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 12, 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 2.02 Results of Operations and Financial Condition.

On May 12, 2022, Cabaletta Bio, Inc. (the "Company") announced its financial results for the first quarter ended March 31, 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form8-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 12, 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 12, 2022

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

Exhibit 99.1

Cabaletta Bio®

Cabaletta Bio Reports First Quarter 2022 Financial Results and Provides Business Update

– DesCAARTes™ trial clinical and translational data from cohorts A3 and A4 and28-day safety data from cohort A5 expected to be presented at upcoming scientific meetings in mid-2022

– Multiple abstracts accepted for presentation at upcoming ASGCT and SID Annual Meetings

– MuSK-CAART first-in-human trial on track to commence in 2022 following Fast Track Designation and IND clearance from the FDA

PHILADELPHIA, May 12, 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 reported financial results for the first quarter ended March 31, 2022, and provided a business update.

"The favorable safety profile from the first four cohorts in the dose escalation phase of our ongoing DesCAARTes™ Phase 1 trial supports our ability to increase in vivo DSG3-CAART exposure to treat patients diagnosed with mucosal pemphigus vulgaris. We look forward to presenting clinical and translational data from the DesCAARTes™ trial at the upcoming ASGCT and SID annual meetings. We continue to progress cohort A5 at a range of 5.0 to 7.5 billion cells. Absent any dose limiting toxicities, we believe we can advance to a dose as high as 10 to 15 billion cells as we continue to optimize our targeted cell therapy in patients with mPV," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "We are also applying our insights learned from the DesCAARTes™ trial as we plan for the initiation of ourfirst-in-human trial of MuSK-CAART for MuSK antibody positive myasthenia gravis this year. We believe these data and learnings advance our efforts toward delivering deep, durable, and potentially curative, responses for patients with autoimmune diseases."

Pipeline Highlights and Anticipated Upcoming Milestones

DSG3-CAART: Desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells as a potential treatment for patients with mucosal pemphigus vulgaris (mPV).

- **DesCAARTes™ Trial Progressing in Cohort A5:** The cohort A5 dose range is 5.0 to 7.5 billion DSG3-CAART cells administered in two fractionated infusions. Assuming no dose limiting toxicities are observed, Cabaletta plans to provide cohort A5 one-month safety data and clinical and translational data from cohorts A3 (500 million cells) and A4 (2.5 billion cells), along with additional details about the planned manufacturing enhancement process, at scientific meetings in mid-2022.
- **Multiple upcoming data presentations at American Society of Gene & Cell Therapy (ASGCT) 25th Annual Meeting and Society For Investigative Dermatology (SID) 2022 Annual Meeting:** Clinical and translational data from the ongoing Phase 1 DesCAARTes™ trial will be presented at the ASGCT and SID meetings.

MuSK-CAART: Muscle-specific kinase (MuSK) chimeric autoantibody receptor T (MuSK-CAART) cells as a potential treatment for patients with MuSK-associated myasthenia gravis.

- **First-in-human trial on track to commence in 2022:** Cabaletta plans to initiate the MusCAARTes™ trial in 2022 and will evaluate MuSK-CAART as a potential treatment for patients with MuSK-associated myasthenia gravis. The trial will be an open-label study consisting of two parts: (i) a dose escalation phase to determine the maximum tolerated dose with two patients planned per cohort for three cohorts and six patients at the highest selected dose and (ii) a cohort expansion phase at the final selected dose. The planned trial incorporates design insights and enhancements supported by data from the DesCAARTes™ trial, including a higher starting dose (100 million MuSK-CAART cells versus 20 million DSG3-CAART cells), a single infusion administration (versus 2-4 infusion fractions of the full dose in the DesCAARTes™ trial), and a 2+4 design strategy. The trial is expected to enroll approximately 24 patients across multiple clinical sites throughout the United States. Cabaletta has established its manufacturing process with WuXi Advanced Therapies, Inc., which will serve as its Good Manufacturing Practices manufacturing partner for the MusCAARTes™ trial.
- **MuSK-CAART granted Fast Track Designation by FDA:** In February 2022, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to MuSK-CAART to improve activities of daily living and muscle strength in patients with MuSK antibody-positive myasthenia gravis. This designation may facilitate the potential for expedited development and review of MuSK-CAART by conferring potential benefits to the program, including the opportunity for more frequent meetings and interactions with the FDA during the clinical development period as well as eligibility for accelerated approval and/or priority review, if relevant criteria are met.
- **Presented preclinical data at the 14th Myasthenia Gravis Foundation of America (MGFA) International Conference On Myasthenia And Related Disorders and American Association of Immunologists (AAI) IMMUNOLOGY2022™:** In May 2022, Jinmin Lee, Ph.D., Associate Principal Scientist and Head of Cellular Immunology at Cabaletta Bio, presented preclinical safety and activity studies supporting precision engineered T-cell therapy for MuSK myasthenia gravis at the MGFA International Conference. In addition, Samik Basu, M.D. delivered an oral presentation on adoptive immunotherapy for MuSK subtype myasthenia gravis at AAI.
- **Upcoming ASGCT data presentation**: Data from preclinical safety and activity studies supporting the potential clinical development of a precision-engineered T-cell therapy for MuSK-associated myasthenia gravis will be presented at ASGCT.

