March 17, 2022

Cabaletta Bio Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

– DesCAARTes™ trial progressing in cohort A5 with presentation of DSG3-CAART clinical and translational data from cohorts A3 and A4 and 28-day safety data for cohort A5 expected at upcoming scientific meetings in mid-2022 –

– MuSK-CAART Investigational New Drug (IND) application cleared and Fast Track Designation granted by the U.S. Food and Drug Administration (FDA); planning to initiate first-in-human trial in 2022 –

– Ended 2021 with $122.2 million in cash on hand to fund operations through 3Q 2023 –

PHILADELPHIA, March 17, 2022 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on the discovery and development of targeted cell therapies for patients with autoimmune diseases, today reported financial results for the fourth quarter and full year ended December 31, 2021, and provided a business update.

“We are encouraged by early data from the DesCAARTes™ trial in patients with mucosal pemphigus vulgaris, including the dose-dependent increase in persistence seen in cohort A3 relative to the two low dose cohorts throughout the 28 days following DSG3-CAART infusion and the absence of dose limiting toxicities observed through cohort A4 as well as continued investigator engagement and patient interest. We look forward to reporting DSG3-CAART clinical and translational data from the middle dose cohorts A3 and A4 along with 28-day safety data from cohort A5 at scientific meetings in mid-2022,” said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. “Learnings from the DesCAARTes™ trial have provided platform-based insights for our growing autoimmune-focused pipeline, including the MusCAARTes™ trial for patients with MuSK-associated myasthenia gravis. MuSK-CAART was recently granted Fast Track Designation by the FDA to improve activities of daily living and muscle strength in patients with MuSK-associated myasthenia gravis, and with our now-cleared IND application, we plan to initiate the MusCAARTes™ trial in 2022 as we continue to advance our mission of delivering deep, durable, and potentially curative, responses for patients with autoimmune diseases.”

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).

- **Observed a dose-dependent increase in DSG3-CAART persistence in cohort A3 relative to cohorts A1 and A2 throughout the 28 days following infusion:** In November 2021, Cabaletta reported 28-day clinical data from cohort A3 (500 million DSG3-CAART cells) in the DesCAARTes™ trial. A dose-dependent increase was

observed in DSG3-CAART persistence in the third cohort relative to the first two low dose cohorts throughout the 28 days following infusion.

- **Reported top-line biologic activity data from the two lowest dose cohorts in the DesCAARTes™ trial:** In December 2021, Cabaletta reported three to six month data on biologic activity from the two lowest dose cohorts (A1 and A2), representing less than 2% of the dose being evaluated in cohort A5, as well as the continued absence of dose limiting toxicities (DLTs) and clinically relevant adverse events. No clear signs of biologic activity were observed in the two lowest cell dose cohorts (20 million and 100 million DSG3-CAART cells).

- **Progressing in cohort A5 of DesCAARTes™ trial:** No DLTs were observed in any patient in cohort A4 (2.5 billion DSG3-CAART cells) in the 28 days following infusion, allowing progression to cohort A5, which is evaluating a dose range of 5.0 to 7.5 billion DSG3-CAART cells administered in two fractionated infusions.

- **Data evaluating biologic activity in cohorts A3 and A4 as well as 28-day safety data from cohort A5 expected to be presented at upcoming scientific meetings in mid-2022:** Cabaletta expects reporting clinical and translational data from cohorts A3 and A4 (500 million and 2.5 billion DSG3-CAART cells) as well as 28-day safety data for cohort A5 (5.0 to 7.5 billion DSG3-CAART cells) in the DesCAARTes™ trial at upcoming scientific meetings in mid-2022. In addition, Cabaletta plans to share additional clinical data updates from the DesCAARTes™ trial at scientific meetings throughout 2022 and 2023.

- **Received FDA clearance to proceed with manufacturing enhancement at a dose of up to 5.0 to 7.5 billion DSG3-CAART cells**. The FDA-cleared manufacturing enhancement aims to amplify desired T cell subtypes in the product in order to potentially improve product potency and trafficking to tissue where the target B cells reside. Additional details about data supporting this enhancement are expected to be presented in a scientific meeting in mid-2022.

