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): **August 12, 2022**

AXCELLA HEALTH INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38901**	**26-3321056**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

840 Memorial Drive **Cambridge, Massachusetts**	**02139**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(857) 320-2200**

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 (see General Instruction A.2. below):

☐ 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, $0.001 Par Value	AXLA	Nasdaq Global 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 x

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 August 12, 2022, Axcella Health Inc., doing business as "Axcella Therapeutics," announced its financial results for the second quarter ended June 30, 2022. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release issued by Axcella Health Inc., doing business as "Axcella Therapeutics," dated August 12, 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.

AXCELLA HEALTH INC.

Date: August 12, 2022

By: /s/ William R. Hinshaw, Jr.
William R. Hinshaw, Jr.
President, Chief Executive Officer and Director

Axcella Reports Second Quarter Financial Results and Provides Business Update

- *Announced Statistically Significant Clinical Improvement in Fatigue in the Phase 2A Long COVID Trial Topline data*
- *NASH Trial interim Data Expected in Late Q3 2022*
- *Company to Host Conference Call at 8:30 a.m. ET today*

Cambridge, Mass., August 12, 2022 – Axcella Therapeutics (Nasdaq: AXLA), a clinical-stage biotechnology company pioneering a new approach to treat complex diseases using multi-targeted endogenous metabolic modulator (EMM) compositions, today announced financial results for the second quarter ended June 30, 2022 and provided a business update.

"Axcella has been a leader in clinical development in Long COVID. We continued this leadership through the second quarter as we advanced the development of our two clinical programs for AXA1125. Our Phase 2A trial of Long COVID in collaboration with Oxford University is now complete. The results were extremely encouraging and showed that administration of AXA1125 to patients significantly reduced mental and physical fatigue," said Bill Hinshaw, President and Chief Executive Officer of Axcella. "Since reporting our data last week, we have received extremely positive feedback from our community of physicians and patients regarding their excitement about the further development of this therapeutic and its potential to benefit patients once it reaches the clinic. In addition, we continue to participate in investors meetings to get the story of the company out to the wider investment community."

Financial Results

Cash Position: As of June 30, 2022, cash, cash equivalents, and marketable securities totaled $44.4 million, compared to $55.0 million as of December 31, 2021. In March 2022, the Company received approximately $25.0 million in gross proceeds from a registered direct offering of common stock. Axcella expects that its current cash balance will be sufficient to meet its operating needs into the first quarter of 2023, provided that, if the Company is unable to satisfy the cash covenants contained in its loan and security agreement with SLR Investment Corp., and SLR Investment Corp. seeks immediate repayment of the loan in full, the Company believes that its cash and cash equivalents will be sufficient to fund its operations into the fourth quarter of 2022.

R&D Expenses: Research and development expenses for the quarter and six months ended June 30, 2022 were $16.9 million and $30.4 million, respectively. Research and development expenses for the same periods ended June 30, 2021 were $10.3 million and $20.5 million, respectively. These increases are the result of the Company's EMMPACT and Long COVID Phase 2 clinical trials, as well as closure costs for its EMMPOWER Phase 2 clinical trial.

G&A Expenses: General and administrative expenses for the quarter and six months ended June 30, 2022 were $3.8 million and $8.5 million, respectively. General and administrative expenses for the same periods ended June 30, 2021 were $4.9 million and $9.2 million. These decreases are primarily the result of lower non-cash stock-based compensation expenses.

Net Loss: Net loss for the quarter and six months ended June 30, 2022 was $21.3 million, or $0.40 per basic and diluted share, and $40.3 million, or $0.86 per basic and diluted share, respectively. This compares with a net loss of $15.9 million, or $0.42 per basic and diluted share, and $31.1 million, or $0.83 per basic and diluted share, for the quarter and six months ended June 30, 2021.

