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): **May 26, 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 ☒

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 8.01 Other Events.

On May 26, 2022, Axcella Health Inc. (the "Company" or "Axcella") issued a press release announcing that it has completed patient enrollment for its Phase 2a clinical trial of AXA1125 for the treatment of Long COVID and that it is suspending its Phase 2 clinical trial of AXA1665 for the reduction in risk of Overt Hepatic Encephalopathy (OHE) recurrence while exploring partnerships and alternate indications for AXA1665.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated May 26, 2022 entitled "Axcella Announces Completion of Enrollment of Clinical Trial for Long COVID and Has Prioritized its Clinical Portfolio"
104	Cover Page Interactive Data (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: May 26, 2022

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

Exhibit 99.1

Axcella Announces Completion of Enrollment of Clinical Trial for Long COVID and Has Prioritized its Clinical Portfolio

- Long COVID Trial Topline data expected in early Q3 2022
- NASH Trial interim data expected in late Q3 2022
- OHE Trial Suspended

CAMBRIDGE, Mass. – May 26, 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 that it has prioritized its clinical development portfolio after rapid enrollment for its Phase 2a clinical trial in Long COVID. The company affirmed topline data readout for its Phase 2a Long COVID trial in early Q3 2022 and interim data readout for NASH in late Q3 2022. The company is suspending its Phase 2 clinical trial in OHE (Overt Hepatic Encephalopathy) while exploring potential partnership for the program.

Long COVID Trial:

Patient enrollment is complete in the prospective, placebo controlled, randomized trial conducted at the John Radcliffe Hospital at Oxford University in England. Lead researcher Dr. Betty Raman, British Heart Foundation Oxford Centre of Research Excellence Clinical Transition Intermediate Fellow said, "We have completed enrollment of the forty patients for this integral study on schedule. We look forward to sharing the results of the trial given the ever growing patient need for a product to address Long COVID fatigue."

"Achieving completion of enrollment is a significant milestone in the development path of AXA1125 as a potential treatment for Long COVID, a large and growing consequence of the global pandemic," said Margaret Koziel, M.D., Chief Medical Officer at Axcella. "We believe mitochondrial dysfunction is a key driver of Long Covid induced fatigue. Preclinical and clinical data indicate that AXA1125 may have an important impact."

Bill Hinshaw, President and CEO of Axcella, continued: "We are a leader in therapeutics for Long COVID and in particular addressing fatigue. We are expecting results from this trial as well as interim results from our Phase 2b NASH trial in the third quarter of 2022. The execution of this Phase 2a Long COVID trial will significantly advance our pipeline and validate the effectiveness of EMMs to address multi-factorial diseases."

Overt Hepatic Encephalopathy (OHE) Trial:

The company is conducting a global Phase 2 randomized, double-blind, placebo-controlled, multi-center investigation on the efficacy and safety of AXA1665 in OHE. The trial commenced in the second quarter of 2021. Despite investigator interest, this is a rare disease of very ill patients with enrollment challenges and timelines to approval will be long; as a result, the Company has made the decision to terminate the trial and focus resources on both the ongoing Long COVID and NASH programs. Bill Hinshaw, President and CEO of Axcella, commented: "We continue to believe that AXA1665 is an effective therapy based upon two prior clinical trials, physician input, and AXA1665's strong scientific support. We will explore partnerships and potentially other indications for AXA1665."

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), and the reduction in risk of overt hepatic encephalopathy (OHE) recurrence. 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 recent federal memoranda. 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 belief that mitochondrial dysfunction is a key driver of Long Covid induced fatigue, 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 AXA1665 and 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 AXA1665 and AXA1125, the clinical development and safety profile of AXA1665 and AXA1125 and their 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.

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