- **Signed new multi-year clinical supply agreement with Oxford Biomedica for DSG3-CAART:** Cabaletta and Oxford Biomedica (UK) Limited, a leading gene and cell therapy group and established commercial supplier of lentiviral vector, entered into a Licence and Supply Agreement granting Cabaletta a non-exclusive license to Oxford Biomedica's LentiVector® platform for its application in Cabaletta's DSG3-CAART program.

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

- **First-in-human trial planned to commence in 2022:** The FDA cleared the Company's IND application for MuSK-CAART within the routine 30-day review period. Cabaletta plans to initiate the MusCAARTes™ trial in 2022, and will evaluate MuSK-CAART as a potential treatment for patients with MuSK-associated myasthenia gravis. The trial will be an open-label study consisting of two parts: (i) a dose escalation phase to determine the maximum tolerated dose with two patients planned per cohort for three cohorts and six patients at the highest selected dose and (ii) a cohort expansion

phase at the final selected dose. The planned trial incorporates design insights and enhancements supported by data from the DesCAARTes™ trial, including a higher starting dose (100 million MuSK-CAART cells versus 20 million DSG3-CAART cells), a single infusion administration (versus 2-4 infusion fractions of the full dose in the DesCAARTes™ trial), and a 2+4 design strategy for the first three dose cohorts. The trial is expected to enroll approximately 24 patients across multiple clinical sites throughout the United States. Cabaletta has established its manufacturing process with WuXi Advanced Therapies, Inc., which will serve as its Good Manufacturing Practices manufacturing partner for the MusCAARTes™ trial.

- **MuSK-CAART granted Fast Track Designation by FDA:** In February 2022, the FDA granted Fast Track Designation to MuSK-CAART to improve activities of daily living and muscle strength in patients with MuSK antibody-positive myasthenia gravis. This designation may facilitate the potential for expedited development and review of MuSK-CAART by conferring potential benefits to the program, including the opportunity for more frequent meetings and interactions with the FDA during the clinical development period as well as eligibility for accelerated approval and/or priority review, if relevant criteria are met.

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

- **Presented early preclinical validation of PLA2R-CAART cell candidates at the American Society of Nephrology Kidney Week 2021:** In October 2021, Aimee Payne, M.D., Ph.D., Co-Founder and Scientific Advisory Board co-chair of Cabaletta, presented preclinical data demonstrating that chimeric autoantibody receptor (CAAR) T cells specifically recognized and eliminated PLA2R antibody-expressing B cells and that membrane proteome arrays screened with PLA2R CAAR candidates did not identify off-target interactions.

- **Completed pre-IND interaction with the FDA to advance PLA2R-CAART toward clinical development:** In the fourth quarter of 2021, Cabaletta completed a routine pre-IND interaction with the FDA as part of Cabaletta's PLA2R-CAART program.

Corporate Highlights

- **Strengthened executive leadership team to support long-term corporate and clinical priorities:** In January 2022, Gwendolyn Binder, Ph.D. was promoted to President, Science and Technology and Arun Das, M.D. was promoted to Chief Business Officer.

Upcoming Events

- Cabaletta will participate in the virtual Needham & Co. Healthcare Conference in April 2022.

- Cabaletta will present a poster on preclinical safety and activity studies to support precision engineered T-cell therapy for MuSK Myasthenia Gravis at the 14th International Conference Myasthenia Gravis and Related Disorders being held in

Miami, FL from May 10-12, 2022.

Fourth Quarter and Full Year 2021 Financial Results

- Research and development expenses were $9.9 million and $32.5 million for the three months ended December 31, 2021 and the full year ended December 31, 2021, respectively, compared to $5.8 million and $21.4 million for the three months ended December 31, 2020 and the full year ended December 31, 2020, respectively.

- General and administrative expenses were $4.0 million and $13.8 million for the three months ended December 31, 2021 and the full year ended December 31, 2021, respectively, compared to $3.6 million and $12.5 million for the three months ended December 31, 2020 and the full year ended December 31, 2020, respectively.

