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 30, 2023**

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.)

P.O. Box 1270 **Littleton, Massachusetts**	**01460**
(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 ☒

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 30, 2023, Axcella Health Inc., doing business as "Axcella Therapeutics," announced its financial results for the fourth quarter and year ended December 31, 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 March 30, 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.

AXCELLA HEALTH INC.

Date: March 30, 2023

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

Axcella Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

- *Long COVID Phase 2b/3 study may proceed under U.S. Investigational New Drug application*
- *MHRA guidance aligns on key measurements for a Long COVID registration trial, including primary endpoint and trial design elements*
- *Axcella presented at Long COVID forum co-sponsored by BIO and Solve M.E.*
- *The Company repositioned its strategy to focus on Long COVID*
- *Engaged an investment bank to act as a strategic advisor as we explore a range of strategic alternatives to maximize stakeholder value*

Cambridge, Mass., March 30, 2023 – 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 fourth quarter and full year ended December 31, 2022 and provided a business update.

"The year 2022 was one of significant achievement for Axcella Therapeutics that was highlighted by the results from the Phase 2a of AXA1125 in patients with fatigue related to Long COVID and positive data from a preplanned interim analysis from the trial of AXA1125 in NASH," said Bill Hinshaw, President and Chief Executive Officer of Axcella. "In addition, the Company raised around $60 million, allowing completion of the Long COVID trial and positioning for regulatory interactions. The Company cleared a path forward for a registration study in Long COVID fatigue and focused the company and resources to support this opportunity."

Recent Accomplishments and Developments

- **Statistically Significant and Meaningful Clinical Results in the Treatment of Long COVID Fatigue:** Axcella's Phase 2a clinical trial results demonstrated the potential of AXA1125 to play an important role in treating patients suffering from Long COVID fatigue. Axcella's Phase 2a trial has been the only controlled trial to demonstrate statistically and clinically relevant improvement in fatigue in patients with Long COVID. This randomized, double-blind, placebo-controlled investigation evaluated the efficacy and safety of AXA1125 in patients with fatigue related to Long COVID. The study, which did not meet an experimental biomarker primary endpoint, found that subjects who received AXA1125 experienced clinically and statistically significant improvement in mental ($p=0.0097$) and physical ($p=0.0097$) fatigue scores compared to placebo subjects. Understanding of the relevant biological activity and safety were complemented by concurrent data generated in the NASH program.

- **FDA Clearance of IND for a Phase 2b/3 Trial:** Axcella announced its Investigational New Drug (IND) application to initiate a Phase 2b/3 trial in the U.S. for AXA1125 in the treatment of Long COVID fatigue had been cleared by the U.S. Food and Drug Administration (FDA). The Company reported that it had received regulatory guidance from the FDA, supporting a trial that is designed to serve as the registration trial for patients with Long COVID fatigue. Fatigue is the most common symptom associated with Long COVID, impacting a majority of patients.

- **Regulatory Path to Registration of AXA1125 in Long COVID:** The Company received regulatory guidance from The Medicines and Healthcare products Regulatory Agency (MHRA), the U.K.'s regulatory agency, supporting a single trial that could serve as the registration trial for patients with Long COVID fatigue, and aligning on key measurements, including primary endpoint and trial design.

- **Restructuring the Company to Advance AXA1125 in Long COVID Fatigue:** Axcella discontinued its Phase 2b clinical trial of AXA1125 in NASH despite reporting positive data from a preplanned interim analysis in September. At 24 weeks, there were statistically significant and clinically relevant improvements in the liver stiffness measurement (LSM) compared to placebo in the high dose arm for all subjects and statistically significant improvements in other non-invasive tests of liver fat and stiffness. Axcella also realigned the organization to correspond to this shift in strategy and reprioritization of its programs.

- **Financial Performance**: Axcella completed registered direct offerings in March 2022 and October 2022, yielding gross proceeds of approximately $59 million. Expenses for the three clinical trials and payments of about $27 million to extinguish the debt with SLR Investment Corp. led the Company to restructure in December and to explore a range of strategic alternatives to maximize stakeholder value. With respect to the Company's plans, no assurances can be made as to whether a strategic transaction will be recommended by the Board of Directors, and the Company does not intend to discuss developments with respect to the evaluation process unless a transaction is approved, or disclosure otherwise becomes appropriate.

