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): May 15, 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 May 15, 2025, Cabaletta Bio, Inc. ("Cabaletta" or the "Company") disclosed that its cash and cash equivalents as of March 31, 2025 was $131.8 million, compared to $164.0 million as of December 31, 2024. The Company expects that this cash position as of March 31, 2025 will enable it to fund its operating plan into the first half of 2026.

The information contained in Item 2.02 of this Form 8-K does not present all information necessary for an understanding of the Company's financial condition as of March 31, 2025 and 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 (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure

On May 15, 2025, the Company posted to the "Investors & Media" section of the Company's website at *www.cabalettabio.com* an updated corporate presentation (the "Corporate Presentation").

On May 15, 2025, the Company issued a Press Release entitled "Cabaletta Bio Announces 2027 Rese-cel BLA Submission Anticipated in Myositis Following Recent FDA Alignment on Registrational Cohorts" (the "Press Release"). A copy of the Press Release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 7.01 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 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 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 May 15, 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: May 15, 2025

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

Exhibit 99.1

Cabaletta Bio®

Cabaletta Bio Announces 2027 Rese-cel BLA Submission Anticipated in Myositis Following Recent FDA Alignment on Registrational Cohorts

– Two subtype specific cohorts with ~15 patients each added to the ongoing RESET-Myositis™ trial –

– RMAT designation granted for rese-cel in myositis, which is a disabling, multi-system autoimmune disease affecting approximately 80,000 U.S. patients with no approved treatments other than monthly IVIg –

– Multiple Phase 1/2 disease cohorts fully enrolled across the RESET™ clinical development program; 44 patients enrolled and 23 patients dosed as of May 9, 2025 –

– SLE and LN registrational discussions with FDA anticipated in 3Q25; systemic sclerosis registrational discussions with FDA anticipated in 4Q25 –

– New clinical data on rese-cel in myositis, SLE / LN and systemic sclerosis to be presented in three oral sessions at the EULAR 2025 Congress in June –

PHILADELPHIA, May 15, 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 announced plans for an anticipated 2027 rese-cel BLA submission following a recent U.S. Food and Drug Administration (FDA) meeting on a proposed registrational cohort design for the RESET-Myositis trial of rese-cel (resecabtagene autoleucel, formerly known as CABA-201).

“Myositis is a severe, disabling, and potentially life-threatening multi-system disease that affects approximately 80,000 patients in the U.S. with a three-fold increased mortality risk primarily due to interstitial lung disease, cardiovascular disease and an increased risk of cancer. Chronic, monthly IVIg infusion is the only FDA-approved treatment option for a subset of these patients,” said David J. Chang, M.D., Chief Medical Officer of Cabaletta. “The clinical safety and efficacy data evaluating a single, weight-based dose of rese-cel after discontinuation of all immunosuppressants in the RESET-Myositis trial and data from the broader RESET clinical program supported the recent discussions with FDA and RMAT designation for rese-cel in myositis. Based on the minutes from our recent FDA meeting, we are proceeding with a registrational study design that includes two independent, subtype specific cohorts, each with approximately 15 patients and a primary endpoint within 26 weeks of rese-cel infusion. The primary endpoint incorporates a validated clinical improvement score used in the approval of IVIg for patients with dermatomyositis. The clinical data that supported the FDA discussions will be presented in three oral sessions at the upcoming EULAR congress while correlative basic science data is being presented at the ongoing ASGCT conference. With the completion of enrollment in the Phase 1/2 RESET-Myositis trial and the ability to leverage our industry-leading

U.S. clinical trial network, we look forward to expanding our ongoing clinical study and submitting our first BLA for rese-cel."

Regulatory and Manufacturing Updates

Following a Type C meeting with the FDA and receipt of meeting minutes in April 2025, Cabaletta is planning to implement the following design for two single-arm, disease-specific registrational cohorts in the ongoing RESET-Myositis trial, either of which, if successful, enable a future Biologics License Application (BLA) submission for rese-cel in myositis:

- One cohort will evaluate approximately 15 patients with either dermatomyositis (DM) or antisynthetase syndrome (ASyS) and one cohort will evaluate approximately 15 patients with immune-mediated necrotizing myopathy (IMNM). Inclusion and exclusion criteria will remain highly similar to the Phase 1/2 cohorts. While a BLA for either cohort can be submitted independently, we believe that together, these two cohorts have the potential to support a broad label to address many of the approximately 80,000 myositis patients in the U.S., including those with or without a history of IVIg use.

