May 15, 2024

Cabaletta Bio Reports First Quarter 2024 Financial Results and Provides Business Update

– No CRS or ICANS of any grade observed during the 28-day DLT observation window for either of the first patients dosed with CABA-201 in the RESET-Myositis™ and RESET-SLE™ trials –

– Initial clinical data from each of the first patients in the RESET-Myositis and RESET-SLE trials to be presented at a satellite symposium at the EULAR 2024 Congress in June –

– Evaluating CABA-201 without preconditioning by initiation of the RESET-PV™ sub-study within the ongoing DesCAARTes™ trial in pemphigus vulgaris –

PHILADELPHIA, May 15, 2024 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies designed specifically for patients with autoimmune diseases, today reported financial results for the first quarter ended March 31, 2024, and provided a business update.

“With no CRS or ICANS of any grade observed in either of the first patients from the RESET-Myositis and RESET-SLE trials, we look forward to presenting initial translational and clinical data from both patients during a satellite symposium at the EULAR 2024 Congress on June 14th,” said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. “In addition to implementing our development path for CABA-201, we have made substantial progress on two innovations designed to optimize the patient and physician experience. First, we are evaluating CABA-201 without preconditioning through the incorporation of the RESET-PV sub-study within the ongoing DesCAARTes trial in patients with pemphigus vulgaris, expanding CABA-201 development into dermatology. Second, we demonstrated the potential to eliminate the need for apheresis by using a blood draw to obtain the starting material for the CABA-201 manufacturing process as presented at the ASGCT meeting. We are evaluating the opportunity to incorporate an apheresis-free process into our ongoing CABA-201 clinical program. By executing on our CABA-201 development strategy and integrating these types of innovations, we believe that we are well positioned to deliver on the full potential of the targeted cell therapies that we are developing to provide durable, drug-free remissions for patients with a broad range of autoimmune diseases.”

Recent Operational Highlights and Upcoming Anticipated Milestones

Chimeric Antigen Receptor T cells for Autoimmunity (CARTA) Strategy

CABA-201: Autologous, engineered T cells designed 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 across multiple therapeutic portfolios

where B cells contribute to the initiation and/or maintenance of disease.

Rheumatology Portfolio

- **Myositis (idiopathic inflammatory myopathies)**
  - In March 2024, Cabaletta announced the first patient had been dosed in the Phase 1/2 RESET-Myositis trial. No evidence of cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) of any grade was observed during the 28-day dose-limiting toxicity (DLT) observation window following administration. Patient enrollment in the Phase 1/2 RESET-Myositis trial is ongoing and initial clinical data from the first patient is anticipated to be presented in a satellite symposium at the EULAR 2024 Congress in June.
  - During the first quarter of 2024, Cabaletta announced that the U.S. Food and Drug Administration (FDA) granted regulatory designations to CABA-201 in myositis, including Fast Track Designation for the treatment of patients with dermatomyositis, Orphan Drug Designation for the treatment of idiopathic inflammatory myopathies (IIM, or myositis) and Rare Pediatric Disease Designation for the treatment of juvenile dermatomyositis.

- **Systemic lupus erythematosus (SLE)**
  - The first patient has been dosed in the Phase 1/2 RESET-SLE trial. No evidence of CRS or ICANS of any grade was observed during the 28-day DLT observation window following administration. Patient enrollment in the Phase 1/2 RESET-SLE trial is ongoing and initial clinical data from the first patient is anticipated to be presented in a satellite symposium at the EULAR 2024 Congress in June.
  - In March 2024, Health Canada issued a No Objection Letter in response to a Clinical Trial Application for the RESET-SLE trial submitted by Cabaletta, enabling the Company to begin the process to activate clinical trial sites and pursue patient enrollment for the RESET-SLE trial in Canada.

