Cue Biopharma Reports Second Quarter 2020 Results and CUE-101 Phase 1 Dose Escalation Trial Updates

August 31, 2020

CAMBRIDGE, Mass., Aug. 31, 2020 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (NASDAQ: CUE), a clinical-stage biopharmaceutical company engineering a novel class of injectable biologics to selectively engage and modulate targeted T cells within the body, provided a business update for the second quarter of 2020.

“We are very pleased with the progress we continue to make advancing CUE-101 through the ongoing Phase 1 monotherapy dose-escalation trial,” said Daniel Passeri, chief executive officer of Cue Biopharma. “We are highly encouraged with the emerging data sets from this ongoing study, have completed dosing cohorts 4 and 5 in July and August, and recently were cleared by the Safety Review Committee to begin dosing cohort 6, at 4mg/kg.”

“We remain well positioned for continued execution of our development plans for our lead asset CUE-101 which is representative of our IL-2 based CUE-100 series and the continued build out of our pipeline via our proprietary protein engineering approach,” said Anish Suri, chief scientific officer and president of Cue Biopharma.

Second-Quarter 2020 Financial Results

The Company had steady collaboration revenue of approximately $1.1 million for the three months ended June 30, 2020 and 2019.

Research and development expenses were $8.1 million and $6.9 million for the three months ended June 30, 2020 and 2019, respectively. This increase of approximately $1.3 million was due primarily to the increase in laboratory and drug manufacturing costs, stock-based compensation and clinical expenses, offset by a decrease in travel expenses as the COVID-19 pandemic hampered business travel throughout the second quarter.

General and administrative expenses were $3.9 million and $3.4 million for the three months ended June 30, 2020 and 2019, respectively. This increase of approximately $0.5 million was due primarily to stock-based compensation and legal fees offset by a decrease in travel expenses for the second quarter.

“As of June 30, 2020, we had approximately $85 million in cash and marketable securities which will allow us to support the continued development of our Immuno-STAT platform, including the clinical development of CUE-101, into 2022,” said Kerri-Ann Millar, chief financial officer of Cue Biopharma, Inc.

Recent News & Business Updates

- Advancing CUE-101 into cohort 6 in its ongoing multicenter, open-label, dose escalation Phase 1 monotherapy trial for patients with human papilloma virus-positive recurrent/metastatic head and neck squamous cell carcinoma (HPV+ HNSCC).
- Extended cash runway during the second quarter through an ATM equity offering sales agreement for aggregate proceeds of $42.4 million, net of commissions paid, with Stifel Nicolaus & Company, Inc., who acted as sales agent.
- Announced a peer-reviewed paper titled “Mechanistic dissection of the PD-L1:B7-1 co-inhibitory immune complex” in *PLOS ONE*. The study results describe novel functional interactions that regulate responses mediated by the B7 family of immune checkpoint molecules and the generation and evaluation of libraries of these molecules with directed mutations providing novel biological properties with potential therapeutic applications.
- Entered into a research collaboration agreement with Dr. Michael Dustin and the University of Oxford to determine the molecular mechanisms underlying the activity of its IL-2 based CUE-100 series Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* Biologics.
- Appointed Kerri-Ann Millar as Chief Financial Officer after serving as the company’s principal finance and accounting officer since 2018.

Members of the Cue Biopharma executive management team will provide an update on the ongoing Phase 1 clinical trial of CUE-101 for the treatment of HPV+ HNSCC, technology platforms and pipeline progress, as well as updates on its strategic objectives and anticipated milestones today, Monday, August 31 at 4:30 p.m. EDT.

Investors:	855-327-6837
International:	631-891-4304
Conference ID:	10010557

Webcast: http://public.viavid.com/index.php?id=141034

About Cue Biopharma
Cue Biopharma, a clinical-stage biopharmaceutical company, is engineering a novel class of injectable biologics to selectively engage and modulate targeted T cells within the body to transform the treatment of cancer, infectious diseases and autoimmune diseases. The company's proprietary Immuno-STAT ™*(Selective Targeting and Alteration of T cells)* platform is designed to harness the body's intrinsic immune system without the need for ex vivo manipulation.

Headquartered in Cambridge, Massachusetts, we are led by an experienced management team and independent Board of Directors with deep expertise in the design and clinical development of protein biologics, immunology and immuno-oncology treatments.

For more information, visit www.cuebiopharma.com and follow us on Twitter https://twitter.com/CueBiopharma.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate," "strategy," "future," "likely" or other comparable terms. All statements other than statements of historical facts included in this press release regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding anticipated results of our drug development efforts, including study results, and our expectations regarding regulatory developments and expected future operating results. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, our limited operating history, limited cash and a history of losses; our ability to achieve profitability; potential setbacks in our research and development efforts including negative or inconclusive results from our preclinical studies, our ability to secure required U.S. Food and Drug Administration ("FDA") or other governmental approvals for our product candidates and the breadth of any approved indication; adverse effects caused by public health pandemics, including COVID-19, including possible effects on our operations and clinical trials; negative or inconclusive results from our clinical studies or serious and unexpected drug-related side effects or other safety issues experienced by participants in our clinical trials; delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications to the FDA; our reliance on licensors, collaborators, contract research organizations, suppliers and other business partners; our ability to obtain adequate financing to fund our business operations in the future; ; and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our most recently filed Annual Report on Form 10-K and any subsequently filed Quarterly Report(s) on Form 10-Q. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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Cue Biopharma, Inc.
Selected Consolidated Statement of Operations
(in thousands)

	Three Months Ended June 30,	
	2020	**2019**
Collaboration revenue	$ 1,075	$ 1,055
Operating expenses:		
General and administrative	3,898	3,419
Research and development	8,119	6,867
Total operating expenses	12,017	10,286
Loss from operations	(10,942)	(9,231)
Other income:		

Interest income	134	96
Other income / (expense) net	(25)	26
Net Loss	$ (10,833)	$ (9,109)
Net loss per common share – basic and diluted	$ (0.38)	$ (0.46)
Weighted average common shares outstanding – basic and diluted	28,222	20,821

Cue Biopharma, Inc.
Selected Consolidated Balance Sheet Data
(in thousands)

	June 30, 2020	December 31, 2019
Cash and cash equivalents	$ 59,749	$ 44,290
Marketable securities	25,179	15,120
Total current assets	88,353	61,025
Working Capital	73,491	49,370
Total assets	101,353	71,605
Total Stockholders' equity	80,154	54,584

Source: Cue Biopharma, Inc.