
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

May 2, 2022
Date of Report (Date of earliest event reported)

CABALETTA BIO, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

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

001-39103
(Commission
File Number)

82-1685768
(I.R.S. Employer
Identification No.)

19104
(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 May 2, 2022, Cabaletta Bio, Inc. issued a press release announcing that data from its two lead programs, DSG3-CAART and MuSK-CAART, will be presented at multiple upcoming scientific meetings in May 2022. A copy of the full text of the press release referenced above is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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 9.01. Financial Statements and Exhibits.**(d) Exhibits**

99.1 [Press Release issued by the registrant on May 2, 2022, 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: May 2, 2022

By: /s/ Steven Nichtberger

Steven Nichtberger, M.D.

President and Chief Executive Officer



Cabaletta Bio to Present DSG3-CAART Clinical Data and
MuSK-CAART Preclinical Data at Upcoming Scientific
Meetings in May

PHILADELPHIA, May 2, 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 data from its two lead programs, DSG3-CAART and MuSK-CAART, will be presented at multiple upcoming scientific meetings in May 2022. The DSG3-CAART presentations will include Phase 1 clinical data from the ongoing DesCAARTes™ trial. The MuSK-CAART presentations will contain preclinical safety and activity studies to support potential clinical development of precision engineered T-cell therapy for MuSK-associated myasthenia gravis.

Desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells are currently being evaluated in the Phase 1 DesCAARTes™ trial as a potential treatment for patients with mucosal pemphigus vulgaris (mPV). Details of the presentations are as follows:

American Society of Gene & Cell Therapy 25th Annual Meeting at Walter E. Washington Convention Center in Washington, D.C. from May 16-19, 2022

Title: A Phase 1 Trial of Targeted DSG3-CAART Cell Therapy in Mucosal-Dominant Pemphigus Vulgaris (mPV) Patients: Early Cohort Data

Abstract Number: 793

Poster Number: Tu-298

Date and Time: Tuesday, May 17, 2022, 5:30 p.m. – 6:30 p.m. ET

Presenter: David J. Chang, M.D., Chief Medical Officer at Cabaletta Bio

Title: Characterization of DSG3-CAART Cells Prior to & Following Adoptive Transfer in Mucosal Pemphigus Vulgaris

Abstract Number: 698

Poster Number: Tu-203

Date and Time: Tuesday, May 17, 2022, 5:30 p.m. – 6:30 p.m. ET

Presenter: Samik Basu, M.D., Chief Scientific Officer at Cabaletta Bio

In addition to these poster presentations, 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 at Cabaletta Bio, will deliver a presentation titled “Genetically Engineered CAAR T Cell Therapies for B cell-mediated Autoimmune Diseases” on Wednesday, May 18, 2022, at 9:12 a.m. ET.

Society For Investigative Dermatology 2022 Annual Meeting at Oregon Convention Center in Portland, OR from May 18-21, 2022

Title: A phase 1 trial of DSG3-CAART cells in mucosal-dominant pemphigus vulgaris (mPV) patients: Preliminary data

Abstract Number: LB952

Date and Time: Friday, May 20, 2022, 4:30 p.m. – 6:30 p.m. PT

Presenter: 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 at Cabaletta Bio

Cabaletta plans to begin a clinical study in 2022 to evaluate muscle-specific kinase (MuSK) chimeric autoantibody receptor T (MuSK-CAART) cells as a potential treatment for patients with MuSK-associated myasthenia gravis. Details of the presentations on the MuSK-CAART program are as follows:

American Association of Immunologists IMMUNOLOGY2022™ at Oregon Convention Center in Portland, OR from May 6-10, 2022

Title: Adoptive immunotherapy for MuSK subtype myasthenia gravis

Session Title: NextGen Transformative Immunologic Therapies for Human Disease

Date and Time: Sunday, May 8, 2022, 8:00 a.m. – 10:00 a.m. PT

Location: Room A107-109

Presenter: Samik Basu, M.D., Chief Scientific Officer at Cabaletta Bio

14th MGFA International Conference On Myasthenia And Related Disorders at Hyatt Regency Hotel in Miami, FL from May 10-12, 2022

Title: Preclinical Safety and Activity Studies Supporting Precision Engineered T-Cell Therapy for MuSK Myasthenia Gravis

Date and Time: Tuesday, May 10, 2022, 6:00 p.m. – 7:30 p.m. ET and Wednesday, May 11, 2022, 6:00 p.m. – 7:30 p.m. ET

Location: Regency Ballroom

Presenter: Jinmin Lee, Ph.D., Associate Principal Scientist at Cabaletta Bio

In addition to this presentation, Dr. Aimee Payne will deliver a presentation titled “Precision Cellular Immunotherapy for Myasthenia Gravis” on Tuesday, May 10, 2022, at 11:30 a.m. ET.

American Society of Gene & Cell Therapy 25th Annual Meeting at Walter E. Washington Convention Center in Washington, D.C. from May 16-19, 2022

Title: Muscle-Specific Tyrosine Kinase Chimeric Autoantibody Receptor T Cells (MuSK-CAART): A Precision Cellular Immunotherapy for Antigen-Specific B Cell Depletion in MuSK Myasthenia Gravis

Session Title: Musculo-skeletal Diseases

Abstract Number: 29

Date and Time: Monday, May 16, 2022, 10:15 a.m. – 10:30 a.m. ET

Location: Salon G

Presenter: Sangwook Oh, Ph.D., a Senior Research Investigator in Dr. Payne’s lab at the University of Pennsylvania

Additional information, including the [ASGCT abstracts](#) as submitted in February 2022, can be found on the respective scientific conferences’ websites. 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. The co-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 around the clinical data updates to be provided at the scientific meetings 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; expectations regarding the intended incentives conferred by Fast Track Designation for MuSK-CAART to improve activities of daily living and muscle strength in patients with MuSK antibody-positive myasthenia gravis; the expectation that Cabaletta Bio may improve outcomes for patients suffering from MuSK MG; plans to initiate patient dosing in an open-label Phase 1 clinical trial to evaluate MuSK-CAART safety and tolerability in MuSK MG patients in 2022; Cabaletta's ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and progress the MusCAARTes™ trial; the ability of MuSK-CAART to target B cells that differentiate into antibody secreting cells, which produce autoantibodies against muscle-specific kinase; the expected significance around

the preclinical data updates to be provided at the scientific meetings described herein; Cabaletta's plans to advance development of its preclinical pipeline; presentation of additional data at upcoming scientific conferences, and other preclinical data; 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 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 and MuSK-CAART; 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; 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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