August 5, 2021

Cabaletta Bio Reports Second Quarter 2021 Financial Results and Provides Business Update

– Company continues to make progress on the DesCAARTes™ trial for DSG3-CAART; expects to report second and third cohort safety data in 3Q21 and 4Q21, respectively, and data on target engagement 3 to 6 months after each completed cohort –

– Investigational New Drug (IND) application submission to U.S. Food and Drug Administration (FDA) for MuSK-CAART expected in 2H21 and pre-IND meeting request submitted to FDA for PLA2R-CAART –

PHILADELPHIA, Aug. 05, 2021 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies for patients with B cell-mediated autoimmune diseases, today reported financial results for the second quarter ended June 30, 2021, and provided a business update.

“During the quarter, we did not observe any clinically relevant adverse events in the first, low-dose patient cohort of the DesCAARTes™ clinical trial for DSG3-CAART, our lead clinical product candidate for the treatment of patients with mucosal-dominant pemphigus vulgaris. We remain well-positioned to achieve multiple near-term clinical milestones for this program, including our plan to report safety data from the higher dose second and third patient cohorts in the third and fourth quarters of 2021, respectively, as well as target engagement data 3 to 6 months after each cohort is completed,” said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. “Additionally, we remain on track to submit an IND to the FDA for MuSK-CAART, our lead preclinical product candidate, and we expect to conduct a pre-IND meeting with the FDA to discuss the development path for PLA2R-CAART in the second half of 2021.”

Autoimmune Disease-Focused Pipeline Highlights and Anticipated Upcoming Milestones

DSG3-CAART: Desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells as a potential treatment for patients with mucosal-dominant pemphigus vulgaris (mPV).

- In May 2021, Cabaletta announced acute safety data from three patients in the first cohort in the DesCAARTes™ trial. As of August 4, 2021, no dose limiting toxicities (DLTs) or clinically relevant adverse events, including cytokine release syndrome or neurotoxicity, were observed. These safety data were observed with an administered dose of 20 million DSG3-CAART cells, without preconditioning and in the presence of circulating anti-DSG3 antibodies. DSG3-CAART was detected at low levels via qPCR in all three patients during the 28-day DLT monitoring window.

- In August 2021, with FDA clearance, a protocol amendment was implemented in the DesCAARTes™ trial to allow a minimum dosing interval of 7 days between patients within a cohort, versus 14 days.

- Cabaletta remains on track to announce 28-day safety data for the second and third cohorts in the third and fourth quarters of 2021, respectively, in addition to target engagement data 3 to 6 months after dosing of each cohort is completed. Cabaletta will continue to provide additional safety and top-line target engagement data from the DesCAARTes™ trial, once available, on a cohort-by-cohort basis.

MuSK-CAART: Muscle Specific Kinase (MuSK) chimeric autoantibody receptor T (MuSK-CAART) cells as a potential treatment for patients with MuSK-associated myasthenia gravis.

- IND-enabling studies consistent with FDA guidance received during the pre-IND meeting are ongoing and the Company remains on track to submit an IND to the FDA in the second half of 2021. This IND submission will incorporate clinical trial design and data insights from the DesCAARTes™ trial, including starting dose and dose fractionation regimen.

PLA2R-CAART: Phospholipase A2 receptor (PLA2R) chimeric autoantibody receptor T (PLA2R-CAART) cells as a potential treatment for patients with PLA2R-associated membranous nephropathy.

- Cabaletta has submitted a request for a pre-IND meeting with the FDA. The Company expects to conduct the meeting during the second half of 2021 in order to gain clarity on the future development path and determine its potential IND submission timing for the program.

Corporate Highlights

- In June 2021, Scott Brun, M.D. joined the Company's Board of Directors and became a member of the Audit Committee and the Nominating and Corporate Governance Committee. Dr. Brun is currently President at Gold Mast Consulting, LLC, an advisory firm he founded, and has over 20 years of wide-ranging drug and business development experience, including his time as Head of Abbvie Ventures and Vice President of Scientific Affairs at Abbvie. Dr. Brun succeeded Brian Daniels, M.D., who stepped down from the Board of Directors and is now a member of the Scientific Advisory Board.

Upcoming Events in the Third Quarter of 2021

- Cabaletta will participate in a fireside chat at the Morgan Stanley 19th Annual Global Healthcare Conference in September 2021.

- Cabaletta will present a company presentation at the H.C. Wainwright 23rd Annual Global Investment Conference in September 2021.

Second Quarter 2021 Financial Results

The Company expects that its cash, cash equivalents and investments as of June 30, 2021,

will enable it to fund its operating plan through at least the fourth quarter of 2022.

- Research and development expenses for the three months ended June 30, 2021, were $7.9 million, compared to $5.3 million for the same period in 2020.

- General and administrative expenses for the three months ended June 30, 2021, were $3.3 million, compared to $2.9 million for the same period in 2020.

