November 14, 2024

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

– Clinical data from the RESET-Myositis™ and RESET-SLE™ trials, along with initial clinical data from the RESET-SSc™ trial, to be presented this weekend in oral and poster presentations at ACR Convergence 2024 –

– 16 patients enrolled with 10 patients dosed as of November 12 across the RESET™ clinical development program; 40 U.S. clinical sites actively recruiting patients –

– Data permitting, anticipate meeting with the FDA in 2025 regarding potential registrational program designs for CABA-201 –

– Clinical development expanding efficiently into Europe with EMA CTA authorization for CABA-201 received in lupus; Gerwin Winter appointed as Senior VP and Head of International –

– Cash, cash equivalents and short-term investments total $183.0 million as of September 30, 2024, expected to support operations into the first half of 2026 –

PHILADELPHIA, Nov. 14, 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 third quarter ended September 30, 2024, and provided a business update.

“Focused clinical execution has resulted in 40 U.S. clinical sites actively recruiting patients for the RESET clinical trial program for CABA-201. At the ACR Convergence conference this coming weekend, we are looking forward to sharing clinical safety and efficacy data from the first 8 myositis, lupus and scleroderma patients in the RESET clinical trial program evaluating whether a single dose of CABA-201 can provide compelling clinical responses without the need for immunosuppressants,” said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. “We are encouraged by the accelerating pace of enrollment and, data permitting, anticipate meeting with the FDA next year regarding registrational program designs for CABA-201. As we expand our clinical trial network beyond the U.S., we are pleased to welcome Gerwin Winter as Head of International for Cabaletta. Gerwin was most recently head of Europe for Beigene from inception through commercialization leveraging his prior experiences at Portola, Celgene and BMS. His team is already well positioned to leverage the recent EMA CTA authorization for the RESET-SLE trial. We look forward to expanding the opportunity for CABA-201 globally as we seek to develop and launch the first targeted curative cell therapies for patients with autoimmune diseases.”

Recent Operational Highlights and Upcoming Anticipated Milestones

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

Rheumatology Portfolio

- **Myositis (idiopathic inflammatory myopathies, IIM)**
  - Patient enrollment in the RESET-Myositis trial is ongoing and additional clinical and translational data from the trial will be presented at the American College of Rheumatology (ACR) Convergence 2024 conference this coming weekend.

- **Systemic lupus erythematosus (SLE)**
  - In October 2024, the European Medicines Agency (EMA) allowed a Clinical Trial Application (CTA) submitted by Cabaletta for the RESET-SLE trial to proceed, enabling the Company to begin the process of activating clinical trial sites and pursuing patient enrollment for the RESET-SLE trial.
  - Patient enrollment in the RESET-SLE trial is ongoing and additional clinical and translational data from the trial will be presented at ACR Convergence 2024 this coming weekend.

- **Systemic sclerosis (SSc)**
  - Patient enrollment in the RESET-SSc trial is ongoing and initial clinical data from the trial will be presented at ACR Convergence 2024 this coming weekend.

Neurology Portfolio

- **Generalized myasthenia gravis (gMG)**
  - Patient enrollment in the RESET-MG™ trial is ongoing and initial clinical data from the trial are expected in the first half of 2025.

Dermatology Portfolio

- **Pemphigus vulgaris (PV)**
  - Patient enrollment is ongoing in the RESET-PV™ trial, formerly referred to as the DesCAARTes™ trial. The trial is evaluating CABA-201 as a monotherapy without preconditioning in patients with mucosal PV (mPV) and mucocutaneous PV (mcPV).

External Scientific Presentations and Publications

- In October 2024, Cabaletta presented multiple oral and poster presentations at the European Society of Gene and Cell Therapy (ESGCT) 31st Annual Congress, which was held at La Nuvola in Rome, Italy from October 22-25, 2024. Details of the presentations and their associated key findings are below:
  - Oral presentation (OR022): Correlative findings following DSG3-CAART infusion with and without preconditioning in patients with pemphigus vulgaris (DesCAARTes™ trial). The data showed that the use of preconditioning with DSG3-CAART did not provide serologic or clinical improvement and did not deeply deplete B-cell levels in patients with mPV.