- **Systemic sclerosis (SSc)**
  - During the first quarter of 2024, Cabaletta announced that the FDA granted regulatory designations to CABA-201 in SSc, including Fast Track Designation for the treatment of patients with SSc and Orphan Drug Designation for the treatment of SSc.
  - Cabaletta expects to report initial clinical data from the Phase 1/2 RESET-SSc™ trial in the second half of 2024.

Dermatology Portfolio

- **Pemphigus vulgaris (PV)**
  - Cabaletta is working with active clinical sites to incorporate the RESET-PV sub-study within the Phase 1 DesCAARTes trial following the submission of a protocol amendment. The RESET-PV sub-study will evaluate CABA-201 as a monotherapy without preconditioning in patients with mucosal PV (mPV) and mucocutaneous PV (mcPV).

Neurology Portfolio

- **Generalized myasthenia gravis (gMG)**

    - Cabaletta expects to report initial clinical data from the Phase 1/2 RESET-MG™ trial in the second half of 2024.

Past and Upcoming External Scientific Presentations

- In May 2024, Cabaletta presented new preclinical data at the American Society of Gene and Cell Therapy (ASGCT) 27th Annual Meeting demonstrating the ability to manufacture autologous CD19-CAR T cells from a blood draw as a potential alternative to apheresis. Whole blood collections from 80mL to 200mL were successfully used in lieu of apheresis material to produce CAR T cells that demonstrated similar growth, viability, memory phenotype and cytotoxicity across 3 healthy donors. In addition, CD19-CAR T cells were manufactured successfully from whole blood sourced from 2 lupus patients and showed expected T cell memory subtype and cytotoxic functionality.

- In June 2024, Cabaletta plans to present initial clinical data from each of the first patients treated with CABA-201 in the RESET-Myositis and RESET-SLE trials in a EULAR European Congress of Rheumatology 2024 Industry Symposia session titled “Immune Reset: The Potential of CAR T Cell Therapy to Transform the Treatment of Patients with Autoimmune Disease” at 8:15 a.m. CEST on Friday, June 14, 2024, in Vienna, Austria.

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 mPV. The DesCAARTes trial is not currently dosing patients with DSG3-CAART as we evaluate clinical and translational data from the combination cohort, where patients were pre-treated with IVIg, cyclophosphamide and fludarabine prior to DSG3-CAART infusion, with the aim of improving persistence and activation of DSG3-CAART compared to findings from the no preconditioning cohorts previously reported.

- **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 (MuSK MG). The MusCAARTes™ trial is not currently dosing patients as we evaluate clinical and translational data from the A1 and A2 cohorts, where patients were treated with MuSK-CAART without preconditioning.

Upcoming Investor Events

Cabaletta plans to participate in the following upcoming investor conferences:

- H.C. Wainwright 2nd Annual BioConnect Investor Conference at NASDAQ, which is being held on May 20, 2024 in New York, NY.

- Jefferies Global Healthcare Conference, which is being held from June 5-6, 2024 in New York, NY.

- Goldman Sachs 45th Annual Global Healthcare Conference, which is being held from June 10-13, 2024 in Miami, FL.

First Quarter 2024 Financial Results

- Research and development expenses were $22.0 million for the three months ended March 31, 2024, compared to $12.4 million for the same period in 2023.

- General and administrative expenses were $6.1 million for the three months ended March 31, 2024, compared to $4.5 million for same period in 2023.

- As of March 31, 2024, Cabaletta had cash, cash equivalents and short-term investments of $223.8 million, compared to $241.2 million as of December 31, 2023.

The Company expects that its cash, cash equivalents and short-term investments as of March 31, 2024, will enable it to fund its operating plan into the first half of 2026.