- As of June 30, 2021, cash, cash equivalents and investments totaled $102.8 million, compared to $108.7 million as of December 31, 2020. During the quarter, the company received net proceeds of approximately $7.7 million pursuant to its at-the-market (ATM) stock offering program.

About Cabaletta Bio
Cabaletta Bio is a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies, and exploring their potential to provide a deep and durable, perhaps curative, treatment for patients with B cell-mediated autoimmune diseases. The Cabaletta Approach to selective B cell Ablation (CABA™) platform, in combination with Cabaletta's proprietary technology, utilizes Chimeric AutoAntibody Receptor (CAAR) T cells that are designed to selectively bind and eliminate only specific autoantibody-producing B cells while sparing normal antibody-producing B cells, which are essential for human health. The Company's lead product candidate, DSG3-CAART, is being evaluated in the DesCAARTes™ Phase 1 clinical trial as a potential treatment for patients with mucosal pemphigus vulgaris, a prototypical B cell-mediated autoimmune disease. The FDA granted Fast Track Designation for DSG3-CAART in May 2020. For more information about the DesCAARTes™ Phase 1 clinical trial, please see www.clinicaltrials.gov. The Company's lead preclinical product candidate, MuSK-CAART, is in IND-enabling studies and is designed as a potential treatment for patients with MuSK-associated myasthenia gravis. For more information, visit www.cabalettabio.com.

Forward-Looking Statements
This press release contains "forward-looking statements" of Cabaletta within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including without limitation, express or implied statements regarding expectations regarding: the progress and results of its DesCAARTes™ Phase 1 trial, including Cabaletta's ability to enroll the requisite number of patients, progress of the trial, results and expected timing to report additional data for the second and third cohorts in the third and fourth quarters of 2021, respectively, in addition to target engagement data 3 to 6 months after dosing of each cohort is completed; the expectation that Cabaletta may improve outcomes for patients suffering from mPV; the effectiveness and timing of product candidates that Cabaletta may develop, including in collaboration with academic partners; the safety, efficacy and tolerability of DSG3-CAART for the treatment of mPV; the progress of its MuSK-CAART program, including the completion and expected results of its ongoing IND-enabling studies and plans to submit an IND application or equivalent regulatory filing for MuSK-CAART in the second half of 2021; Cabaletta's plans to conduct a pre-IND meeting with the FDA for PLA2R-CAART in the second half of 2021; presentation of additional data at upcoming scientific conferences, and other preclinical data; expectations regarding the design, implementation, timing and success of its current and planned clinical trials and the successful completion of nonclinical studies; planned potential timing and advancement of its preclinical studies and clinical trials

and related regulatory submissions; ability to replicate results achieved in preclinical studies or clinical trials in any future studies or trials; ability to continue its growth and realize the anticipated contribution of the members of its board of directors and executives to its operations and progress; expectations of the potential impact of COVID-19 on strategy, future operations, and the timing of its clinical trials, including the potential impacts on enrollment and initiation of its DesCAARTes™ Phase 1 trial; statements regarding regulatory filings regarding its development programs; use of capital, expenses, future accumulated deficit and other financial results in the future; and ability to fund operations through the fourth quarter of 2022.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks related to the impact of COVID-19 affecting countries or regions in which we have operations or do business, including potential negative impacts on our employees, customers, supply chain and production as well as global economies and financial markets; risks related to Cabaletta's ability to protect and maintain its intellectual property position; Cabaletta's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its clinical trials of DSG3-CAART; risks related to clinical trial site activation or enrollment rates that are lower than expected; risks related to unexpected safety or efficacy data observed during clinical studies; risks related to Cabaletta's ability to protect and maintain its intellectual property position; uncertainties related to the initiation and conduct of studies and other development requirements for its product candidates; and the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Cabaletta's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Cabaletta's most recent annual report on Form 10-K as well as discussions of potential risks, uncertainties, and other important factors in Cabaletta's other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Cabaletta undertakes no duty to update this information unless required by law.

CABALETTA BIO, INC.
SELECTED FINANCIAL DATA
(unaudited; in thousands, except share and per share data)

Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2021**	**2021**	**2020**
	unaudited		**unaudited**	
Operating expenses:				

Research and development	$ 7,850	$ 5,331	$ 14,406	$ 9,951
General and administrative	3,295	2,861	6,451	6,136
Total operating expenses	11,145	8,192	20,857	16,087
Loss from operations	(11,145)	(8,192)	(20,857)	(16,087)
Other income:				
Interest income	6	40	16	450
Net loss	(11,139)	(8,152)	(20,841)	(15,637)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.45)	$ (0.35)	$ (0.86)	$ (0.68)

Selected Balance Sheet Data

	June 30, 2021	December 31, 2020
	(unaudited)	
Cash, cash equivalents and investments	$ 102,808	$ 108,662
Total assets	106,930	114,724
Total liabilities	5,601	5,180
Total stockholders' equity	101,329	109,544

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