- The registrational cohorts will evaluate the same single, weight-based infusion of rese-cel at 1 x 10^6 cells/kg as used in the Phase 1/2 myositis cohorts. The primary endpoint for the registrational cohorts is based on the total improvement score (TIS) to evaluate patient outcomes within 26 weeks of rese-cel infusion.

- The FDA supported the use of pooled rese-cel safety data from across the entire RESET clinical trial program to supplement myositis specific safety data for the BLA submission in myositis. In the recent Type C meeting, Cabaletta aligned with the FDA on the size of the required safety database, which is expected to be approximately 100 autoimmune disease patients treated with the same single weight-based dose, over 40% of which have already been enrolled across the RESET clinical development program.

The FDA also granted Regenerative Medicine Advanced Therapy (RMAT) designation to rese-cel for the treatment of myositis. The advantages of RMAT designation include all the benefits of Fast Track and Breakthrough Therapy Designation programs, including potential for expedited review of the BLA submission, and provide opportunities for more frequent interactions with the FDA with the goal of facilitating drug development. New clinical data from each of the RESET-Myositis, RESET-SLE™ and RESET-SSc™ trials will be presented in three oral presentations at the upcoming EULAR 2025 Congress from June 11-14, 2025, in Barcelona, Spain.

Cabaletta also continues to make timely and disciplined investments in its manufacturing strategy, which is designed to reduce the cost of goods sold, increase scale and shorten the vein-to-vein time. To support commercial supply readiness, Cabaletta has been advancing BLA-enabling activities for our lentiviral vector process at Oxford Biomedica and implementing the planned commercial drug product process at Lonza, which is expected to come online in early 3Q25 to support registrational enrollment.

Financial Updates

As of March 31, 2025, the Company had cash and cash equivalents of $131.8 million, per our Form 10-Q being filed this morning, compared to $164.0 million as of December 31, 2024. The

Company expects that its cash and cash equivalents as of March 31, 2025, will enable it to fund its operating plan into the first half of 2026.

About myositis
Myositis refers to a group of severe, disabling and potentially life-threatening autoimmune diseases characterized by severe inflammation and muscle weakness. It commonly impacts women of middle age, and patients can experience weakness, fatigue, pain, shortness of breath and difficulty swallowing in addition to symptoms in other organ systems, such as the lung, heart or skin. The risk of mortality is approximately 3 times higher than the general population, primarily due to interstitial lung disease, or ILD, cardiovascular disease and/or malignancy. Myositis is classified into several subtypes based on the underlying immune mechanisms and clinical characteristics, including dermatomyositis, or DM, antisynthetase syndrome, or ASyS, and immune-mediated necrotizing myopathy, or IMNM. These subtypes affect approximately 80,000 patients in the U.S. and approximately 85,000 patients in Europe. Current standard of care typically involves medications to suppress the immune system and/or chronic intensive therapies such as monthly infusions of intravenous immunoglobulin, or IVIg, which is the only FDA approved therapy for adult DM patients. Despite these therapies, many myositis patients have disease that remains refractory to existing medications. Based on quantitative market research with myositis treating physicians, we believe approximately 20% to 25% of the 80,000 patients in the US with myositis, representing those with refractory moderate or severe disease, would be potential candidates for treatment with rese-cel.

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 ability to capitalize on and potential benefits resulting from its research and translational insights; including those related to any similarly-designed constructs or dosing regimens; Cabaletta’s expectation regarding the clinical data to be presented at the upcoming EULAR congress; Cabaletta’s expectations around the potential success and therapeutic benefits of rese-cel; 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 leverage its existing industry-leading U.S. clinical trial network to initiate enrollment in the myositis registrational cohorts in the second half of 2025 and accelerate development of its therapy for patients and to generate clinical and translational data; Cabaletta’s expectations surrounding the RMAT designation and the anticipated initiation of new registrational cohorts and potential BLA submission; Cabaletta’s belief regarding alignment with FDA on registrational trial design; 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 Regenerative Medicine Advanced Therapy, 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; 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; the Company's ability to fund its operations and continue as a going concern. 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.

Contacts:

Anup Marda
Chief Financial Officer
investors@cabalettabio.com