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 6, 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 August 6, 2020, Cabaletta Bio, Inc. announced its financial results for the second quarter ended June 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 August 6, 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: August 6, 2020

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

Cabaletta Bio™

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

PHILADELPHIA, Aug. 06, 2020 (GLOBE NEWSWIRE) — 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 second quarter ended June 30, 2020 and provided a business update.

“The recent initiation of patient recruitment in the DesCAARTes™ Phase 1 trial is an important milestone for Cabaletta that reflects the commitment of our outstanding team and academic partners to patients suffering with mucosal pemphigus vulgaris. This trial, evaluating the safety and tolerability of DSG3-CAART, is the first trial exploring whether a highly specific targeted cellular therapy can provide a deep and durable, perhaps curative, treatment for patients with a B cell-mediated autoimmune disease. We look forward to reporting acute safety data from the initial cohort by the first half of 2021,” said Steven Nichtberger, M.D., Chief Executive Officer and co-founder of Cabaletta. “Our lead preclinical program targeting patients with the MuSK form of myasthenia gravis is currently advancing with IND-enabling studies ongoing. We remain on track to submit an IND in the second half of 2021. Based on progress with our two lead programs, we recently added three new undisclosed disease targets to our pipeline through the expansion of our Sponsored Research Agreement with the University of Pennsylvania. In addition, the recent announcement of our gene editing research and collaboration agreement with Artisan Bio may potentially allow us to expand and enhance our product portfolio by creating the next-generation of CAAR T cell therapies for B cell- mediated autoimmune diseases.”

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 (DesCAARTesTM) to evaluate the safety and tolerability of DSG3-CAART in relapsed/refractory mPV patients is now open for recruitment with clinical acute safety data from the initial cohort expected by the first half of 2021.

In May 2020, the Company announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to DSG3- CAART, which provides independent validation of mPV as a serious and unmet medical need in patients.

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 FDA anticipated in the second half of 2021.

In May 2020, *in vivo* target engagement data was presented at the American Academy of Neurology 2020 Science Highlights Virtual Platform. The data demonstrated *in vitro* cytotoxicity towards a B cell line expressing anti-MuSK antibodies, but no observed cytotoxicity when the anti-MuSK antibody was not expressed. MuSK CAAR T cells also targeted and eliminated a panel of B cells targeting different MuSK epitopes. In an *in vivo* mouse model, MuSK CAAR T cells, but not control CAAR T cells, showed biological activity by blocking the growth of B cell lines expressing an anti-MuSK antibody. This study demonstrated that MuSK CAAR T cells were able to deplete B cells expressing anti-MuSK antibodies.

Manufacturing

Cell processing capacity is contractually secured at the University of Pennsylvania for the Phase 1 study of DSG3-CAART. Pilot partnerships with two commercial grade contract manufacturers have been initiated to support later-stage clinical development.

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 in the second half of 2020.

Corporate Highlights

In August 2020, Dr. Carl June, M.D., joined the Company’s Scientific Advisory Board. Dr. June led the research team that discovered and developed the first FDA-approved Chimeric Antigen Receptor (CAR) T cell therapy. He is the Richard W. Vague Professor of Immunotherapy in the Department of Pathology and Laboratory Medicine at the University of Pennsylvania, Director of the Center for Cellular Immunotherapies at the Perelman School of Medicine and Director of the Parker Institute for Cancer Immunotherapy at the University of Pennsylvania.

In July 2020, the Company signed a gene editing research and collaboration agreement with Artisan Bio, Inc., a precision cell therapy engineering company, to accelerate development of next-generation CAAR T cell therapies with the potential for improved manufacturing and/or clinical outcomes for patients with B-cell mediated autoimmune diseases.

In May 2020, the Company expanded its Sponsored Research Agreement with the University of Pennsylvania. The agreement expands the scope of sponsored research to include three additional B cell-mediated autoimmune diseases under the direction of Aimee Payne, M.D., Ph.D., a Professor of Dermatology in the Perelman School of Medicine at the University of Pennsylvania, Director of the Penn Clinical Autoimmunity Center of Excellence, and a co-founder of Cabaletta and co-chair of the Scientific Advisory Board.

Upcoming August Events

Cabaletta will participate in a fireside chat at the BTIG Virtual Biotechnology Conference on Monday, August 10, 2020 at 1:00 p.m. ET.

Cabaletta will participate in a fireside chat at the Wedbush PacGrow Healthcare Virtual Conference on Tuesday, August 11, 2020 at 8:35 a.m. ET.

Cabaletta will participate in a fireside chat at the 40th Annual Canaccord Genuity Growth Conference on Wednesday, August 12, 2020 at 11:30 a.m. ET.

Second Quarter 2020 Financial Results

Research and development (R&D) expenses for the three months ended June 30, 2020 were $5.3 million, compared to $2.7 million for the same period in 2019.

General and administrative (G&A) expenses for the three months ended June 30, 2020 were $2.9 million, compared to $1.1 million for the same period in 2019.

As of June 30, 2020, cash and cash equivalents and investments totaled $123.2 million, compared to $136.2 million as of December 31, 2019.

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

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 being evaluated in the DesCAARTesTM 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; DesCAARTesTM 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	unaudited		unaudited	
Operating expenses:				
Research and development	$ 5,331	$ 2,664	$ 9,951	$ 5,425
General and administrative	2,861	1,138	6,136	2,367
Total operating expenses	8,192	3,802	16,087	7,792
Loss from operations	(8,192)	(3,802)	(16,087)	(7,792)
Other income:				
Interest income	40	444	450	902
Net loss	(8,152)	(3,358)	(15,637)	(6,890)
Deemed dividend	—	—	—	(5,326)
Net loss attributable to common stockholders	$(8,152)	$(3,358)	$(15,637)	$(12,216)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.35)	$ (1.87)	$ (0.68)	$ (7.48)

Selected Balance Sheet Data

	June 30, 2020	December 31, 2019
	unaudited	
Cash, cash equivalents and investments	$123,178	$ 136,204
Total assets	127,898	141,468
Total liabilities	3,263	3,147
Total stockholders' equity	124,635	138,321

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