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 30, 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 March 30, 2020, Cabaletta Bio, Inc. announced its financial results for the fourth quarter and fiscal year ended December 31, 2019. 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 30, 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: March 30, 2020

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

Cabaletta Bio™

Cabaletta Bio Reports Fourth Quarter and Full-Year 2019 Financial Results and Provides Business Update

- *DSG3-CAART IND clearance received in October 2019 and Orphan Drug Designation granted by the FDA for the treatment of pemphigus vulgaris (PV) in January 2020; anticipated delay in reporting the acute safety data from the first cohort of the DesCAARTes™ trial due to the COVID-19 pandemic*
- *IND-enabling studies for MuSK-CAART, targeting the MuSK form of myasthenia gravis, to be initiated in 2020*
- *Ended 2019 with approximately $136 million in cash and cash equivalents; including net proceeds from initial public offering of approximately $71 million, sufficient to fund operations through at least the third quarter of 2022*

PHILADELPHIA, March 30, 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 fourth quarter and full year ended December 31, 2019.

"2019 was a foundational year highlighted by the FDA clearance of the IND for our lead product candidate, DSG3-CAART, for patients with mucosal pemphigus vulgaris (mPV). We obtained intellectual property protection and engaged with key partners to enable the rapid startup of this program, while at the same time making meaningful progress on our broader pipeline of additional programs," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "With respect to the COVID-19 pandemic, our top priority is to ensure the safety of our employees, collaborators, and others involved in our research and development efforts. As a result, we now anticipate a delay in reporting the acute safety data from the first cohort in the Phase 1 DesCAARTes™ trial. Once we have visibility on the impact of the pandemic, possibly during the second quarter of this year, we expect to issue revised guidance on our timeline for reporting the acute safety data from this trial. The recent extension of our cash runway until at least the end of the third quarter of 2022, two quarters beyond previous guidance, provides additional flexibility for the business."

Recent Business 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 September 2019, the U.S. Food and Drug Administration (FDA) cleared Cabaletta's first Investigational New Drug application (IND) for DSG3-CAART to initiate a first-in-human clinical trial of DSG3-CAART in patients with mPV.
- In January 2020, the FDA granted DSG3-CAART Orphan Drug Designation for the treatment of PV.
- The Company plans to initiate an open-label Phase 1 clinical trial (DesCAARTes™) to evaluate the safety and tolerability of DSG3-CAART in relapsed/refractory mPV patients.

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

- In October 2019, *in vitro* preclinical data were presented at the American Neurological Association Annual Meeting showing specific CAAR T activity against anti-MuSK-expressing B cells.
- *In vivo* target engagement data was accepted for presentation during an oral session at the American Academy of Neurology (AAN) Annual Meeting. The April 2020 meeting has been cancelled, and guidance on an alternative venue for presentation has not yet been provided by AAN.
- Cabaletta plans to initiate IND-enabling studies in 2020.

Manufacturing

- Ample cell processing capacity is contractually secured for the planned Phase 1 study of DSG3-CAART.
- Vector supply for DSG3-CAART has been secured for the next two to three years with partnerships established for process development of additional vector at commercial grade and scale.
- Cabaletta expects to initiate validation of cell processing for clinical trials with a contract manufacturing partner for MuSK-CAART in 2020.
- Manufacturing expectations are subject to change based on the impact of the COVID-19 pandemic.

Corporate Updates

- Recruited a uniquely qualified leadership team in 2019 and grew Cabaletta to approximately two dozen employees. Key hires included:
  - Gwendolyn Binder, Ph.D., Executive Vice President, Science & Technology
  - David J. Chang, M.D, M.P.H., Chief Medical Officer
  - Anup Marda, Chief Financial Officer
  - Brian Stalter, General Counsel
  - Martha O'Connor, Chief Human Resources Officer

- Strengthened and diversified the Board of Directors by appointing immunologist and cell therapy expert, Catherine Bollard, M.D., and experienced financial executive, Richard Henriques.
- Raised gross proceeds of $130 million in 2019 through a $50 million private financing in January 2019 followed by an $80 million initial public offering in October 2019.
- The Company has updated its operating plan and now expects cash on hand as of December 31, 2019 will be sufficient to fund operations through at least the third quarter of 2022. Cabaletta expects to be able to further extend its cash runway into 2023 if needed, while continuing to invest in its lead candidates.

Fourth Quarter and Full Year 2019 Financial Results

- Research and development (R&D) expenses for the three months ended December 31, 2019 were $3.0 million and $11.7 million for the full year ended December 31, 2019.
- General and administrative (G&A) expenses for the three months ended December 31, 2019 were $2.8 million and $7.0 million for the full year ended December 31, 2019.
- As of December 31, 2019, cash and cash equivalents totaled $136.2 million.

About Cabaletta Bio

Cabaletta Bio is a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies 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 in development as a potential treatment for a prototypical B cell-mediated autoimmune disease, mucosal pemphigus vulgaris. For more information, visit www.cabalettabio.com.

Forward-Looking Statements

This press release contains "forward-looking statements" of Cabaletta Bio, Inc. ("Cabaletta" or the "Company") 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, contract manufacturing agreements, collaboration, and the timing of its clinical trials, as well as potential impacts on enrollment and initiation; plans to initiate patient dosing in an open-label Phase 1 clinical trial to evaluate DSG3-CAART safety and tolerability in relapsed/refractory mPV patients, including the potential timing of the initiation of patient dosing; potential manner and timing of data readouts of its ongoing and planned clinical trials; plans to initiate IND-enabling studies of MuSK-CAART in 2020; 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 tolls 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 2019 financial results or 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 public health epidemics affecting countries or regions in which we have operations or do business, such as COVID-19, which has been labelled a pandemic by the World Health Organization, 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 December 31,		Year Ended December 31,	
	2019	2018	2019	2018
	Unaudited			
Operating expenses:				
Research and development	3,026	1,239	11,671	4,467
General and administrative	2,834	826	7,012	1,726
Total operating expenses	5,860	2,065	18,683	6,193
Loss from operations	(5,860)	(2,065)	(18,683)	(6,193)
Other income (expense):				
Interest income	457	160	1,740	235
Fair value adjustments on convertible notes	—	—	—	(6,244)
Net loss	(5,403)	(1,905)	(16,943)	(12,202)
Deemed dividend	—	—	(5,326)	—
Net loss attributable to common stockholders	(5,403)	(1,905)	(22,269)	(12,202)
Net loss per voting and non-voting share, basic and diluted	$ (0.33)	$ (1.35)	$ (4.07)	$ (6.87)

Selected Balance Sheet Data

	December 31,	
	2019	2018
	Unaudited	
Cash and cash equivalents	$ 136,204	$ 33,017
Total assets	141,468	34,174
Total liabilities	3,147	943
Convertible preferred stock	—	43,921
Total stockholders' equity (deficit)	138,321	(10,690)

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