UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 31, 2025

CABALETTA BIO, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39103**	**82-1685768**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2929 Arch Street **Suite 600** **Philadelphia, Pennsylvania**	**19104**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (267) 759-3100

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.00001 per share	CABA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 31, 2025, Cabaletta Bio, Inc. announced its financial results for the fourth quarter and fiscal year ended December 31, 2024. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by the registrant on March 31, 2025, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CABALETTA BIO, INC.

Date: March 31, 2025

By: /s/ Steven Nichtberger
Steven Nichtberger
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 99.1

Cabaletta Bio Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

– FDA meeting to align on myositis registrational trial designs for rese-cel in 1H25 on track –

– Enrolling approximately one patient per week across the RESET™ clinical development program since ACR Convergence presentation in November 2024 with 33 patients enrolled across 56 active clinical trial sites in the U.S. & Europe as of March 14, 2025 –

– Clinical and translational data on rese-cel to be presented in three oral presentations at the EULAR 2025 Congress in June –

– Operational runway into 1H26 with cash and cash equivalents of $164.0 million as of December 31, 2024 –

PHILADELPHIA, March 31, 2025 -- 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 fourth quarter and full year ended December 31, 2024, and provided a business update.

“We are looking forward to meeting with the FDA to align on registrational trial designs in myositis, which affects approximately 70,000 patients in the U.S., by leveraging our emerging clinical data and our efficient development strategy. Since presenting clinical and translational data from the RESET program demonstrating that a single weight-based dose of rese-cel was able to provide potentially transformative clinical responses after discontinuation of all immunosuppressants and while off or tapering off steroids, we have seen robust physician and patient interest in the RESET clinical program," said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. “In addition, we are advancing innovations that have the potential to enhance the patient and physician experience, including an apheresis-free approach and evaluation of a RESET-PV™ cohort with no preconditioning."

Recent Operational Highlights and Upcoming Anticipated Milestones

Rese-cel (resecabtagene autoleucel, formerly referred to as 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 infused as a single weight-based dose 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

- **Systemic sclerosis (SSc)**

- In March 2025, Cabaletta learned of an important protocol deviation in the RESET-SSc™ trial. The protocol requires that in any patient with a fever or infection during the two weeks prior to rese-cel infusion, the investigator promptly discuss the appropriateness and timing of infusion with the trial's Medical Monitor. In this case, the patient reported a fever three days prior to infusion. The Cabaletta Medical Monitor was not notified prior to the site infusing the patient. Nine days following rese-cel infusion, the patient experienced a dose-limiting toxicity of grade 3 immune effector cell-associated neurotoxicity syndrome (ICANS) based on a transient period of confusion. There was no cerebral edema, seizures or motor dysfunction associated with the ICANS event, and the patient was arousable throughout. The ICANS resolved rapidly following treatment with dexamethasone, and the patient was discharged without further symptoms. After data review, the Independent Data Monitoring Committee recommended that the trial proceed at the current dose without delay and endorsed Cabaletta's proposal to require investigators to affirmatively confirm in writing to the company the absence of fevers or evidence of infection in patients during the two weeks prior to rese-cel infusion.
- In February 2025, Cabaletta announced the first patient dosed with rese-cel in the severe skin cohort of the RESET-SSc™ trial continued to demonstrate clinically meaningful skin improvements across several body areas at three months post-infusion, in addition to improvement in lung function, after discontinuing all disease-specific therapies.

- **Myositis (idiopathic inflammatory myopathies, IIM)**
  - In February 2025, Cabaletta announced the first adult dermatomyositis patient maintained a major total improvement score (TIS) improvement at three months post-infusion, off all immunosuppressants and tapering steroids, showing the potential for patients with refractory myositis to achieve drug-free remission. In addition, initial clinical responses in the first two immune-mediated necrotizing myopathy (IMNM) patients continued to show gradual improvement, consistent with published academic data, suggesting response kinetics may differ among myositis subtypes.
  - In January 2025, Cabaletta announced the first juvenile myositis clinical site in the RESET-Myositis™ trial is open and actively recruiting. The U.S. Food and Drug Administration (FDA) previously granted Rare Pediatric Disease designation for rese-cel in juvenile dermatomyositis.

- **Systemic lupus erythematosus (SLE) and lupus nephritis (LN)**
  - In February 2025, Cabaletta announced three out of four patients in the SLE cohort of the RESET-SLE™ trial achieved DORIS (definition of remission in SLE) remission. In addition, the first patient dosed with rese-cel in the lupus nephritis (LN) cohort of the same trial achieved a complete renal response (CRR). All 6 SLE and LN patients dosed, including these patients, demonstrated clinical responses, including improvements on the SLEDAI-2K score and/or urine protein-creatinine ratio, while off all immunosuppressants and steroids as of the data cut-off date of January 8, 2025.

Neurology Portfolio

- **Generalized myasthenia gravis (gMG)**

- In January 2025, Cabaletta announced the first patient has been enrolled in the RESET-MG™ trial, evaluating rese-cel in patients with myasthenia gravis.

- **Multiple sclerosis (MS)**
  - In January 2025, Cabaletta announced the Investigational New Drug (IND) application for rese-cel has been allowed to proceed within the routine 30-day window by the FDA for the RESET-MS™ trial, a Phase 1/2 study evaluating rese-cel in patients with multiple sclerosis. In addition, the FDA has granted Fast Track Designation to rese-cel for the treatment of relapsing and progressive forms of MS.

