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 10, 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 2.02 Results of Operations and Financial Condition.

On August 10, 2023, Cabaletta Bio, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 2023. 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 August 10, 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: August 10, 2023

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

Cabaletta Bio®

Cabaletta Bio Reports Second Quarter 2023 Financial Results and Provides Business Update

– Received second IND application clearance for CABA-201 in myositis as well as Fast Track Designation in SLE and LN –

– Strengthened balance sheet by closing $100M public offering extending cash runway into the fourth quarter of 2025 –

PHILADELPHIA, Aug. 10, 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 reported financial results for the second quarter ended June 30, 2023, and provided a business update.

"As we continue to pursue our vision of launching the first CD19CAR-T product for patients with autoimmune diseases, we accelerated the progress of CABA-201 in the first half of 2023 by securing FDA clearance to initiate two separate and efficiently designed Phase 1/2 clinical trials in patients with systemic lupus erythematosus and myositis. With separate parallel cohorts in each trial, we are well positioned to rapidly evaluate and develop CABA-201 for patients with autoimmune diseases," said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. "Backed by a strong balance sheet that we believe positions us to deliver on our milestones, we continue to expect 3-month clinical data for initial patients treated with CABA-201 by the first half of 2024. With expanding clinical evidence in the field, we look forward to building on our momentum and advancing our mission to develop and launch the first curative targeted cellular therapies for patients with autoimmune diseases."

Recent Operational Highlights and Upcoming Anticipated Milestones

Chimeric Antigen Receptor T cells for Autoimmunity (CARTA) Strategy

CABA-201: Autologous, engineered T cells with a chimeric antigen receptor containing a fully human CD19 binder and a 4-1BB co-stimulatory domain as a potential treatment for a broad range of autoimmune diseases where B cells contribute to the initiation and/or maintenance of disease.

- **Preparations on track to initiate clinical trials of CABA-201:** The Company plans to initiate a Phase 1/2 clinical trial of CABA-201 for the treatment of systemic lupus erythematosus (SLE), including two separate parallel cohorts of six SLE patients with active lupus nephritis (LN) and six patients with active SLE without renal involvement. In addition, the Company plans to initiate a Phase 1/2 clinical trial of CABA-201 for the treatment of idiopathic inflammatory myopathy (myositis), including three separate parallel cohorts of six patients with dermatomyositis (DM), six patients with anti-synthetase syndrome (ASyS), and six patients with immune-mediated necrotizing myopathy (IMNM). An initial CABA-201 dose of 1.0×10^6 is expected to be used in both trials for SLE and myositis. Cabaletta anticipates generating 3-month clinical data on efficacy and tolerability in initial CABA-201 treated patients by the first half of 2024.

- **Second IND application for CABA-201 cleared:** In May 2023, Cabaletta announced that the U.S. Food and Drug Administration (FDA) cleared the Company's second Investigational New Drug (IND) application for CABA-201 for a Phase 1/2 study in patients with active myositis.
- **Granted Fast Track Designation in LN and SLE by FDA:** In May 2023, Cabaletta announced that the FDA granted Fast Track Designation to CABA-201, which is designed to deplete CD19-positive B cells and improve disease activity in patients with LN and SLE. This designation may facilitate the potential for expedited review and development of CABA-201 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 new preclinical data at ASGCT 26th Annual Meeting:** In May 2023, Cabaletta presented IND-enabling preclinical data for CABA-201 which characterized the specificity and activity of CABA-201 in a poster presentation at the American Society of Gene and Cell Therapy (ASGCT) 26th Annual Meeting.

Chimeric AutoAntibody Receptor T (CAART) cells Strategy

- **DSG3-CAART:** Cabaletta is evaluating desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells as a potential treatment for patients with mucosal pemphigus vulgaris (mPV). Based on updated clinical and translational data from the ongoing DesCAARTes™ trial that showed combination therapy with intravenous immunoglobulin (IVIg) and cyclophosphamide modestly increased DSG3-CAART persistence and activation, the Company has initiated enrollment in an additional combination cohort where patients are pre-treated with IVIg, cyclophosphamide and fludarabine prior to DSG3-CAART infusion.
- **MuSK-CAART:** Cabaletta is evaluating muscle-specific kinase (MuSK) chimeric autoantibody receptor T (MuSK-CAART) cells as a potential treatment for patients with MuSK-associated myasthenia gravis (MG). Based on emerging data from the DesCAARTes™ study, clinical trial timelines are under evaluation for the Phase 1, open-label MusCAARTes™ study of MuSK-CAART in patients with MuSK autoantibody-positive MG.

