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

March 16, 2021
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 March 16, 2021, Cabaletta Bio, Inc. announced its financial results for the fourth quarter and fiscal year ended December 31, 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 March 16, 2021, 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: March 16, 2021

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

Cabaletta Bio™

Cabaletta Bio Reports Fourth Quarter and Full Year 2020 Financial Results and Provides a Business Update

PHILADELPHIA, March 16, 2021 — 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 fourth quarter and full year ended December 31, 2020.

"At the end of 2020, we achieved an important milestone when we dosed the first patient without any dose limiting toxicities in our Phase 1 clinical trial for DSG3-CAART, our lead product candidate being developed for the treatment of patients with mucosal pemphigus vulgaris. This is the first time a highly targeted, antigen specific cell therapy has been dosed in a patient with an autoimmune disease. We continue to expect to report acute safety data from the initial cohort in this study in the first half of 2021 followed by additional topline data on any completed dose cohorts throughout the second half of 2021," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "We also continue to advance our pipeline, and as such, remain on track to submit the Investigational New Drug Application for MuSK-CAART in the second half of 2021. To support this effort, we have secured a long-term commercial manufacturing partnership."

Autoimmune Disease-Focused Pipeline Highlights and Anticipated Upcoming Milestones

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

- In December 2020, the Company announced that the first patient was dosed in an open-label, multi-center Phase 1 clinical trial (DesCAARTes™) to evaluate the safety and tolerability of DSG3-CAART in relapsed/refractory mPV adult patients. The trial is actively enrolling patients across multiple sites in the U.S and is expected to enroll a total of approximately 30 patients. The Company expects to report acute safety data from the initial cohort in the study in the first half of 2021 followed by additional topline data on any completed dose cohorts throughout the second 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.
- In May 2020, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation for DSG3-CAART for the improving healing of mucosal blisters in patients with mPV.

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

- Investigational New Drug (IND)-enabling studies consistent with FDA guidance are ongoing and the Company anticipates submitting an IND to the FDA in the second half of 2021.
- Cabaletta has selected WuXi Advanced Therapies, Inc., a leading global pharmaceutical development and manufacturing company, as its GMP manufacturing partner for its planned MuSK-CAART clinical study. This partnership provides Cabaletta with a path to commercial production capabilities, and is complementary to its current ongoing manufacturing partnership for DSG3-CAART.

Corporate Highlights

- In March 2021, Cabaletta was selected nationally as one of the FORTUNE® 2021 "20 Best Workplaces in Biotechnology and Pharmaceuticals[1]". The recognition highlights the team-first, feedback rich culture cultivated at Cabaletta which provides a foundation for the team to improve the lives of patients while making a difference in the communities where they live and work.

Upcoming Events

- Cabaletta will participate in a fireside chat at the virtual Guggenheim Healthcare Talks Genomic Medicines and Rare Disease Day on April 1, 2021.
- Cabaletta will participate in a fireside chat at the virtual Needham & Co. Virtual Healthcare Conference on April 12-15, 2021.

Fourth Quarter and Full Year 2020 Financial Results

The Company expects that its cash and cash equivalents and investments as of December 31, 2020 will enable it to fund its operating plan through at least the third quarter of 2022.

- Research and development expenses for the three months ended December 31, 2020 were $5.8 million and $21.4 million for the full year ended December 31, 2020, compared to $3.0 million for the three months ended December 31, 2019 and $11.7 million for the full year ended December 31, 2019.
- General and administrative expenses for the three months ended December 31, 2020 were $3.6 million and $12.5 million for the full year ended December 31, 2020, compared to $2.8 million for the three months ended December 31, 2019 and $7.0 million for the full year ended December 31, 2019.
- As of December 31, 2020, cash and cash equivalents totaled $108.7 million, compared to $136.2 million as of December 31, 2019.

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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 Bio within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including without limitation, 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 progress, results and ability to enroll the requisite number of patients and the results and expected timing to report clinical acute safety data from the initial cohort by the first half of 2021 and additional topline data on any completed dosing cohorts in the second 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; 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 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.

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

Statements of Operations

	Three months ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
	Unaudited			
Operating expenses:				
Research and development	5,775	3,026	21,376	11,671
General and administrative	3,555	2,834	12,457	7,012
Total operating expenses	9,330	5,860	33,833	18,683
Loss from operations	(9,330)	(5,860)	(33,833)	(18,683)
Other income				
Interest income	21	457	494	1,740
Net loss	(9,309)	(5,403)	(33,339)	(16,943)
Deemed dividend	—	—	—	(5,326)
Net loss attributable to common stockholders	(9,309)	(5,403)	(33,339)	(22,269)
Net loss per voting and non-voting share, basic and diluted	$ (0.40)	$ (0.33)	$ (1.44)	$ (4.07)

Selected Balance Sheet Data

	December 31,	
	2020	2019
	Unaudited	
Cash, cash equivalents and investments	$108,662	$136,204
Total assets	114,724	141,468
Total liabilities	5,180	3,147
Total stockholders' equity	109,544	138,321

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