PLA2R-CAART: Phospholipase A2 receptor (PLA2R) chimeric autoantibody receptor T (PLA2R-CAART) cells as a potential treatment for patients with PLA2R-associated membranous nephropathy.

- **Progressing PLA2R-CAART toward clinical development:** Following the completion of a routine pre-Investigational New Drug (IND) interaction with the FDA in the fourth quarter of 2021, Cabaletta has continued preclinical activities associated with preparing PLA2R-CAART for an IND submission and subsequent clinical development.

Upcoming Events

- Multiple abstracts to be presented for two lead programs, DSG3-CAART and MuSK-CAART, at ASGCT, which is being held at the Walter E. Washington Convention Center in Washington, D.C. from May 16-19, 2022.
- Data from the DSG3-CAART program will be presented at SID, which is being held at the Oregon Convention Center in Portland, OR from May 18-21, 2022.
- Cabaletta will participate in the H.C. Wainwright Global Investment Conference, which is being held virtually and in person in Miami, FL from May 23-26, 2022.

First Quarter 2022 Financial Results

- Research and development expenses were $9.2 million for the three months ended March 31, 2022, compared to $6.6 million for the same period in 2021.
- General and administrative expenses were $3.8 million for the three months ended March 31, 2022, compared to $3.2 million for the same period in 2021.
- As of March 31, 2022, Cabaletta had cash, cash equivalents and investments of $109.2 million, compared to $122.2 million as of December 31, 2021.

The Company expects that its cash, cash equivalents and investments as of March 31, 2022 will enable it to fund its operating plan through the third quarter of 2023.

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.

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 meetings described herein; the expected timing and significance of the announcement of 28-day safety for cohort A5 and clinical and translational data for cohorts A3 and A4 in mid-2022; the expectation that Cabaletta may improve outcomes for patients suffering from mPV; Cabaletta's ability to continue progressing in cohort A5 and to escalate dosing as high as 10 to 15 billion cells; 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; 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 and impact around the preclinical data updates to be provided at the scientific meetings described herein; the ability of WuXi Advanced Therapies to supply sufficient quality and quantity of MuSK-CAART for the planned MusCAARTes™ trial; Cabaletta's plans to advance development of its preclinical pipeline; the effectiveness and timing of product candidates that Cabaletta may develop, including in collaboration with academic partners; 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 continue its growth and realize the anticipated contribution of the members of its board of directors and executives to its operations and progress; 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; use of capital, expenses, future accumulated deficit and other financial results in the future; and ability to fund operations through the third quarter of 2023.

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; 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; Cabaletta's ability to retain and recognize 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; 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 fostering and maintaining successful relationships with Cabaletta's manufacturing partners; 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.

Statements of Operations

	Three Months Ended March 31,	
	2022	2021
	Unaudited	
Operating expenses:		
Research and development	$ 9,170	$ 6,556
General and administrative	3,829	3,156
Total operating expenses	12,999	9,712
Loss from operations	(12,999)	(9,712)
Other income:		
Interest income	53	10
Net loss	(12,946)	(9,702)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.45)	$ (0.41)

Selected Balance Sheet Data

	March 31, 2022	December 31, 2021
	(unaudited)	
Cash, cash equivalents and investments	$109,213	$ 122,222
Total assets	113,655	126,336
Total liabilities	6,935	8,380
Total stockholders' equity	106,720	117,956

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