    - Poster presentation (P0744): Clinical and translational findings following MuSK-CAART infusion without preconditioning in patients with MuSK-associated myasthenia gravis (MuSCAARTes™ trial) in the first two cohorts. The data indicated MuSK-CAART cells demonstrated evidence of biologic and clinical activity in treated patients, suggesting it may be possible to achieve clinical activity with CAR T cells in patients with autoimmune disease without preconditioning. The MusCAARTes™ trial is not currently dosing patients as we evaluate clinical and translational data from the first two cohorts.
    - Poster presentation (P0824): At-scale autologous CD19-CAR T manufacturing from whole blood collection for the treatment of autoimmune disease: process and product quality assessment. The data demonstrated large scale runs using 200mL whole blood collections yielded similar amounts of CD19-CAR T cells as runs using leukapheresis material and demonstrated similar cytotoxicity across a range of effector to target ratios.

- In November 2024, Cabaletta plans to present new and updated clinical and translational data on CABA-201 in oral and poster presentations at the ACR Convergence 2024 conference, which is being held at the Walter E. Washington Convention Center in Washington, D.C. from November 14-19, 2024.

Corporate Updates

- In October 2024, Gerwin Winter joined the Company as Senior Vice President and Head of International to lead a focused team that has recently been assembled to expand our clinical development in Europe. Mr. Winter has nearly three decades of experience building and leading global clinical and commercial operations teams to bring innovative medicines closer to patients. Prior to joining Cabaletta, he was Senior Vice President, Head of Europe at BeiGene. Before that, Mr. Winter was Senior Vice President and Head of Europe for Portola Pharmaceuticals, building European operations through its acquisition by Alexion in 2020. Previously, he served in multiple positions of increasing responsibility at Celgene and Bristol-Myers Squibb where he was responsible for multiple launches in hematology and oncology. Mr. Winter holds a PharmD in pharmacy from the University of Munich, Germany and an M.B.A. in general management from CEDEP at INSEAD University of Fontainebleau, France.

- In November 2024, Nicolette Sherman joined the Company as Chief Human Resources Officer (CHRO). Ms. Sherman succeeds Martha O'Connor, who is retiring and will move into an advisory role as part of a planned transition. Ms. Sherman brings more than two decades of experience leading human resources and organizational functions at biotechnology and pharmaceutical companies. Prior to joining Cabaletta, Ms. Sherman was CHRO at Certara, where she developed and implemented an award-winning human resources program that innovated talent management strategies, strengthened workforce planning and fostered a future-ready culture. Before that, she was CHRO at Oyster Point Pharma, Inc. Earlier, Ms. Sherman served in multiple roles of increasing responsibility at Sanofi, Schering-Plough, AT&T and Prudential. She holds master's degrees in human resource management from Rutgers University and political science from the University of Delaware, in addition to a B.A. in government from Lehigh University.

Upcoming Investor Events

- The Company will host an investor conference call and webcast on Monday, November 18, 2024, at 8:00 a.m. ET to review the CABA-201 clinical data presented at ACR Convergence 2024 and provide an update on the RESET clinical development program.

- The Company will participate in a fireside chat at the Jefferies London Healthcare Conference on Wednesday, November 20, 2024, at 11:30 a.m. GMT in London, UK.

A live webcast of each presentation will be available on the News and Events section of the Company's website at www.cabalettabio.com. Replays will be available on the website for a limited time.

Third Quarter 2024 Financial Results

- Research and development expenses were $26.3 million for the three months ended September 30, 2024, compared to $13.8 million for the same period in 2023.

- General and administrative expenses were $6.8 million for the three months ended September 30, 2024, compared to $4.9 million for the same period in 2023.

- As of September 30, 2024, Cabaletta had cash, cash equivalents and short-term investments of $183.0 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 September 30, 2024, will enable it to fund its operating plan into the first half of 2026.

