ (64,827)	\$ (37,348)
Stock-based compensation expense	1,605	202	8,105	437
Depreciation and amortization	1,513	127	3,671	280
Non-cash interest and other expense	5	4,729	270	7,568
Impairment of long-lived assets	(183)	—	1,439	—
Inventory obsolescence charge	5,223	—	6,507	—
Preapproval inventories	—	(953)	(1,394)	(953)
Non-GAAP Net Income (loss)	<u>\$ 348</u>	<u>\$ (13,082)</u>	<u>\$ (46,229)</u>	<u>\$ (30,016)</u>