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

FORM 8-K/A
(Amendment No. 1)

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

February 18, 2025
Date of Report (Date of earliest event reported)

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)	(I.R.S. Employer Identification No.)

2929 Arch Street, Suite 600, Philadelphia, PA	19104
(Address of principal executive offices)	(Zip Code)

(267) 759-3100
(Registrant's telephone number, including area code)

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. ☐

Explanatory Note

Cabaletta Bio, Inc. (the "Company" or "Cabaletta") filed a Current Report on Form8-K on February 18, 2025 in connection with a press release announcing new and updated clinical data from the first 10 patients dosed with resecabtagene autoleucel (rese-cel, formerly referred to as CABA-201) across the RESET clinical development program (the "Original 8-K"). This Amendment No. 1 ("Amendment No. 1") to the Original8-K is being filed to clarify that as of the data cut-off date of January 8, 2025, in the RESET-Myositis trial, the first adult dermatomyositis patient was off all immunosuppressants and tapering steroids, to revise other similar statements, and to note that a revised copy of the corporate presentation has been posted to the Company's website and a copy of the revised press release has been furnished herewith to reflect the same, and no changes to the other information filed with the Original Form 8-K have been made.

Item 7.01 Regulation FD Disclosure

On February 18, 2025, the Company filed Amendment No. 1. A revised copy of the corporate presentation has been posted to the Company's website and a copy of the revised press release is attached hereto as Exhibit 99.1, and no changes to the other information filed with the Original Form 8-K have been made.

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 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 8.01 Other Events.

On February 18, 2025, the Company issued a revised press release to clarify that as of the datacut-off date of January 8, 2025, in the RESET-Myositis trial, the first adult dermatomyositis patient was off all immunosuppressants and tapering steroids.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by the registrant on February 18, 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

CABALETTA BIO, INC.

Date: February 18, 2025

By: /s/ Steven Nichtberger
Steven Nichtberger, M.D.
President and Chief Executive Officer

Cabaletta Bio®

Cabaletta Bio Announces Updated Clinical Data Demonstrating Deepening Clinical Responses across Multiple Indications with Rese-cel at February Scientific Meetings

– Clinical efficacy continued to deepen over time with three SLE patients in DORIS remission, the first LN patient achieving complete renal response, and the first dermatomyositis patient maintaining a major TIS improvement; each of these patients discontinued all immunosuppressants and are off or tapering steroids as of the latest follow-up –

– Safety profile continues to suggest favorable risk-benefit in the first 10 patients dosed; 90% of patients experienced either no CRS or Grade 1 CRS (fever) and 90% of patients experienced no ICANS –

– Deep B cell depletion observed in all patients after rese-cel infusion with a transitional naïve B cell phenotype upon repopulation; tissue-resident B cell elimination confirmed by a lymph node biopsy in a scleroderma patient –

– 50 clinical sites in the U.S. and Europe actively recruiting with 26 patients enrolled across the RESET™ clinical development program as of February 13, 2025 –

PHILADELPHIA, Feb. 18, 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 new and updated clinical data from the first 10 patients dosed with resecabtagene autoleucel (rese-cel, formerly referred to as CABA-201) across the RESET clinical development program. These data were presented by Aimee Payne, M.D., Ph.D., Co-founder of and Scientific Advisory Board Co-chair at Cabaletta Bio in the 'Science Breakthroughs' session at the 2025 annual meeting of the American Association for the Advancement of Science, which was held in Boston, MA from February 13-15, 2025, and are being presented by Samik Basu, M.D., Chief Scientific Officer at Cabaletta Bio at the 5th International Conference on Lymphocyte Engineering, which is being held in Munich, Germany from February 20-22, 2025.