Dermatology Portfolio

- **Pemphigus vulgaris (PV)**
  - In January 2025, Cabaletta announced the first patient has been enrolled in the RESET-PV™ trial, evaluating rese-cel without preconditioning in patients with PV.

Upcoming External Scientific Presentations

- In June 2025, Cabaletta plans to present new and updated clinical and translational data on rese-cel from the RESET-Myositis™, RESET-SLE™ and RESET-SSc™ trials in three oral presentations at the upcoming EULAR 2025 Congress, which is being held at Fira de Barcelona in Barcelona, Spain from June 11-14, 2025.

Corporate Updates

- In March 2025, Cabaletta and Cellares announced the successful conclusion of the Technology Adoption Program on Cellares' automated cell therapy manufacturing Cell Shuttle™, facilitating the potential integration of the Cell Shuttle into Cabaletta's clinical and commercial, if approved, manufacturing strategy for rese-cel.

- In January 2025, Cabaletta announced an expanded Contract Development and Manufacturing Organization (CDMO) agreement with Lonza to supply rese-cel clinical product under current Good Manufacturing Practices as soon as the second half of 2025. This expanded CDMO agreement is intended to address the increasing pace of enrollment in clinical trials evaluating rese-cel as well as to prepare for registrational trial(s) across the RESET clinical development program.

Fourth Quarter and Full Year 2024 Financial Results

- Research and development expenses were $25.5 million and $97.2 million for the three months ended December 31, 2024, and the full year ended December 31, 2024, respectively, compared to $17.4 million and $55.4 million for the three months ended December 31, 2023, and the full year ended December 31, 2023, respectively.

- General and administrative expenses were $8.3 million and $27.9 million for the three months ended December 31, 2024, and the full year ended December 31, 2024,

respectively, compared to $5.7 million and $19.2 million for the three months ended December 31, 2023, and the full year ended December 31, 2023, respectively.

•As of December 31, 2024, Cabaletta had cash, cash equivalents and short-term investments of $164.0 million, compared to $241.2 million as of December 31, 2023.

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

About rese-cel (formerly referred to as CABA-201)
Rese-cel 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 of a weight-based dose, rese-cel is designed to transiently and deeply deplete all CD19-positive cells in both the peripheral circulation and within tissues. We believe this approach has the potential to reset the immune system and result in profound clinical responses without chronic therapy requirements in patients. Cabaletta is currently evaluating rese-cel in the RESET™ (REstoring SElf-Tolerance) clinical development program which includes multiple disease-specific, company-sponsored clinical trials across expanding 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 rese-cel, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy. Rese-cel 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 rese-cel's safety and activity profile; statements regarding the timing of interactions with regulatory authorities, including such authorities' review of safety information from Cabaletta's ongoing clinical trials and potential registrational pathway for rese-cel; Cabaletta's ability to leverage its emerging clinical data and its efficient development strategy; Cabaletta's belief that the pace of

enrollment in each of the RESET clinical cohorts is providing early insight into the most compelling rese-cel use cases for physicians and their patients; Cabaletta's ability to develop innovations that can enhance the patient and physician experience; Cabaletta's belief that rese-cel is a one-time treatment that can potentially free patients from their autoimmune disease; Cabaletta's expectations around the potential success and therapeutic benefits of rese-cel, including its belief that rese-cel has the potential to reset the immune system and result in profound clinical responses without chronic therapy requirements in patients; the Company's advancement of separate Phase 1/2 clinical trials of rese-cel in patients with SLE, myositis, SSc and gMG and advancement of the RESET-PV™ and RESET-MS™ trials, including updates related to status, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise; Cabaletta's ability to expand its clinical supply for registrational trial(s) across the RESET clinical development program as well as to expand its manufacturing options for rese-cel; Cabaletta's ability to increase enrollment in its US and Europe clinical networks; Cabaletta's ability to leverage its growing clinical trial network to accelerate development of its therapy for patients and to generate clinical and translational data; Cabaletta's plans to meet with the FDA to discuss registrational trials; and Cabaletta's use of capital, expense and other financial results in the future and its ability to fund operations into the first half of 2026.

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 rese-cel; 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 rese-cel; 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; 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 subsequent 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,	
	2024	2023	2024	2023
	Unaudited			
Operating expenses:				
Research and development	25,532	17,405	97,203	55,424
General and administrative	8,253	5,741	27,938	19,236
Total operating expenses	33,785	23,146	125,141	74,660
Loss from operations	(33,785)	(23,146)	(125,141)	(74,660)
Interest income	1,947	2,260	10,025	6,985
Interest expense	(748)	—	(748)	—
Net loss	(32,586)	(20,886)	(115,864)	(67,675)
Net loss per voting and non-voting share, basic and diluted	$ (0.65)	$ (0.46)	$ (2.34)	$ (1.65)

Selected Balance Sheet Data

	December 31,	
	2024	2023
	Unaudited	
Cash, cash equivalents and short-term investments	$ 163,962	$ 241,249
Total assets	185,046	253,650
Total liabilities	32,711	17,452
Total stockholders' equity	152,335	236,198

Contacts:

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