November 9, 2023

Cabaletta Bio Reports Third Quarter 2023 Financial Results and Provides Business Update

– Initial clinical data from CABA-201 treated patients in Phase 1/2 trials for lupus and/or myositis expected in the first half of 2024, with the first lupus clinical site actively recruiting patients –

– Expanded CABA-201 clinical development program within rheumatology and into neurology with additional IND clearances in systemic sclerosis and generalized myasthenia gravis –

– CABA-201 now being evaluated in four concurrent Phase 1/2 studies, each with an initial dose of 1 x 10^6 cells/kg and a parallel cohort design to accelerate development –

– Cash, cash equivalents and short-term investments expected to support operations into the fourth quarter of 2025 –

PHILADELPHIA, Nov. 09, 2023 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies for patients with autoimmune diseases, today reported financial results for the third quarter ended September 30, 2023, and provided a business update.

“Inspired by the recent flow of academic clinical publications and industry sponsored case reports of multiple other CD19-CAR T candidates suggesting that a single dose of CD19-CAR T can provide deep and durable responses in patients across an increasing number of autoimmune diseases, our team has continued to expand the breadth of our program in the U.S. with what we believe are the first U.S. IND clearances for a CD19-CAR T product candidate in myositis, systemic sclerosis and generalized myasthenia gravis. With the opening of our initial U.S. clinical site in lupus and now four Phase 1/2 studies incorporating a total of nine cohorts that could enroll in parallel, we believe we are in a position to realize our vision of developing and launching the first curative targeted cellular therapies for patients with autoimmune diseases,” said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. “We look forward to reporting initial clinical data on patients treated with CABA-201 in the first half of next year.”

Recent Operational Highlights and Upcoming Anticipated Milestones

Chimeric Antigen Receptor T cells for Autoimmunity (CARTA) Strategy

CABA-201: Autologous, engineered T cells with a chimeric antigen receptor containing a fully human CD19 binder and a 4-1BB co-stimulatory domain as a potential treatment for a broad range of autoimmune diseases where B cells contribute to the initiation and/or maintenance of disease.

- **Initial clinical data from Phase 1/2 trials in lupus and/or myositis expected by the first half of 2024:** Cabaletta anticipates reporting initial clinical efficacy and tolerability data for patients treated with CABA-201 from the Phase 1/2 trials in lupus and/or myositis in the first half of 2024. The Phase 1/2 trial of CABA-201 in systemic lupus erythematosus (SLE) will consist of two separate parallel cohorts, including six SLE patients with active lupus nephritis (LN) and six patients with active SLE without renal involvement. The Phase 1/2 trial of CABA-201 in myositis will consist of three separate parallel cohorts, including six patients with dermatomyositis (DM), six patients with anti-synthetase syndrome (ASyS) and six patients with immune-mediated necrotizing myopathy (IMNM). The CABA-201 starting dose of 1 x 10^6 cells/kg is equivalent to the CD19-CAR T dose used in the academic studies in SLE and myositis.

- **Clinical development program expanded to include SSc and gMG:** In October 2023, Cabaletta announced the Company's third Investigational New Drug (IND) application for CABA-201 was cleared by the U.S. Food and Drug Administration (FDA) for a Phase 1/2 study in patients with systemic sclerosis (SSc). In November 2023, Cabaletta announced the Company's fourth IND application for CABA-201 was cleared by the FDA for a Phase 1/2 study in patients with generalized myasthenia gravis (gMG). We believe that these IND clearances represent the first in each of these diseases for a CD19-CAR T product candidate in the U.S. Consistent with the previously announced CABA-201 IND application clearances for lupus and myositis, the separate Phase 1/2 studies in patients with SSc and gMG will feature a starting dose of 1 x 10^6 cells/kg and parallel cohort design.