About CABA-201
CABA-201 is designed to deeply and transiently deplete CD19-positive B cells following a one-time infusion, which may enable an "immune system reset" with the potential for durable remission without chronic therapy in patients with autoimmune diseases. Cabaletta is evaluating CABA-201 in multiple autoimmune conditions including systemic lupus erythematosus (SLE), myositis, systemic sclerosis (SSc), generalized myasthenia gravis (gMG) and pemphigus vulgaris (PV). Cabaletta is conducting four Phase 1/2 RESET™ clinical trials evaluating CABA-201 with a total of nine cohorts that can advance simultaneously, employing a similar parallel cohort design and starting dose of 1 x 10^6 cells/kg without a dose escalation requirement. CABA-201 is also being evaluated in the absence of preconditioning in a separate sub-study within the DesCAARTes™ trial for patients with PV.

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 the RESET™ (REstoring SElf-Tolerance) clinical trials in systemic lupus erythematosus, myositis, systemic sclerosis and generalized myasthenia gravis and in the RESET-PV™ sub-study within the DesCAARTes™ clinical trial in pemphigus vulgaris, along with 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-associated 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: Cabaletta's ability to grow its autoimmune pipeline; Cabaletta's future plans and strategies for its CAAR T and CARTA

technologies and the company's business plans and objectives as a whole; statements regarding regulatory filings for its development programs, including the planned timing of such regulatory filings and potential review by regulatory authorities; Cabaletta's ability to retain and recognize and its expectations around the intended incentives conferred by Fast Track Designation and/or Orphan Drug Designation for CABA-201 for the treatment of multiple autoimmune diseases; Cabaletta's ability to retain and recognize and its expectations around the potential benefits and incentives provided by FDA's rare pediatric disease designation for CABA-201; Cabaletta's expectations around the potential success and therapeutic benefits of CABA-201, including its belief that CABA-201 may enable an "immune system reset" with the potential for durable remission without chronic therapy in patients with autoimmune diseases; the Company's advancement of separate Phase 1/2 clinical trials of CABA-201 in patients with SLE, myositis, SSc and gMG and advancement of a RESET-PV sub-study within the ongoing DesCAARTes trial in PV, including updates related to status, safety data, or otherwise and the expected timing of the related data read-outs; Cabaletta's plans to eliminate the need for apheresis by using a simpler collection process to obtain the starting material for the CABA-201 manufacturing process; Cabaletta's ability to accelerate its pipeline, develop meaningful therapies for patients and leverage its research and translational insights; the Company's expectations for the efficiency of the trial design for its Phase 1/2 clinical trials of CABA-201 and for its RESET-PV sub-study within the ongoing DesCAARTes trial in PV; Cabaletta's planned initial clinical data read-out at the EULAR 2024 Congress in June 2024 for patients with myositis and SLE treated with CABA-201; Cabaletta's additional planned initial clinical data read-outs for patients with SSc and gMG treated with CABA-201 or otherwise; Cabaletta's advancement of the process to activate clinical trial sites and pursue patient enrollment for the RESET-SLE trial in Canada; Cabaletta's planned assessment of its DesCAARTes™ and MusCAARTes™ trials; use of capital, expense and other financial results in the future; ability to fund operations into the first half of 2026 and the anticipated contribution of the members of Cabaletta's executives to the company's operations and progress.

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 CABA-201; the risk that the results observed with the similarly-designed construct employed in 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, delays in enrollment generally or enrollment rates that are lower than expected; delays related to assessment of clinical trial results; 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 or other designations 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, including in light of recent legislation; 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 March 31,	
	2024	**2023**
	Unaudited	
Operating expenses:		
Research and development	$ 21,954	$ 12,435
General and administrative	6,077	4,521
Total operating expenses	28,031	16,956
Loss from operations	(28,031)	(16,956)
Other income:		
Interest income	2,984	1,102
Net loss	(25,047)	(15,854)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.51)	$ (0.45)

Selected Balance Sheet Data

	March 31, 2024	**December 31, 2023**
	(unaudited)	
Cash, cash equivalents and investments	$ 223,845	$ 241,249
Total assets	240,457	253,650
Total liabilities	18,737	17,452

Total stockholders' equity	221,720	236,198

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