Internet Posting of Information

Axcella uses the "Investors and News" section of its website, www.axcellatx.com, as a means of disclosing material nonpublic information, to communicate with investors and the public, and for complying with its disclosure obligations under Regulation FD. Such disclosures include, but may not be limited to, investor presentations and FAQs, Securities and Exchange Commission filings, press releases, and public conference calls and webcasts. The information that we post on our website could be deemed to be material information. As a result, we encourage investors, the media and others interested to review the information that we post there on a regular basis. The contents of our website shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

About Axcella Therapeutics (Nasdaq: AXLA)

Axcella is a clinical-stage biotechnology company pioneering a new approach to treat complex diseases using compositions of endogenous metabolic modulators (EMMs). The company's product candidates are comprised of EMMs and derivatives that are engineered in distinct combinations and ratios to restore cellular homeostasis in multiple key biological pathways and improve cellular energetic efficiency. Axcella's pipeline includes lead therapeutic candidates in Phase 2 development for the treatment of Long COVID, and non-alcoholic steatohepatitis (NASH). The company's unique model allows for the evaluation of its EMM compositions through non-IND clinical studies or IND clinical trials. For more information, please visit www.axcellatx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the timing of the company's clinical trial data readouts, its expected cash runway and the potential impact of the company's recent clinical trial data readouts on market interest and acceptance of the company's product candidates and investment interest in the company's securities. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those related to the potential impact of COVID-19 on the company's ability to conduct and complete its ongoing or planned clinical studies and clinical trials in a timely manner or at all due to patient or principal investigator recruitment or availability challenges, clinical trial site shutdowns or other interruptions and potential limitations on the quality, completeness and interpretability of data the company is able to collect in its clinical trials of AXA1125, other potential impacts of COVID-19 on the company's business and financial results, including with respect to its ability to raise additional capital and operational disruptions or delays, changes in law, regulations, or interpretations and enforcement of regulatory guidance, whether data readouts support the company's clinical trial plans and timing, clinical trial design and target indications for AXA1125, the clinical development and safety profile of AXA1125 and its therapeutic potential, whether and when, if at all, the company's product candidates will receive approval from the FDA or other comparable regulatory authorities, potential competition from other biopharma companies in the company's target indications, and other risks identified in the company's SEC filings, including Axcella's Annual Report on Form 10-K, Quarterly Report on Form 10-Q and subsequent filings with the SEC. The company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Axcella disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent the company's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. The company explicitly disclaims any obligation to update any forward-looking statements.

Axcella Therapeutics
Unaudited Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2022	December 31, 2021
Assets:		
Cash and cash equivalents	$ 34,077	$ 23,574
Marketable securities	10,323	31,474
Operating lease right-of-use asset	2,686	—
Other assets	2,892	2,679
Total assets	$ 49,978	$ 57,727
Liabilities and stockholders' equity:		
Accounts payable	$ 3,995	$ 4,301
Accrued expenses and other current liabilities	8,216	5,849
Current portion of long-term debt	3,467	—
Operating lease liability	1,497	—
Total current liabilities	17,175	10,150
Long-term debt, net of current portion and discount	21,701	25,070
Operating lease liability, net of current portion	1,391	—
Other liabilities	413	499
Liabilities	40,680	35,719
Stockholders' equity	9,298	22,008
Total liabilities and stockholders' equity	$ 49,978	$ 57,727

Axcella Therapeutics
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 16,866	$ 10,298	$ 30,410	$ 20,538
General and administrative	3,753	4,946	8,539	9,202
Total operating expenses	20,619	15,244	38,949	29,740
Loss from operations	(20,619)	(15,244)	(38,949)	(29,740)
Other income (expense):				
Interest income (expense) and other income (expense), net	(687)	(691)	(1,396)	(1,384)
Total other income (expense), net	(687)	(691)	(1,396)	(1,384)
Net loss	$ (21,306)	$ (15,935)	$ (40,345)	$ (31,124)
Net loss per share, basic and diluted	$ (0.40)	$ (0.42)	$ (0.86)	$ (0.83)
Weighted average common shares outstanding, basic and diluted	52,616,279	37,732,196	47,052,105	37,692,398

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