Financial Results

Cash Position: As of December 31, 2022, cash and cash equivalents totaled $17.1 million, compared to cash, cash equivalents, and marketable securities of $55.0 million as of December 31, 2021. As mentioned above, subsequent to the close of 2021, the Company received approximately $59 million in gross proceeds from registered direct offerings of common stock. Based on the Company's current financial resources and forecasted operating plan, the Company believes that it will be able to operate into the second quarter of 2023.

R&D Expenses: Research and development expenses for the quarter and year ended December 31, 2022 were $13.3 million and $57.0 million, respectively. Research and development expenses for the same periods ended December 31, 2021 were $12.5 million and $43.1 million, respectively. These increases are primarily the result of the costs to run multiple Phase 2 clinical trials.

G&A Expenses: General and administrative expenses for the quarter and year ended December 31, 2022 were $3.5 million and $15.8 million, respectively. General and administrative expenses for the same periods ended December 31, 2021 were $4.7 million and $18.7 million, respectively. These decreases are primarily the result of lower non-cash stock-based compensation expenses from expense reversals on forfeited equity awards.

Restructuring and impairment charges: Other operating expenses were $4.2 million for the quarter and year ended December 31, 2022 due to: (i) a $2.1 million impairment charge on its right-of-use operating lease asset, (ii) a $0.2 million impairment charge on its finance lease asset, and (iii) a $1.9 million charge for severance expenses, all related to the corporate restructuring.

Other (expense) income: Other (expense) income, net for the quarter and year ended December 31, 2022 was $2.1 million and $4.2 million, respectively. Other (expense) income, net for the same periods ended December 31, 2021 was $0.7 million and $2.8 million, respectively. In December 2022, the Company repaid its debt with SLR Investment Corp. and recorded a $1.5 million loss on debt extinguishment. The remaining loss relates to legal fees related to the promissory note conversion in October 2022 in connection with the registered direct offering.

Net Loss: Net loss for the quarter and year ended December 31, 2022 was $23.0 million, or $0.33 per basic and diluted share, and $81.2 million, or $1.49 per basic and diluted share, respectively. The net loss for the quarter and year ended December 31, 2021 was $17.9 million, or $0.46 per basic and diluted share, and $64.6 million, or $1.70 per basic and diluted share, respectively. These increases are primarily the result of higher expenses in 2022 for clinical trials, restructuring and impairment charges, and a debt extinguishment loss.

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 reset multiple biological pathways, improve cellular energetics, and restore homeostasis. Axcella's pipeline includes lead therapeutic candidates 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, the outcome of strategic alternatives, restructuring the company to advance AXA1125 in Long COVID Fatigue and its financial condition and expected cash runway into the second quarter of 2023. 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)

	December 31, 2022	December 31, 2021
Assets:		
Cash and cash equivalents	$ 17,147	$ 23,574
Marketable securities	—	31,474
Other assets	1,780	2,679
Total assets	$ 18,927	$ 57,727
Liabilities and stockholders' equity:		
Accounts payable	$ 4,707	$ 4,301
Accrued expenses and other current liabilities	7,849	5,849
Current portion of operating lease liability	1,592	—
Total current liabilities	14,148	10,150
Long-term debt, net of discount	—	25,070
Operating lease liability	569	—
Other non-current liabilities	46	499
Total liabilities	14,763	35,719
Stockholders' equity	4,164	22,008
Total liabilities and stockholders' equity	$ 18,927	$ 57,727

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 13,257	$ 12,467	$ 56,984	$ 43,135
General and administrative	3,500	4,736	15,815	18,711
Restructuring and impairment charges	4,189	—	4,189	—
Total operating expenses	20,946	17,203	76,988	61,846
Loss from operations	(20,946)	(17,203)	(76,988)	(61,846)
Other income (expense):				
Loss on extinguishment of debt	(1,601)	—	(1,601)	—
Interest income (expense) and other income (expense), net	(453)	(688)	(2,597)	(2,782)
Total other income (expense), net	(2,054)	(688)	(4,198)	(2,782)
Net loss	$ (23,000)	$ (17,891)	$ (81,186)	$ (64,628)
Net loss per share, basic and diluted	$ (0.33)	$ (0.46)	$ (1.49)	$ (1.70)
Weighted average common shares outstanding, basic and diluted	70,435,331	38,847,669	54,355,769	38,110,420

Company Contact
ir@axcellatx.com
(857) 320-2200