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

November 6, 2023
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. ☐

Item 7.01 Regulation FD Disclosure.

On November 6, 2023, Cabaletta Bio, Inc. (the "Company" or "Cabaletta") issued a press release announcing that the Company's fourth Investigational New Drug ("IND") application for CABA-201, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy, has been cleared by the U.S. Food and Drug Administration (the "FDA") for a Phase 1/2 study in patients with generalized myasthenia gravis (the "Press Release"). A copy of the Press Release is attached hereto 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 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 8.01 Other Events.

On November 6, 2023, the Company issued the Press Release announcing that the Company's fourth IND application for CABA-201, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy, has been allowed to proceed by the FDA for a Phase 1/2 study in patients with generalized myasthenia gravis ("gMG"). The Company plans to initiate a Phase 1/2 clinical trial of CABA-201 across two parallel gMG cohorts based on autoantibody status – one cohort of six patients with acetylcholine receptor ("AChR") antibody-positive gMG and a second cohort of six patients with AChR antibody-negative gMG. Consistent with the previously announced CABA-201 IND application clearances for lupus, myositis and systemic sclerosis, the starting dose for the Phase 1/2 trial evaluating CABA-201 in gMG will be 1 x 10^6 cells/kg.

Myasthenia gravis ("MG") is a rare autoimmune disease characterized by autoantibodies that interfere with signaling at the neuromuscular junction ("NMJ"), leading to potentially life-threatening muscle weakness. The majority of patients with MG have autoantibodies known to be pathogenic based on their interference with proteins in the NMJ, of which the majority target AChR. gMG affects approximately 85% of the between 50,000 and 80,000 estimated MG patients in the United States. Symptoms of gMG include profound muscle weakness throughout the body, disabling fatigue, shortness of breath due to respiratory muscle weakness and risk for episodes of respiratory failure. Standard of care therapies include cholinesterase inhibitors, steroids, immunomodulators, and biologics, which often provide modest clinical effect and require chronic administration, increasing the risk of serious long-term side effects.

The Phase 1/2 clinical trial will be an open-label study of CABA-201 in subjects with gMG across two parallel cohorts. The first cohort will include six patients with AChR antibody-positive gMG, and the second will include six patients with AChR antibody-negative gMG. Participants will receive a one-time infusion of CABA-201, using the same dose being used in the lupus, myositis and systemic sclerosis clinical trials of CABA-201, 1 x 10^6 cells/kg, preceded by a standard preconditioning regimen of fludarabine and cyclophosphamide. Key inclusion criteria include patients between ages 18 and 70 (inclusive), a diagnosis of gMG, and disease activity despite standard of care therapies. Key exclusion criteria include MG with only ocular manifestations, an active or untreated thymoma, and treatment with a B cell depleting agent within six months. As the fourth trial within Cabaletta's CARTA (Chimeric Antigen Receptor T cells for Autoimmunity) strategy, this study is intended to evaluate the potential ability of CABA-201 to transiently, but completely, eliminate B cells throughout the body.

Forward Looking Statements

The information under this Item 8.01 contains "forward-looking statements" of the Company within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including without limitation, express or implied statements regarding its expectations regarding: Cabaletta's ability to grow its autoimmune-focused pipeline; the anticipated market opportunities for CABA-201 in gMG patients; the Company's business plans and objectives; Cabaletta's expectations around the potential success and therapeutic benefits of CABA-201, including its belief in the potential forCABA-201 to provide a deep and durable, perhaps curative, outcome with a single dose in patients with gMG; the Cabaletta clinical operations team's ability to execute the gMG program based on experience with MG sites in the Company's legacy CAART platform; the Company's plans to initiate and progress separate Phase 1/2 clinical trials of CABA-201 in subjects with gMG, SSc, SLE and myositis; and Cabaletta's ability to enroll the requisite number of patients and dose each dosing cohort in the intended manner in its Phase 1/2 clinical trials of CABA-201. Any forward-looking statements in this Item 8.01 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 DSG3-CAART, MuSK-CAART and CABA-201; the risk that the results observed with the similarly-designed construct employed in the recent academic publications, including due to the dosing regimen, are not indicative of the results we seek to achieve withCABA-201; risks related to clinical trial site activation or enrollment rates that are lower than expected; risks related to unexpected safety or efficacy data observed during clinical studies; risks related to volatile market and economic conditions and public health crises; 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; 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 and subsequent filings with the Securities and Exchange Commission. All information in this Item 8.01 is as of the date of this Current Report on Form 8-K, and the Company undertakes no duty to update this information unless required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exbibits

99.1	Press Release issued by the registrant on November 6, 2023, 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: November 6, 2023

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

Cabaletta Bio®

Cabaletta Bio Receives FDA Clearance of CABA-201 IND Application for Treatment of Generalized Myasthenia Gravis

– First cleared CD19-CAR T IND application for generalized myasthenia gravis announced in the U.S. and fourth IND clearance for CABA-201 across a broad range of autoimmune diseases –

– Clearance expands the clinical development of CABA-201 beyond rheumatology into neurology –