Corporate Updates

- **Raised $93.8 million in net proceeds from public offering:** In May 2023, Cabaletta closed an underwritten public offering of 8,337,500 shares of its common stock, including the exercise in full by the underwriters of their option to purchase an additional 1,087,500 shares, at the public offering price of $12.00 per share. The net proceeds raised in the offering, after underwriting discounts and commissions and estimated expenses of the offering, were approximately $93.8 million.

- **Appointed Shawn Tomasello to Board of Directors:** In July 2023, Shawn Tomasello joined the Company's Board of Directors and became a member of the Compensation and Science & Technology Committees. Ms. Tomasello most recently served as the Chief Commercial Officer of Kite Pharma, now part of Gilead Sciences, where she oversaw the global commercialization of Yescarta®, the first approved CAR-T therapy for non-Hodgkin lymphoma.

Upcoming Events

Cabaletta plans to participate in the following upcoming investor conferences:

- Citi's 18th Annual BioPharma Conference, which is being held September 6-7, 2023 in Boston, MA.
- Wells Fargo Healthcare Conference, which is being held from September 6-8, 2023 in Boston, MA.
- Morgan Stanley 21st Annual Global Healthcare Conference, which is being held from September 11-13, 2023 in New York, NY.
- H.C. Wainwright 25th Annual Global Investment Conference, which is being held from September 11-13, 2023 in New York, NY.
- 2023 Cantor Global Healthcare Conference, which is being held from September 26-28, 2023 in New York, NY.

Second Quarter 2023 Financial Results

- Research and development expenses were $11.8 million for the three months ended June 30, 2023, compared to $9.5 million for the same period in 2022.
- General and administrative expenses were $4.1 million for the three months ended June 30, 2023, compared to $3.5 million for the same period in 2022.
- As of June 30, 2023, Cabaletta had cash, cash equivalents and short-term investments of $176.3 million, compared to $106.5 million as of December 31, 2022.

The Company expects that its cash, cash equivalents and short-term investments as of June 30, 2023, will enable it to fund its operating plan into the fourth quarter of 2025.

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 and myositis, 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; its plans around CABA-201, including its ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner and advance the separate Phase 1/2 clinical trials of CABA-201 in each indication, as well as leverage the potential therapeutic benefits from using the initial dose used in the September 2022 *Nature Medicine* publication; Cabaletta's ability to retain and recognize the intended incentives conferred from the Fast Track Designation for CABA-201; the Company's business plans and objectives; the progress and results of its DesCAARTes™ Phase 1 trial, including Cabaletta's ability to enroll the requisite number of patients in the additional combination cohort, dose each dosing cohort in the intended manner, and progress the trial; expectations for the MusCAARTes™ Phase 1 trial, including potential trial timelines and the therapeutic benefits of MuSK-CAART; statements regarding anticipated significance of, and timing of release of, efficacy endpoints and tolerability data for CABA-201 and its safety and persistence data and combination sub-study cohort data for its DesCAARTes trial; statements regarding regulatory filings for its development programs, including the planned timing of such regulatory filings and potential review by such regulatory authorities; the expectation that Cabaletta Bio may improve outcomes for patients suffering from SLE, mPV, MG, or other autoimmune diseases as well as expected therapeutic benefits of the Company's product candidates; the ability to accelerate Cabaletta's pipeline and develop meaningful therapies for patients, including in collaboration with academic and industry partners and the ability to optimize such collaborations on its development programs; use of capital, expenses, future accumulated deficit and other financial results in the future; availability of funding for existing programs; and ability to fund operations into the fourth quarter of 2025.

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 *Nature Medicine* publication, 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 subsequent and 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.

CABALETTA BIO, INC.
SELECTED FINANCIAL DATA
(unaudited; in thousands, except share and per share data)

Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	unaudited		unaudited	
Operating expenses:				
Research and development	$ 11,797	$ 9,514	$ 24,232	$ 18,684
General and administrative	4,093	3,546	8,614	7,375
Total operating expenses	15,890	13,060	32,846	26,059
Loss from operations	(15,890)	(13,060)	(32,846)	(26,059)
Other income:				
Interest income	1,403	150	2,505	203
Net loss	(14,487)	(12,910)	(30,341)	(25,856)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.37)	$ (0.45)	$ (0.81)	$ (0.89)

Selected Balance Sheet Data

	June 30, 2023	December 31, 2022
	(unaudited)	
Cash, cash equivalents and investments	$176,328	$ 106,547
Total assets	184,637	116,968
Total liabilities	10,496	12,448
Total stockholders' equity	174,141	104,520

Contacts:

Anup Marda
Chief Financial Officer
investors@cabalettabio.com

William Gramig
Stern Investor Relations, Inc.
william.gramig@sternir.com