November 1, 2021

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

– Dose dependent increase in DSG3-CAART persistence observed in the third dose cohort with 500 million DSG3-CAART cells relative to the first two low dose cohorts in DesCAARTes™ Phase 1 clinical trial throughout the 28 days following infusion –

– No dose limiting toxicities (DLTs) or clinically relevant adverse events observed as of October 31, 2021, in the first three dose cohorts –

– Dosing initiated in fourth patient cohort at a dose of 2.5 billion DSG3-CAART cells DesCAARTes™ trial advancing toward key milestones; top-line biologic activity data from first two low dose cohorts expected to be announced in 4Q21 –

– Lead preclinical program, MuSK-CAART, Investigational New Drug (IND) submission on track for 4Q21; PLA2R-CAART preclinical data to be presented at the American Society of Nephrology's Kidney Week that show potential as a precision therapy for patients with PLA2R membranous nephropathy –

– Ended the quarter with $119.3M in cash, extending the cash runway to fund operations through at least 1Q23 –

PHILADELPHIA, Nov. 01, 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 third quarter ended September 30, 2021, and provided a business update.

"The DesCAARTes™ trial for DSG3-CAART for patients with mucosal-dominant pemphigus vulgaris has demonstrated encouraging momentum, with continued strong patient enrollment as well as new site and investigator engagement. Dose dependent increases in DSG3-CAART persistence in the third cohort through 28 days following infusion have been observed, as well as the continued absence of any DLTs or clinically relevant adverse events for the first three cohorts as of October 31, 2021. Our next anticipated data readout will include top-line biologic activity data from the first two low dose cohorts, which we expect to announce in the fourth quarter of 2021. We look forward to continuing to generate data on potential biologic activity as we proceed to higher dosing cohorts, with the goal of providing a targeted, highly effective, and potentially curative, therapy without generalized immunosuppression," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "We are operating under a strengthened balance sheet as a result of $32 million in additional gross proceeds through our "at-the-market" (ATM) equity offering program. In addition to advancing the DesCAARTes™ trial, we are also focused on growing our novel pipeline. To that end, we expect to progress our two lead preclinical programs in

the balance of the year with the submission of an IND to the FDA for MuSK-CAART being developed for patients with the MuSK form of myasthenia gravis, and a pre-IND interaction with the FDA to align on a development path for PLA2R-CAART being developed for patients with PLA2R-associated membranous nephropathy."

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 pemphigus vulgaris (mPV).

- Observance of dose dependent DSG3-CAART persistence and favorable safety profile through cohort three of the DesCAARTes™ Phase 1 trial: The Company announced today that three patient cohorts in the DesCAARTes™ Phase 1 trial have completed DSG3-CAART dosing as of October 31, 2021. The Company observed a dose dependent increase in persistence of DSG3-CAART in the third 500 million cell cohort relative to the first two low dose cohorts throughout the 28 days following infusion. In addition, no clinically relevant adverse events or DLTs were observed during the 28-day monitoring period post-infusion. These safety data were observed without preconditioning, and in the presence of circulating anti-DSG3 antibodies. This safety profile builds off 28-day safety data from three patients in the second cohort that the Company reported in August 2021.

- New site activations driving patient enrollment: As of October 31, 2021, three additional clinical sites were opened for recruitment, doubling the total number of activated DesCAARTes™ trial sites to six.

- Trial advancing through fourth patient cohort: Dosing was initiated in the fourth patient cohort at a dose of 2.5 billion DSG3-CAART cells. The Company anticipates announcing 28-day safety data for the fourth dose cohort in the first quarter of 2022.

- Near-term biologic activity data expected for the first two low dose cohorts: Cabaletta plans to announce top-line biologic activity data from the first two low dose cohorts in the fourth quarter of 2021.

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 studies ongoing and Phase 1 trial planned for 2022: IND-enabling studies consistent with U.S. Food and Drug Administration (FDA) guidance received during the pre-IND meeting are ongoing. The Company remains on track to submit an IND to the FDA in the fourth quarter of 2021. This IND submission will incorporate clinical trial design and data insights from the DesCAARTes™ trial, including starting dose and dose fractionation regimen.

- GMP manufacturing secured with WuXi: The Company has implemented its manufacturing process with WuXi Advanced Therapies, Inc., its GMP manufacturing partner for the planned MuSK-CAART clinical study.

PLA2R-CAART: Phospholipase A2 receptor (PLA2R) chimeric autoantibody receptor T

(PLA2R-CAART) cells as a potential treatment for patients with PLA2R-associated membranous nephropathy.

- Early preclinical validation of PLA2R-Chimeric AutoAntibody Receptor T cell candidates will be presented at ASN Kidney Week 2021: Preclinical data demonstrated that Chimeric Auto Antibody Receptor (CAAR) T cells specifically recognized and eliminated anti-PLA2R antibody-expressing B cells and membrane proteome arrays screened with PLA2R CAAR candidates did not identify off-target interactions. These data will be presented as an oral abstract by University of Pennsylvania professor Aimee Payne, M.D., Ph.D., Cabaletta Bio co-founder and Scientific Advisory Board co-chair, at the American Society of Nephrology (ASN) Kidney Week 2021.