– Phase 1/2 clinical trial evaluating CABA-201 in generalized myasthenia gravis features parallel cohort design and a starting dose consistent with the previously announced Phase 1/2 trials of CABA-201 for lupus, myositis and systemic sclerosis –

PHILADELPHIA, Nov. 6, 2023 – Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies for patients with autoimmune diseases, today announced that the Company's fourth Investigational New Drug (IND) application for CABA-201, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy, has been allowed to proceed by the U.S. Food and Drug Administration (FDA) for a Phase 1/2 study in patients with generalized myasthenia gravis (gMG). The Company plans to initiate a Phase 1/2 clinical trial of CABA-201 across two parallel gMG cohorts based on autoantibody status – one cohort of six patients with acetylcholine receptor (AChR) antibody-positive gMG and a second cohort of six patients with AChR antibody-negative gMG. Consistent with the previously announced CABA-201 IND application clearances for lupus, myositis and systemic sclerosis, the starting dose for the Phase 1/2 trial evaluating CABA-201 in gMG will be 1 x 10^6 cells/kg.

"While we remain on track to deliver initial clinical data from CABA-201 treated patients with lupus and/or myositis in the first half of 2024, we are continuing to expand our CABA-201 portfolio beyond rheumatology and into neurology. The announcement of our fourth CABA-201 IND clearance is also our first IND clearance for the product candidate in a predominantly autoantibody mediated disease. Consistent with previously announced CABA-201 trials, the Phase 1/2 clinical trial design for CABA-201 in gMG includes the same starting dose as used in the previously cleared clinical trials with CABA-201 and parallel cohorts of six patients. While prioritizing delivery of initial clinical data in the first half of 2024 from our myositis and/or lupus trials, our clinical operations team is well positioned to execute the gMG program based on experience with MG sites in our legacy CAART platform," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "Despite recent advances with chronic, broadly immunosuppressive therapies, we believe there is an unmet need for a treatment option like CABA-201 that may provide a deep and durable, perhaps curative, outcome with a single dose in patients with gMG."

Myasthenia gravis (MG) is a rare autoimmune disease characterized by autoantibodies that interfere with signaling at the neuromuscular junction (NMJ), leading to potentially life-threatening muscle weakness. The majority of patients with MG have autoantibodies known to be pathogenic based on their interference with proteins in the NMJ, of which the majority target AChR. Generalized MG affects approximately 85% of the between 50,000 and 80,000 estimated MG patients in the United States. Symptoms of gMG include profound muscle weakness throughout the body, disabling fatigue, shortness of breath due to respiratory muscle weakness and risk for episodes of respiratory failure. Standard of care therapies include cholinesterase inhibitors, steroids, immunomodulators, and biologics, which often provide modest clinical effect and require chronic administration, increasing the risk of serious long-term side effects.

About the Phase 1/2 Clinical Trial ofCABA-201 in gMG

The Phase 1/2 clinical trial will be an open-label study ofCABA-201 in subjects with gMG across two parallel cohorts. The first cohort will include six patients with AChR antibody-positive gMG, and the second will include six patients with AChR antibody-negative gMG. Participants will receive a one-time infusion of CABA-201, using the same dose being used in the lupus, myositis and systemic sclerosis clinical trials ofCABA-201, 1 x 10^6 cells/kg, preceded by a standard preconditioning regimen of fludarabine and cyclophosphamide. Key inclusion criteria include patients between ages 18 and 70 (inclusive), a diagnosis of gMG, and disease activity despite standard of care therapies. Key exclusion criteria include myasthenia gravis with only ocular manifestations, an active or untreated thymoma, and treatment with a B cell depleting agent within six months. As the fourth trial within Cabaletta's CARTA (Chimeric Antigen Receptor T cells for Autoimmunity) strategy, this study is intended to evaluate the potential ability of CABA-201 to transiently, but completely, eliminate B cells throughout the body.

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 systemic lupus erythematosus, myositis, systemic sclerosis and generalized myasthenia gravis, and 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 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 its expectations regarding: Cabaletta's ability to grow its autoimmune-focused pipeline; the ability to capitalize on and potential benefits resulting from published third-party academic clinical data; the anticipated market opportunities for CABA-201 in gMG patients; the Company's business plans and objectives; Cabaletta's expectations around the potential success and therapeutic benefits of CABA-201, including its belief in the potential forCABA-201 to provide a deep and durable, perhaps curative, outcome with a single dose in patients with gMG; the Cabaletta clinical operations team's ability to execute the gMG program based on experience with MG sites in the Company's legacy CAART platform; the Company's plans to initiate and progress separate Phase 1/2 clinical trials of CABA-201 in subjects with gMG, SSc, SLE and myositis; the Company's planned initial clinical data read-out from the CABA-201 program in the first half of 2024; and Cabaletta's ability to enroll the requisite number of patients and dose each dosing cohort in the intended manner in its Phase 1/2 clinical trials of CABA-201.

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 DSG3-CAART, MuSK-CAART and CABA-201; the risk that the results observed with the similarly-designed construct employed in the recent 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 or enrollment rates that are lower than expected; 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 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 and 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.

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