About CABA-201
CABA-201 is a 4-1BB-containing fully human CD19-CAR T cell investigational therapy for patients with autoimmune diseases where B cells contribute to the initiation and/or maintenance of disease. Following a one-time infusion, CABA-201 is designed to transiently and completely deplete all CD19-positive cells. We believe this approach has the potential to reset the immune system and result in compelling clinical responses without chronic therapy requirements in patients. Cabaletta is currently evaluating CABA-201 in the RESET™ (REstoring SElf-Tolerance) clinical development program which includes multiple disease-specific, company-sponsored clinical trials across growing portfolios of autoimmune diseases in a broad range of therapeutic areas, including rheumatology, neurology and dermatology.

About Cabaletta Bio
Cabaletta Bio (Nasdaq: CABA) is a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies designed specifically for patients with autoimmune diseases. The CABA™ platform encompasses two complementary strategies which aim to advance the discovery and development of engineered T cell therapies with the potential to become deep and durable, perhaps curative, treatments for a broad range of autoimmune diseases. The lead CARTA (Chimeric Antigen Receptor T cells for Autoimmunity) strategy is prioritizing the development of CABA-201, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy. CABA-201 is currently being evaluated in the RESET™ (REstoring SElf-Tolerance) clinical development program spanning multiple therapeutic areas, including rheumatology, neurology and dermatology. Cabaletta Bio's headquarters and labs are located in Philadelphia, PA. For more information,

please visit www.cabalettabio.com and connect with 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: Cabaletta's business plans and objectives as a whole; Cabaletta's ability to realize its vision of launching the first curative targeted cell therapy designed specifically for patients with autoimmune diseases; Cabaletta's ability to successfully complete research and further development and commercialization of its drug candidates in current or future indications, including the timing and results of Cabaletta's clinical trials and its ability to conduct and complete clinical trials; expectation that clinical results will support CABA-201's safety and activity profile; statements regarding the expectations of trial modifications and prophylactic measures, continued trial operations; statements regarding the timing of regulatory filings and interactions, including timing of such interactions, with regulatory authorities, including such authorities' review of safety information from Cabaletta's ongoing clinical trials and potential registrational program designs for CABA-201; Cabaletta's expectations around the potential success and therapeutic benefits of CABA-201, including its belief that CABA-201 has the potential to reset the immune system and result in compelling clinical responses without chronic therapy requirements in patients; 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 trial, including updates related to status, safety data, or otherwise and the expected timing of the related data read-outs; the clinical significance of the clinical data read-out at the ACR Convergence 2024 in November 2024 for patients with myositis, SLE and SSc treated with CABA-201; Cabaletta's planned initial clinical data read-out for patients with gMG treated with CABA-201 in the first half of 2025; Cabaletta's ability to increase enrollment from its rapidly expanding clinical network in the RESET clinical program in the United States and beyond; Cabaletta's ability to activate clinical trial sites and pursue patient enrollment for the RESET-SLE trial in Europe and leverage its recent CTA; 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 that modifications to trial design or approach may not have the intended benefits and that the trial design may need to be further modified; 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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
	unaudited		**unaudited**	
Operating expenses:				
Research and development	$ 26,290	$ 13,787	$ 71,671	$ 38,019
General and administrative	6,756	4,881	19,685	13,495
Total operating expenses	33,046	18,668	91,356	51,514
Loss from operations	(33,046)	(18,668)	(91,356)	(51,514)
Other income:				
Interest income	2,417	2,220	8,078	4,725
Net loss	(30,629)	(16,448)	(83,278)	(46,789)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.62)	$ (0.37)	$ (1.69)	$ (1.18)

Selected Balance Sheet Data

	September 30, 2024	December 31, 2023
	(unaudited)	
Cash, cash equivalents and investments	$ 183,012	$ 241,249
Total assets	204,410	253,650
Total liabilities	30,169	17,452
Total stockholders' equity	174,241	236,198

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