May 12, 2020

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

PHILADELPHIA, May 12, 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 first quarter ended March 31, 2020.

“Following the recent Fast Track Designation from the FDA for our lead product candidate, DSG3-CAART, for the treatment of patients with mucosal pemphigus vulgaris (mPV), our Phase 1 DesCAARTes™ trial is ready to launch as soon as COVID-19 related clinical trial activity restrictions are lifted. mPV is a rare, serious, and sometimes fatal disease for which patients have limited treatment options. We are eager to explore the potential of our engineered T cell therapy to fulfill this unmet need,” said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. “We continue to closely monitor the unprecedented challenges and impact of the COVID-19 pandemic while working to ensure that patients, our employees and collaborators remain safe. As evidenced by the recent Fast Track designation, despite working from home over the past two months, our dedicated team continues to make progress across our portfolio wherever possible as we strive to develop potential cures for patients with severe autoimmune diseases.”

Pipeline Highlights and Anticipated Upcoming Milestones

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

- In May 2020, the Company announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to DSG3-CAART. This follows the January 2020 granting of Orphan Drug Designation from the FDA for the treatment of PV.

- The Company is prepared to initiate an open-label Phase 1 clinical trial (DesCAARTes™) to evaluate the safety and tolerability of DSG3-CAART in relapsed/refractory mPV patients in 2020.

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

- Cabaletta plans to initiate Investigational New Drug (IND)-enabling studies in 2020.

- *In vivo* target engagement data were selected for oral presentation at the 72nd American Academy of Neurology (AAN) Annual Meeting and will now be made available online via a virtual presentation, following the cancellation of the in-person conference.

Manufacturing

- Ample cell processing capacity is contractually secured for the Phase 1 study of DSG3-CAART.

- Two to three years of vector supply for DSG3-CAART has been secured through partnerships established for process development of additional vector at commercial grade and scale.

- Cabaletta expects to initiate validation of cell processing for MuSK-CAART clinical trials with a contract manufacturing partner in 2020, barring additional COVID-19 related delays.

Corporate Highlights

- In April, Dr. Iain McInnes, PhD, FRCP, FRSE, FMedSci, joined the Company's Scientific Advisory Board. Dr. McInnes has extensive experience in leading multicenter clinical trials for novel immune therapies, and has built an internationally recognized research program that aims to understand the cellular and molecular pathways behind the development of inflammatory and immune-mediated diseases. His work has been widely published and he has been influential in supporting development efforts for novel therapeutics in the field. Dr. McInnes is currently the Muirhead Chair of Medicine, Versus Arthritis Professor of Rheumatology and Director of Institute of Infection, Immunity and Inflammation at the University of Glasgow.

Upcoming Events

- MuSK-CAART *in vivo* target engagement data to be presented on Monday, May 18, 2020 via a virtual presentation at the AAN 2020 Virtual Forum

- The company will host its virtual Annual Meeting on Tuesday, June 2, 2020 at 10:00 AM Eastern Time.

- Cabaletta will give a corporate presentation at the Jefferies Virtual Global Healthcare Conference on Wednesday, June 3, 2020 at 3:30 PM Eastern Time.

First Quarter 2020 Financial Results

- Research and development (R&D) expenses for the three months ended March 31, 2020 were $4.6 million.

- General and administrative (G&A) expenses for the three months ended March 31, 2020 were $3.3 million.

- As of March 31, 2020, cash and cash equivalents totaled $131.0 million.

The Company expects that its current cash and cash equivalents 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 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 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 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 March 31,	
	2020	**2019**
	Unaudited	
Operating expenses:		
Research and development	$ 4,620	$ 2,761
General and administrative	3,275	1,229
Total operating expenses	7,895	3,990
Loss from operations	(7,895)	(3,990)
Other income:		
Interest income	410	458
Net loss	(7,485)	(3,532)
Deemed dividend	—	(5,326)
Net loss attributable to common stockholders	$ (7,485)	$ (8,858)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.33)	$ (6.05)

Selected Balance Sheet Data

	March 31, 2020	**December 31, 2019**
	(unaudited)	
Cash and cash equivalents	$ 131,003	$ 136,204

Total assets	134,965	141,468
Total liabilities	3,256	3,147
Total stockholders' equity	131,709	138,321

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Source: Cabaletta Bio