- As of December 31, 2021, Cabaletta had cash and cash equivalents and investments of $122.2 million, compared to $108.7 million as of December 31, 2020. This increase primarily reflects net proceeds of $48.3 million from sales of common stock under Cabaletta's at-the-market offering program in the year ended December 31, 2021, partially offset by cash used in operations.

The Company expects that its cash and cash equivalents as of December 31, 2021, will enable it to fund its operating plan through the third quarter of 2023.

About Cabaletta Bio
Cabaletta Bio (Nasdaq: CABA) is a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies that have the potential to provide a deep and durable, perhaps curative, treatment for patients with autoimmune diseases. The CABA™ platform, in combination with Cabaletta Bio's proprietary technology, has advanced a growing pipeline that currently includes potential treatments for patients with mucosal pemphigus vulgaris, MuSK-associated myasthenia gravis, PLA2R-associated membranous nephropathy, mucocutaneous pemphigus vulgaris and hemophilia A with FVIII alloantibodies. Cabaletta Bio's headquarters are located in Philadelphia, PA. For more information, visit www.cabalettabio.com and follow us on LinkedIn.

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: Cabaletta's ability to grow its autoimmune-focused pipeline; 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 cohort A5 and biologic activity data for cohorts A3 and A4 in mid-2022; the expected timing and significance around additional clinical data updates from the DesCAARTes™ trial at scientific meetings throughout 2022 and 2023; the expectation that Cabaletta may improve outcomes for patients suffering from mPV; the ability of Oxford Biomedica to supply Cabaletta with a sufficient quantity and/or quality of lentiviral vector; expectations regarding the intended incentives conferred by Fast Track Designation for MuSK-CAART to improve activities of daily living and muscle strength in patients with MuSK antibody-positive myasthenia gravis; the expectation that Cabaletta Bio may improve outcomes for patients

suffering from MuSK MG; plans to initiate patient dosing in an open-label Phase 1 clinical trial to evaluate MuSK-CAART safety and tolerability in MuSK MG patients in 2022; Cabaletta's ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and progress the MusCAARTes™ trial; the ability of MuSK-CAART to target B cells that differentiate into antibody secreting cells, which produce autoantibodies against muscle-specific kinase; the ability of WuXi Advanced Therapies to supply sufficient quality and quantity of MuSK-CAART for the planned MusCAARTes™ trial; Cabaletta's plans to advance development of its preclinical pipeline; 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; ability to optimize the impact of its collaborations on its development programs; the impact of COVID-19 on the timing, progress, interpretability of data, and results of ongoing or planned preclinical and clinical trials; statements regarding the timing of 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 third 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 ongoing 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 Orphan Drug Designation and Fast Track Designation for DSG3-CAART for improving healing of mucosal blisters in patients with mucosal pemphigus vulgaris; Cabaletta's ability to retain and recognize the intended incentives conferred by Fast Track Designation for MuSK-CAART to improve activities of daily living and muscle strength in patients with MuSK antibody-positive myasthenia gravis; Cabaletta's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical and clinical trials of DSG3-CAART and MuSK-CAART; risks related to fostering and maintaining successful relationships with Cabaletta's manufacturing partners; 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; the risk that any one or more of Cabaletta's product candidates will not be successfully developed and commercialized; 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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
	Unaudited			
Operating expenses:				
Research and development	9,919	5,775	32,494	21,376
General and administrative	3,974	3,555	13,819	12,457
Total operating expenses	13,893	9,330	46,313	33,833
Loss from operations	(13,893)	(9,330)	(46,313)	(33,833)
Other income				
Interest income	5	21	24	494
Net loss	(13,888)	(9,309)	(46,289)	(33,339)
Net loss per voting and non-voting share, basic and diluted	$ (0.49)	$ (0.40)	$ (1.80)	$ (1.44)

Selected Balance Sheet Data

	December 31,	
	2021	2020
	Unaudited	
Cash, cash equivalents and investments	$ 122,222	$ 108,662
Total assets	126,336	114,724
Total liabilities	8,380	5,180
Total stockholders' equity	117,956	109,544

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