- **WuXi ATU selected as a GMP manufacturing partner and Oxford Biomedica as a lentiviral vector supplier for CABA-201 clinical trials:** In August 2023, Cabaletta announced the Company entered into additional work orders under the master services agreement with WuXi Advanced Therapies (WuXi ATU), a global Contract Testing, Development and Manufacturing Organization (CTDMO), to include Good Manufacturing Practice (GMP) manufacturing for CABA-201. Through the work orders, WuXi ATU will serve as a cell processing manufacturing partner, in addition to the University of Pennsylvania, for the planned global clinical development of CABA-201 in multiple indications, including potential late-stage clinical trials and commercial readiness activities for CABA-201. In August 2023, Cabaletta also entered into an amendment to its licensing and supply agreement and vector supply agreement with Oxford Biomedica (UK) Limited (Oxford), a leading gene and cell therapy group and established commercial supplier of lentiviral vector. The vector supply agreement granted Cabaletta a non-exclusive license to Oxford Biomedica's LentiVector® platform for its application in CABA-201. Cabaletta continues to explore multiple paths to scale cell processing and vector manufacturing production in a rapid and reliable manner for CABA-201.

- **Translational data published by Cabaletta scientists in collaboration with Dr. Georg Schett to be presented at ACR Convergence 2023:** In September 2023, Cabaletta scientists published "Cytokine and reactivity profiles in SLE patients following anti-CD19 CART therapy" in *Molecular Therapy: Methods and Clinical Development*, highlighting studies performed on serum samples from the first six SLE patients treated with CD19-CAR T by Dr. Georg Schett. The publication reports that in the three months following CD19-CAR T infusion, cytokine markers of systemic

inflammation resolved, SLE-associated antibodies were reduced, and pre-existing humoral immunity was maintained. Data that characterize the serologic factors associated with CD19-CAR T treatment in autoimmune patients will also be presented in a poster presentation at the upcoming American College of Rheumatology (ACR) Convergence 2023.

Chimeric AutoAntibody Receptor T (CAART) cells Strategy

- **DSG3-CAART:** Cabaletta is evaluating desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells as a potential treatment for patients with mucosal pemphigus vulgaris (mPV). Enrollment in the combination cohort of the DesCAARTes™ trial is ongoing, where patients are pre-treated with intravenous immunoglobulin (IVIg), cyclophosphamide and fludarabine prior to DSG3-CAART infusion, with the aim of improving persistence and activation of DSG3-CAART.

- **MuSK-CAART:** Cabaletta is evaluating muscle-specific kinase (MuSK) chimeric autoantibody receptor T (MuSK-CAART) cells as a potential treatment for patients with MuSK-associated myasthenia gravis (MG). Enrollment in the Phase 1, open-label MusCAARTes™ study of MuSK-CAART in patients with MuSK autoantibody-positive MG is ongoing.

Upcoming Events

Cabaletta plans to participate in the following upcoming scientific conference:

- ACR Convergence 2023, which is being held at the San Diego Convention Center in San Diego, CA from November 10-15, 2023. Cabaletta will present new preclinical data for CABA-201 in a poster presentation and Cabaletta Bio Scientific Advisory Board members Carl June, M.D., and Georg Schett, M.D. will be featured at an Innovation Theater fireside chat presentation titled “Pioneering CAR T Cell Therapy in Autoimmune Diseases” on Tuesday, November 14, 2023, at 12:30 p.m. PT.

Cabaletta plans to participate in the following upcoming investor conferences:

- Stifel 2023 Healthcare Conference, which is being held from November 14-15, 2023 in New York, NY.

- 6th Annual Evercore ISI HealthCONx Conference, which is being held from November 28-30, 2023 in Miami, FL.

Third Quarter 2023 Financial Results

- Research and development expenses were $13.8 million for the three months ended September 30, 2023, compared to $8.2 million for the same period in 2022.

- General and administrative expenses were $4.9 million for the three months ended September 30, 2023, compared to $3.6 million for the same period in 2022.

- As of September 30, 2023, Cabaletta had cash, cash equivalents and short-term investments of $164.4 million, compared to $106.5 million as of December 31, 2022.