- PLA2R-CAART advancing toward clinical development: Cabaletta expects to conduct a pre-IND interaction with the FDA in the fourth quarter of 2021. The Company expects to discuss the future development path and determine its potential IND submission timing for the program.

Corporate Highlights

- Expanded executive leadership team with key appointment to support future growth: In September 2021, Michael Gerard was appointed general counsel. Mr. Gerard joined Cabaletta with a wide range of experience in strategic legal and corporate matters within the life sciences industry. Most recently, Mr. Gerard served as associate general counsel at Spark Therapeutics, Inc., where he supported the global gene therapy Manufacturing, Business Development, Technical Development, Supply Chain, Quality, Alliance Management, Real Estate, IT and Facilities teams.

Upcoming Events in the Fourth Quarter of 2021

- Cabaletta will participate in a fireside chat at the Guggenheim Securities 3rd Annual Neuro/Immunology Conference in November 2021.

- Cabaletta will participate in a fireside chat at the 4th Annual Evercore ISI HealthCONx Conference in November 2021.

Third Quarter 2021 Financial Results

The Company expects that its cash, cash equivalents and investments as of September 30, 2021, will enable it to fund its operating plan through at least the first quarter of 2023.

- Research and development expenses for the three months ended September 30, 2021, were $8.2 million, compared to $5.7 million for the same period in 2020.

- General and administrative expenses for the three months ended September 30, 2021, were $3.4 million, compared to $2.8 million for the same period in 2020.

- As of September 30, 2021, Cabaletta had cash, cash equivalents and investments of $119.3 million, compared to $108.7 million as of December 31, 2020. This increase primarily reflects net proceeds of $34.7 million from sales of common stock under Cabaletta’s ATM offering program in the nine months ended September 30, 2021,

partially offset by cash used in operations. In October 2021, the Company sold an additional 600,000 shares of its common stock through its ATM program, generating additional net proceeds of approximately $6.3 million.

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 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 visit our website (DesCAARTes™ Phase 1 Trial). 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.

University of Pennsylvania Financial Disclosure

Dr. Payne is a University of Pennsylvania (Penn) faculty member, scientific collaborator, key advisor, and co-founder of Cabaletta Bio. As such, she holds an equity stake in the Company, her laboratory at Penn receives sponsored research funding from Cabaletta Bio, and as an inventor of the licensed technology she may receive additional future financial benefits under licenses granted by Penn to Cabaletta Bio. The University of Pennsylvania may also receive future financial benefit under licenses it has granted to Cabaletta Bio.

Forward-Looking Statements

This press release contains "forward-looking statements" of Cabaletta Bio 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, dose each dosing cohort in the intended manner, and progress the trial; the expected timing and significance around the announcement of 28-day safety for the fourth dose cohort in the first quarter of 2022 and top-line biologic activity data for the first two low dose cohorts in the fourth quarter of 2021; the expectation that Cabaletta may improve outcomes for patients suffering from 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 fourth quarter of 2021; Cabaletta's plans to conduct a pre-IND interaction with the FDA for PLA2R-CAART in the fourth quarter of 2021; the effectiveness and timing of product candidates that Cabaletta may develop, including in collaboration with academic partners; 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 continue its growth and realize the anticipated contribution

of the members of its board of directors and executives to its operations and progress; the impact of COVID-19 on the timing, progress, interpretability of data, and results of ongoing or planned preclinical and clinical trials; 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 at least the first quarter of 2023.

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: the risk that signs of biologic activity may not inform long-term results; Cabaletta's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical and 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 the impact of public health epidemics, such as the COVID-19 pandemic, affecting countries or regions in which we have operations or do business; Cabaletta's ability to retain and recognize the intended incentives conferred by Fast Track Designation for DSG3-CAART for improving healing of mucosal blisters in patients with mucosal pemphigus vulgaris, respectively; 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 initial or interim 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 September 30,		Nine Months Ended September 30,	
	2021	**2021**	**2021**	**2020**
	unaudited		**unaudited**	
Operating expenses:				
Research and development	$ 8,169	$ 5,650	$ 22,575	$ 15,601

General and administrative	3,394	2,766	9,845	8,902
Total operating expenses	11,563	8,416	32,420	24,503
Loss from operations	(11,563)	(8,416)	(32,420)	(24,503)
Other income:				
Interest income	3	23	19	473
Net loss	(11,560)	(8,393)	(32,401)	(24,030)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.45)	$ (0.36)	$ (1.31)	$ (1.09)

Selected Balance Sheet Data

	September 30, 2021	December 31, 2020
	(unaudited)	
Cash, cash equivalents and investments	$ 119,260	$ 108,662
Total assets	122,638	114,724
Total liabilities	6,023	5,180
Total stockholders' equity	116,615	109,544

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