Axcella Reports First Quarter Financial Results and Provides Business Update

May 4, 2023

- *Long COVID Phase 2b/3 clinical trial 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*
- *Lancet eClinical Medicine published findings from the Phase 2a clinical trial of AXA1125 in Long COVID Fatigue online on April 14, 2023*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 4, 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 first quarter ended March 31, 2023 and provided a business update.

“Patients are seeking a Long COVID therapy, as we have seen represented at the recent BIO / Solve ME and FDA Patient Driven Drug Development Program forums. Axcella’s receipt of clearance from the FDA and a path to registration from the MHRA, UK’s health authority, for a Phase 2b/3 clinical trial of AXA1125 in Long COVID fatigue is an important step to potentially addressing that need,” said Bill Hinshaw, President and Chief Executive Officer of Axcella. “April also saw two presentations of abstracts from the Phase 2a clinical study of AXA1125 in Long COVID Fatigue at ECCMID and publication of the results in Lancet *eClinical Medicine*, a top tier medical journal.”

The Company has continued its efforts to progress the program and achieve a strategic alternative 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. If a strategic process is unsuccessful, the Company may be unable to continue operations at planned levels and be forced to further reduce or terminate operations.

Recent Accomplishments and Developments

- The results of the Phase 2a clinical trial of AXA1125 in Long COVID Fatigue, including treatment effects on biomarkers of mitochondrial energetics and vascular endothelial function, were delivered in two oral presentations at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID), April 14-18, 2023.

- Lancet *eClinical Medicine*, a leading peer-reviewed medical journal, published findings from the Phase 2a clinical trial of AXA1125 in Long COVID Fatigue online on April 14, 2023. The article reported that treatment with AXA1125 was associated with significantly reduced day 28 Chalder Fatigue Questionnaire [CFQ-11] fatigue score when compared with placebo (least squares mean difference [LSMD] −4.30, 95% confidence interval (95% CI) −7.14, −1.47; P = 0.0039) even though changes in skeletal muscle phosphocreatine recovery time constant (τPCr; primary endpoint) and 6-min walk test (6MWT) did not significantly differ between treatment (n = 21) and placebo group (n = 20). It added that further multicenter studies are needed to validate these findings in a larger cohort of patients with fatigue-dominant Long COVID.

Financial Results

Cash Position: As of March 31, 2023, cash and cash equivalents totaled $12.5 million, compared to $17.1 million as of December 31, 2022.

R&D Expenses: Research and development expenses were $1.4 million and $13.5 million for the quarters ended March 31, 2023 and 2022, respectively. The decrease is the result of the Company’s decision to lay off 85% of its employees and terminate all research and development activity effective December 15, 2022.

G&A Expenses: General and administrative expenses were $2.8 million and $4.8 million for the quarters ended March 31, 2023 and 2022, respectively. The decrease is due to the reduction in force on December 15, 2022.

Other (expense) income: Other income was $0.2 million for the quarter ended March 31, 2023, which consisted of interest income on our cash balances and a gain on the sale of property and equipment. Other expense was $0.7 million in the quarter ended March 31, 2022, which consisted of interest expense on the loan and security agreement with SLR Investment Corp. We repaid the loan in full in December 2022.

Net Loss: Net loss for the quarter ended March 31, 2023 was $4.0 million, or $0.05 per basic and diluted share. This compares with a net loss of $19.0 million, or $0.46 per basic and diluted share, for the quarter ended March 31, 2022.

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)

	March 31, 2023	December 31, 2022
Assets:		
Cash and cash equivalents	$ 12,540	$ 17,147
Other assets	225	1,780
Total assets	$ 12,765	$ 18,927
Liabilities and stockholders' equity:		
Accounts payable	$ 8,150	$ 4,707
Accrued expenses and other current liabilities	2,103	7,849
Current portion of operating lease liability	1,641	1,592
Total current liabilities	11,894	14,148
Operating lease liability	144	569
Other non-current liabilities	—	46
Total liabilities	12,038	14,763
Stockholders' equity	727	4,164
Total liabilities and stockholders' equity	$ 12,765	$ 18,927

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

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 1,433	$ 13,544

General and administrative	2,750	4,786
Total operating expenses	4,183	18,330
Loss from operations	(4,183)	(18,330)
Other income (expense):		
Interest income (expense) and other income (expense), net	207	(709)
Total other income (expense), net	207	(709)
Net loss	$ (3,976)	$ (19,039)
Net loss per share, basic and diluted	$ (0.05)	$ (0.46)
Weighted average common shares outstanding, basic and diluted	73,669,096	41,426,107

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