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 10, 2020
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 November 10, 2020, Cabaletta Bio, Inc. announced its financial results for the third quarter ended September 30, 2020. 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 Form 8-K 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 November 10, 2020, furnished herewith.

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 10, 2020

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

Cabaletta Bio™

Cabaletta Bio Reports Third Quarter 2020 Financial Results and Provides Business Update

PHILADELPHIA, PA – November 10, 2020 – Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies for patients with B cell-mediated autoimmune diseases, today announced financial results for the third quarter ended September 30, 2020 and provided a business update.

"With patient enrollment now underway for our lead program, DSG3-CAART, for patients with mucosal pemphigus vulgaris, we are on track to report acute safety data from the first cohort of patients in the first half of next year. During the quarter, we opened a second site for the trial and also published comprehensive preclinical proof of concept data in *The Journal of Clinical Investigation* further validating the mechanism of action of DSG3-CAART," said Steven Nichtberger, M.D., Chief Executive Officer and co-founder of Cabaletta.

Pipeline Highlights and Anticipated Upcoming Milestones

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

- The Company's open-label Phase 1 clinical trial (DesCAARTes™) to evaluate the safety and tolerability of DSG3-CAART in relapsed/refractory mPV patients is actively recruiting patients at the first two sites in the U.S. The Company expects to report acute safety data from the initial cohort in the study in the first half of 2021.
- In August 2020, the Company announced that comprehensive preclinical data for DSG3-CAART were published in *The Journal of Clinical Investigation*. These data demonstrated that DSG3-CAART achieved autoantibody elimination and resolution of blisters in an active immune mouse model of pemphigus vulgaris and that circulating soluble autoantibodies have the potential to enhance DSG3-CAART efficacy and did not demonstrate off-target toxicity.

MuSK-CAART: Muscle Specific Kinase (MuSK) CAAR T cells as potential treatment for MuSK-associated myasthenia gravis.

- Investigational New Drug (IND)-enabling studies are ongoing with an IND submission to the U.S. Food and Drug Administration (FDA) anticipated in the second half of 2021.

Manufacturing

- Cell processing capacity is contractually secured at the University of Pennsylvania for the Phase 1 study of DSG3-CAART.

- Two to three years of vector supply for DSG3-CAART is secured, and pilot partnerships have been established for the production of additional vector at commercial grade and scale.
- Cabaletta expects to initiate validation of cell processing for MuSK-CAART clinical trials with a commercial grade contract manufacturing partner before the end of 2020.

Upcoming Events

- Cabaletta will participate in a fireside chat at the Piper Sandler Virtual Conference on December 1-3.
- Cabaletta will participate in a fireside chat at the Evercore ISI 3rd Annual HealthconX Conference on December 1-3.

Third Quarter 2020 Financial Results

The Company expects that its cash and cash equivalents and investments as of September 30, 2020 will enable it to fund its operating plan through at least the third quarter of 2022.

- Research and development (R&D) expenses for the three months ended September 30, 2020 were $5.7 million, compared to $3.2 million for the same period in 2019.
- General and administrative (G&A) expenses for the three months ended September 30, 2020 were $2.8 million, compared to $1.8 million for the same period in 2019.
- As of September 30, 2020, cash and cash equivalents and investments totaled $118.1 million, compared to $136.2 million as of December 31, 2019.

About Cabaletta Bio Cabaletta Bio is a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies, and exploring their potential to provide a deep and durable, perhaps curative, treatment, for patients with B cell-mediated autoimmune diseases. The Cabaletta Approach to selective B cell Ablation (CABA) platform, in combination with Cabaletta's proprietary technology, utilizes Chimeric AutoAntibody Receptor (CAAR) T cells that are designed to selectively bind and eliminate only specific autoantibody-producing B cells while sparing normal antibody-producing B cells, which are essential for human health. The Company's lead product candidate, DSG3-CAART, is being evaluated in the DesCAARTes™ phase 1 clinical trial as a potential treatment for patients with mucosal pemphigus vulgaris, a prototypical B cell-mediated autoimmune disease. The FDA granted Fast Track Designation for DSG3-CAART in May 2020. For more information about the clinical trial, please see www.clinicaltrials.gov. The Company's lead preclinical product candidate, MuSK-CAART, is in IND-enabling studies and is designed as a potential treatment for patients with MuSK-associated myasthenia gravis. For more information, visit www.cabalettabio.com.

Forward-Looking Statements

This press release contains “forward-looking statements” of Cabaletta within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding Cabaletta’s beliefs and expectations regarding its: expectations of the potential impact of COVID-19 on strategy, future operations, IND submissions, contract manufacturing agreements, collaboration, and the timing of its clinical trials, as well as potential impacts on enrollment and initiation; DesCAARTes™ phase 1 clinical trial, including the expected completion of its patient recruitment, the potential timing of the initiation of patient dosing, and the results and expected timing to report clinical acute safety data from the initial cohort by the first half of 2021; MuSK-CAART program, including the completion and expected results of its ongoing IND-enabling studies and plans to submit an IND application or equivalent regulatory filing for MuSK-CAART in the second half of 2021; presentation of additional data at upcoming scientific conferences, and other preclinical data in 2020; 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 and the potential to successfully maintain or secure the necessary cell processing capacity and supply for its product candidates for clinical trials, including Cabaletta’s planned development and timing of next generation T cell engineering tools and process advancement; ability to replicate results achieved in preclinical studies or clinical trials in any future studies or trials; 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; 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 2022.

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 the impact of COVID-19 affecting countries or regions in which we have operations or do business, including potential negative impacts on our employees, customers, supply chain and production as well as global economies and financial markets; risks related to Cabaletta’s ability to protect and maintain its intellectual property position; risks related to Cabaletta’s relationship with third parties, including its licensors and licensees; risks related to the ability of its licensors to protect and maintain their 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 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 quarterly report on Form 10-Q 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.

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

Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	unaudited		unaudited	
Operating expenses:				
Research and development	$ 5,650	$ 3,220	$ 15,601	$ 8,645
General and administrative	2,766	1,811	8,902	4,178
Total operating expenses	8,416	5,031	24,503	12,823
Loss from operations	(8,416)	(5,031)	(24,503)	(12,823)
Other income:				
Interest income	23	381	473	1,283
Net loss	(8,393)	(4,650)	(24,030)	(11,540)
Deemed dividend	—	—	—	(5,326)
Net loss attributable to common stockholders	$(8,393)	$(4,650)	$(24,030)	$(16,866)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.36)	$ (2.17)	$ (1.09)	$ (9.34)

Selected Balance Sheet Data

	September 30, 2020	December 31, 2019
	unaudited	
Cash, cash equivalents and investments	$ 118,074	$ 136,204
Total assets	121,770	141,468
Total liabilities	4,265	3,147
Total stockholders' equity	117,505	138,321

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