Axcella Reports First Quarter Financial Results and Provides Business Update

May 5, 2022

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 5, 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 first quarter ended March 31, 2022 and provided a business update.

"Through these first months of 2022 we have continued to make significant progress advancing our EMM clinical programs and executing on our mission to make new multi-targeted therapies for complex diseases and conditions available to patients in need" said Bill Hinshaw, President and Chief Executive Officer of Axcella. "We are extremely pleased with the success of our recent $25M stock offering, which will provide financial resources allowing us to complete our Long COVID Phase 2a clinical trial, complete enrollment of our EMMPACT Phase 2b clinical trial in non-alcoholic steatohepatitis (NASH) and advance our EMMPOWER Phase 2 clinical trial in Overt Hepatic Encephalopathy (OHE). In addition, we are looking forward to further engaging with the growing network of physicians that is excited by our pipeline of therapeutic compositions. We believe that the Biden administration's recent memorandum on the federal research initiative regarding Long COVID points toward a growing recognition at the national level of the need for new and effective therapies for this very serious condition."

Financial Results

Cash Position: As of March 31, 2022, cash, cash equivalents, and marketable securities totaled $63.2 million, compared to $55.0 million as of December 31, 2021. As mentioned above, 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 2023.

R&D Expenses: Research and development expenses were $13.5 million and $10.2 million for the quarters ended March 31, 2022 and 2021, respectively. The increase is primarily the result of the Company's EMMPACT and Long COVID Phase 2 clinical trials.

G&A Expenses: General and administrative expenses were $4.8 million and $4.3 million for the quarters ended March 31, 2022 and 2021, respectively. The increase is due to higher consulting and professional fees.

Net Loss: Net loss for the quarter ended March 31, 2022 was $19.0 million, or $0.46 per basic and diluted share. This compares with a net loss of $15.2 million, or $0.40 per basic and diluted share, for the quarter ended March 31, 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 reset multiple biological pathways, improve cellular energetics, and restore homeostasis. Axcella's pipeline includes lead therapeutic candidates in Phase 2 development for the treatment of Long COVID, NASH, and the reduction in risk of 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 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.

Axcella Therapeutics
Unaudited Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2022	December 31, 2021
Assets:		
Cash and cash equivalents	$ 45,190	$ 23,574
Marketable securities	18,029	31,474
Operating lease right-of-use asset	3,017	–
Other assets	2,144	2,679
Total assets	$ 68,380	$ 57,727
Liabilities and stockholders' equity:		
Accounts payable	$ 4,839	$ 4,301
Accrued expenses and other current liabilities	4,920	5,849
Current portion of long-term debt	1,733	–
Operating lease liability	1,452	–
Total current liabilities	12,944	10,150
Long-term debt, net of current portion and discount	23,385	25,070
Operating lease liability, net of current portion	1,784	–
Other liabilities	375	499
Liabilities	38,488	35,719
Stockholders' equity	29,892	22,008
Total liabilities and stockholders' equity	$ 68,380	$ 57,727

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

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 13,544	$ 10,240
General and administrative	4,786	4,256
Total operating expenses	18,330	14,496
Loss from operations	(18,330)	(14,496)
Other income (expense):		
Interest income (expense) and other income (expense), net	(709)	(693)
Total other income (expense), net	(709)	(693)
Net loss	$ (19,039)	$ (15,189)
Net loss per share, basic and diluted	$ (0.46)	$ (0.40)
Weighted average common shares outstanding, basic and diluted	41,426,107	37,652,158

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Source: Axcella Therapeutics