"The expanding clinical experience with rese-cel underscores its potential to provide compelling clinical responses without the need for immunosuppressants or steroids in patients with active, refractory autoimmune disease. With patients across the ongoing myositis, lupus and systemic sclerosis trials achieving DORIS remission in SLE, complete renal response in LN, and major TIS improvement in dermatomyositis, all while off all immunosuppressants and off or tapering steroids, we believe rese-cel has the potential to transform the lives of patients with autoimmune disease," said David J. Chang, M.D., Chief Medical Officer of Cabaletta. "We intend to include these data when we meet with the FDA to align on registrational trial designs in the first half of 2025. We believe our expanding footprint of clinical sites in the US and Europe has facilitated our ability to accelerate the pace of enrollment and dosing across the RESET program. With an average of one patient enrolling per week since November, we anticipate that we will generate sufficient data to further clarify rese-cel's profile across multiple indications this year to rapidly deliver its therapeutic potential for autoimmune patients."

Cabaletta is currently evaluating rese-cel in the RESET (REstoring SElf-Tolerance) clinical development program, which includes six company-sponsored Phase 1/2 clinical trials with disease-specific cohorts, spanning the therapeutic areas of rheumatology, neurology and dermatology. All cohorts are evaluating a weight-based single infusion of rese-cel following a preconditioning regimen of fludarabine and cyclophosphamide, except for the RESET-PV™ trial, which is evaluating weight-based dosing of rese-cel without preconditioning.

New and Updated Clinical Data Summary

As of the data cut-off date of January 8, 2025, 10 patients had been dosed with rese-cel across the RESET-Myositis™, RESET-SLE™ and RESET-SSc™ trials with sufficient follow-up to be evaluable, providing the following key insights:

- In the RESET-Myositis trial, the first adult dermatomyositis patient maintained a major total improvement score (TIS) improvement at 3 months post-infusion, off all immunosuppressants and tapering steroids, showing potential for achieving drug-free remission in patients with refractory myositis. In addition, initial clinical responses in the first 2 immune-mediated necrotizing myopathy (IMNM) patients continued to show more gradual improvement, consistent with published academic data, suggesting response kinetics may differ among myositis subtypes.
- In the RESET-SLE trial, 3 out of 4 patients in the non-renal systemic lupus erythematosus (SLE) cohort achieved DORIS (definition of remission in SLE) remission as of the most recent follow-up visit. The first patient dosed with rese-cel in the lupus nephritis (LN) cohort achieved a complete renal response (CRR). All 6 SLE and LN patients dosed, including these patients, demonstrated clinical responses off all immunosuppressants and steroids as of the data cut-off date.
- In the RESET-SSc trial, the first patient dosed with rese-cel in the severe skin cohort continued to demonstrate clinically meaningful skin improvements across an increasing number of body areas at 3 months post-infusion, in addition to improvement in lung function, after discontinuing all disease-specific therapies.
- Rese-cel consistently demonstrated deep depletion of B cells in the periphery within the first month of infusion. Tissue resident depletion consistent with the deep B cell depletion in circulation was confirmed by a lymph node biopsy in a systemic sclerosis patient. B cell repopulation has typically started around 2 months post-infusion and exhibited a transitional naïve phenotype, reflecting the production of new B cells after deep systemic depletion.
- Across the first 10 patients dosed with rese-cel with at least one month offollow-up, 90% experienced either no cytokine release syndrome (CRS) or grade 1 CRS (fever) and 90% experienced no immune effector cell-associated neurotoxicity syndrome.

Additional information can be accessed on the website of each scientific meeting. Presentation materials will be made available on the Posters & Publications section of the Company's website following each event.

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. 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 with a single weight-based dosing regimen across 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 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; the clinical significance of the clinical data read-out at upcoming scientific meetings; Cabaletta's belief that its expanding clinical experience with rese-cel underscores its potential to provide compelling clinical responses

without the need for immunosuppressants or steroids in patients with active, refractory autoimmune disease, as well as its belief that rese-cel has the potential to transform the disease outcome and the lives of patients with autoimmune disease; and Cabaletta's belief that its growing number of sites will allow it to continue accelerating the pace of enrollment and dosing across the RESET program, further enabling it to evaluate the emerging clinical profile of rese-cel and its therapeutic potential for autoimmune patients.

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.

Contacts:

Anup Marda
Chief Financial Officer
investors@cabalettabio.com