The Company expects that its cash, cash equivalents and short-term investments as of September 30, 2023, will enable it to fund its operating plan into the fourth quarter of 2025.

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 encompasses two strategies: the CARTA (chimeric antigen receptor T cells for autoimmunity) strategy, with CABA-201, a 4-1BB-containing fully human CD19-CAR T, as the lead product candidate being evaluated in systemic lupus erythematosus, myositis, systemic sclerosis and generalized myasthenia gravis, and the CAART (chimeric autoantibody receptor T cells) strategy, with multiple clinical-stage candidates, including DSG3-CAART for mucosal pemphigus vulgaris and MuSK-CAART for MuSK myasthenia gravis. The expanding CABA™ platform is designed to develop potentially curative therapies that offer deep and durable responses for patients with a broad range of autoimmune diseases. Cabaletta Bio's headquarters and labs are located in Philadelphia, PA.

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 its expectations regarding: timing for the Company's initial clinical data from patients treated with CABA-201 in Phase 1/2 trials for lupus and/or myositis in the first half of 2024; Cabaletta's ability to grow its autoimmune-focused pipeline; its ability to capitalize on and potential benefits resulting from published third-party academic clinical data; the Company's belief in the potential for CABA-201 to provide a deep and durable responses in patients across an increasing number of autoimmune diseases; Cabaletta Bio's belief that it is making meaningful progress toward the development and launch of the first curative targeted cellular therapies for patients with autoimmune diseases; the Company's plans to initiate and progress separate Phase 1/2 clinical trials of CABA-201 in patients with SLE, myositis, SSc and gMG, including its clinical trial design, expectations for site activation and enrollment and ability to leverage its experience in autoimmune cell therapy and autoimmune disease product development for each clinical trial; the Company's business plans and objectives; the progress and results of its DesCAARTes™ Phase 1 trial and MusCAARTes™ Phase 1 trial, including Cabaletta's ability to enroll the requisite number of patients and dose each dosing cohort in the intended manner; Cabaletta's ability to capitalize on and the potential benefits of the expanded scope of its collaborations with WuXi ATU and Oxford; the ability to accelerate Cabaletta's pipeline and develop meaningful therapies for patients, including in collaboration with academic and industry partners and the ability to optimize such collaborations on its development programs; use of capital, expenses, future accumulated deficit and other financial results in the future; availability of funding for existing programs; and ability to fund operations into the fourth quarter of 2025.

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 regulatory filings and potential clearance; the risk that signs of biologic activity or persistence may not inform long-term results; Cabaletta's ability

to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical studies and clinical trials of DSG3-CAART, MuSK-CAART and CABA-201; the risk that the results observed with the similarly-designed construct employed in the recent academic publications, including due to the dosing regimen, are not indicative of the results we seek to achieve with CABA-201; 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 volatile market and economic conditions and public health crises; Cabaletta's ability to retain and recognize the intended incentives conferred by Orphan Drug Designation and Fast Track Designation for its product candidates, as applicable; risks related to Cabaletta's ability to protect and maintain its intellectual property position; risks related to fostering and maintaining successful relationships with Cabaletta's collaboration and manufacturing partners; 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/or 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 September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
	unaudited		**unaudited**	
Operating expenses:				
Research and development	$ 13,787	$ 8,216	$ 38,019	$ 26,900
General and administrative	4,881	3,562	13,495	10,937
Total operating expenses	18,668	11,778	51,514	37,837
Loss from operations	(18,668)	(11,778)	(51,514)	(37,837)
Other income:				
Interest income	2,220	351	4,725	554
Net loss	(16,448)	(11,427)	(46,789)	(37,283)

Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.37)	$ (0.39)	$ (1.18)	$ (1.29)

Selected Balance Sheet Data

	September 30, 2023	December 31, 2022
	(unaudited)	
Cash, cash equivalents and investments	$ 164,391	$ 106,547
Total assets	173,287	116,968
Total liabilities	12,364	12,448
Total stockholders' equity	160,923	104,520

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