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

August 29, 2022
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 8.01 Other Events.

On August 29, 2022, Cabaletta Bio, Inc. issued a press release announcing that it will present new clinical and translational data from cohort A4 and safety data from cohort A5 in the DesCAARTes™ trial of DSG3-CAART in a late-breaking oral presentation at the upcoming 31st European Academy of Dermatology and Venereology (EADV) Congress. A copy of the full text of the press release referenced above is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference into this Item 8.01 of this Current Report onForm 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by the registrant on August 29, 2022.
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: August 29, 2022

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

Exhibit 99.1

Cabaletta Bio®

Cabaletta Bio to Present Data at the 31st EADV Congress and Provides Update on DesCAARTes™ Trial

PHILADELPHIA, Aug. 29, 2022 — Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on the discovery and development of targeted cell therapies for patients with autoimmune diseases, today announced that it will present new clinical and translational data from cohort A4 and safety data from cohort A5 in the DesCAARTes™ trial of DSG3-CAART in a late-breaking oral presentation at the upcoming 31st European Academy of Dermatology and Venereology (EADV) Congress, which is being held virtually and in person in Milan, Italy from September 7-10, 2022.

Details of the presentation are as follows:

Title: A Phase 1 trial of DSG3-CAART cells in mucosal-dominant pemphigus vulgaris patients: preliminary data
Abstract Number: 3551
Session Title: Late-breaking news
Date and Time: Saturday, September 10, 2022, 10:30 a.m. – 10:45 a.m. CEST
Presenter: David J. Chang, M.D., Chief Medical Officer at Cabaletta Bio

In addition to this late-breaking presentation, Aimee Payne, M.D., Ph.D., a Professor of Dermatology at the Perelman School of Medicine at the University of Pennsylvania, co-chair of the Cabaletta Bio Scientific Advisory Board and co-founder of Cabaletta Bio, will deliver an invited talk titled “Bench to bedside development of CA(A)R T cells in dermatology” on Friday, September 9, 2022, at 11:15 a.m. CEST.

The DesCAARTes™ Phase 1 trial is an open-label, dose escalation, multi-center study of DSG3-CAART in adults with mucosal-dominant pemphigus vulgaris (mPV). The trial is designed to determine the maximum tolerated dose of DSG3-CAART in adult subjects with active, anti-DSG3 Ab positive, biopsy confirmed mPV that is inadequately managed by one or more standard therapies. The primary endpoint is incidence of adverse events (AEs), including dose-limiting toxicities (DLTs), such as cytokine release syndrome (CRS) and neurotoxicity, related to DSG3-CAART within three months of infusion. Secondary endpoints include CAART persistence (qPCR), anti-DSG3 Ab levels (ELISA) and disease activity (PDAI).

Based on the evaluation of emerging data in cohorts A4 and A5, which will be presented at the EADV Congress, and subject to the finalization of the study protocol, as applicable, Cabaletta plans to prioritize initiation of the cohort in the combination sub-study (2.5 billion cells in addition to patient pre-treatment with intravenous immunoglobulin [IVIg] and cyclophosphamide) relative to its other additional planned cohort, cohort A6m (multi-dose regimen at 10 to 15 billion total cells).

“The totality of the data generated to date from the DesCAARTes™ trial has provided important insights that have guided our efforts to enhance *in vivo* DSG3-CAART exposure. We believe that the prioritization of a planned combination cohort with intravenous immunoglobulin and cyclophosphamide administered prior to DSG3-CAART infusion represents a preferred approach to potentially further increase DSG3-CAART exposure and activity, which we believe may generate clinical responses in patients with mPV,” said David Chang, M.D., Chief Medical Officer of Cabaletta.

Additional information, including the EADV abstract as submitted in July 2022, can be found at https://www.cabalettabio.com/technology/posters-publications. Presentation materials will be made available under the Posters & Publications section of the Company's website shortly after the event.

About CAAR T Cell Therapy

Chimeric AutoAntibody Receptor (CAAR) T cells are designed to selectively bind and eliminate only disease-causing B cells, while sparing the normal B cells that are essential for human health. CAAR T cells are based on the chimeric antigen receptor (CAR) T cell technology. While CAR T cells typically contain a CD 19-targeting molecule, CAAR T cells express an autoantibody-targeted antigen on their surface. Theco-stimulatory domain and the signaling domain of both a CAR T cell and a CAAR T cell carry out the same activation and cytotoxic functions. Thus, Cabaletta's CAARs are designed to direct the patient's T cells to kill only the pathogenic cells that express disease-causing autoantibodies on their surface, potentially leading to complete and durable remission of disease while sparing all other B cell populations that provide beneficial immunity from infection.

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, in combination with Cabaletta Bio's proprietary technology, has advanced a growing pipeline that currently includes potential treatments for patients with mucosal pemphigus vulgaris, MuSK-associated myasthenia gravis, PLA2R-associated membranous nephropathy, mucocutaneous pemphigus vulgaris and hemophilia A with FVIII alloantibodies. Cabaletta Bio's headquarters are located in Philadelphia, PA. For more information, visit www.cabalettabio.com and follow us on LinkedIn.

University of Pennsylvania Financial Disclosure

Dr. Payne is a Penn faculty member, scientific collaborator, key advisor, and co-founder of Cabaletta Bio. As such, she holds an equity stake in the Company, her laboratory at Penn receives sponsored research funding from Cabaletta Bio, and as an inventor of the licensed technology she may receive additional future financial benefits under licenses granted by Penn to Cabaletta Bio. The University of Pennsylvania may also receive future financial benefit under licenses it has granted to Cabaletta Bio.

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 expectations regarding: Cabaletta's ability to grow its autoimmune-focused pipeline; the progress and results of its DesCAARTes™ Phase 1 trial, including Cabaletta's ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and progress the trial; the expected significance and impact around the clinical and translational data updates to be provided at the scientific meeting described herein and the expected timing and significance around additional clinical data updates from the DesCAARTes™ trial at additional scientific meetings throughout 2022 and 2023; the

expectation that Cabaletta may improve outcomes for patients suffering from mPV; Cabaletta's ability to escalate dosing as high as 10 to 15 billion cells in a planned future cohort, initiate dosing in a combination cohort or otherwise; Cabaletta's plans to implement a pre-treatment regimen; Cabaletta's ability to advance dose escalation in the DesCAARTes™ Phase 1 trial at the current dose ranges for the current cohorts and any projected potential dose ranges for future cohorts, and to optimize its targeted cell therapy; Cabaletta's ability to evaluate, and the potential significance of, the relationship between DSG3-CAART persistence and potential clinical responses in patients with mPV; trial; expectations regarding the design, implementation, timing and success of its current and planned clinical trials and the successful completion of nonclinical studies; planned potential timing and advancement of its preclinical studies and clinical trials and related regulatory submissions; ability to optimize the impact of its collaborations on its development programs; the impact of COVID-19 on the timing, progress, interpretability of data, and results of ongoing or planned preclinical and clinical trials; statements regarding the timing of regulatory filings regarding its development programs.

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: 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 and clinical trials of DSG3-CAART; the risk that persistence observed with effective CART-19 oncology studies in combination with lymphodepletion is not indicative of, or applicable to, clinical responses in patients with mPV; Cabaletta's ability to retain and recognize the intended incentives conferred by Orphan Drug Designation and Fast Track Designation for DSG3-CAART for improving healing of mucosal blisters in patients with mucosal pemphigus vulgaris; 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 the impact of public health epidemics, such as the ongoing COVID-19 pandemic, affecting countries or regions in which we have operations or do business; risks related to Cabaletta's ability to protect and maintain its intellectual property position; 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 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.

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