Cue Biopharma Reports Second Quarter 2022 Financial Results

August 4, 2022

BOSTON, Aug. 04, 2022 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of injectable biologics to selectively engage and modulate tumor-specific T cells directly within the patient's body, reported today second quarter 2022 financial results. The Company will host a business update call and webcast on Tuesday, August 23, 2022 at 4:30 p.m. EDT. Live and archived versions of the event can be accessed via the Company's website.

Webcast Details

Tuesday, August 23, 2022 at 4:30 p.m. EDT	
Investors:	877-407-9208
International:	201-493-6782
Conference ID:	13732164
Webcast:	https://viavid.webcasts.com/starthere.jsp?ei=1563330&tp_key=21ee024fb9

Recent Business Updates

- Investigational New Drug (IND) application accepted by the U.S. Food and Drug Administration (FDA) for CUE-102 in Wilms' Tumor 1 (WT1) expressing cancers. Based on the premise that CUE-102 possesses the same molecular framework as CUE-101 except for the nine amino acid sequence difference between HPV-E7 and WT1, the IND was supported by clinical and safety data from the ongoing CUE-101 monotherapy trial and did not require additional IND-enabling toxicology studies.

- Initiated a dose escalation monotherapy Phase 1 trial with CUE-102 at a starting dose of 1mg/kg. The trial will focus on patients with WT1-positive recurrent/metastatic gastric, pancreatic, ovarian and colorectal cancers.

- Presented interim CUE-101 clinical data at the American Society of Clinical Oncology (ASCO) on June 6th. Eight of the nine evaluable patients treated with CUE-101 and KEYTRUDA® in the dose escalation portion of our combination study had at least one post dose scan at the time of the data cut-off of April 22. Of the eight patients, two patients, one patient at the 2mg/kg dose and one patient at the 4mg/kg dose, had confirmed ongoing partial responses and two additional patients had durable stable disease, defined as stable disease on at least two consecutive post-treatment scans lasting at least 12 weeks.

- Extended cash runway with an aggregate of $23.6 million, net of commissions paid, from the sale of 3,593,407 shares of our common stock pursuant to our ATM equity offering sales agreement with Jefferies LLC during the first six months of 2022.

"As we continue to progress the IL-2-based CUE-100 series for oncology, our confidence is bolstered by the growing body of evidence that our Immuno-STAT™ platform and therapeutic approach appear to represent a potential breakthrough in oncology," said Daniel Passeri, chief executive officer of Cue Biopharma. "We are encouraged with the continued progress of the CUE-101 monotherapy and combination trials and look forward to providing a business update during our upcoming call. We are also pleased with the recent acceptance of the IND for the CUE-102 Phase 1 dose escalation trial, which importantly will begin at 1mg/kg dose, as compared to 0.16mg/kg in the Phase 1 dose escalation of CUE-101 saving us valuable time and resources in determining the tolerability and recommended Phase 2 dose of CUE-102. In summary, we are very pleased with our clinical trial progress and associated data to date as we continue to further the clinical development of our CUE-100 series pipeline throughout fiscal year 2022."

Kerri-Ann Millar, chief financial officer of Cue Biopharma added, "During the second quarter of 2022, management took proactive steps to decrease the Company's office and lab footprint and restructure in support of newly prioritized corporate objectives and strategies. These important steps, resulting in a significant cost savings that has been allocated to key clinical programs, coupled with successfully accessing our at-the-market (ATM) common stock facility will allow us to assess the data readouts from our CUE-101 Phase 1 monotherapy and combination clinical trials."

Second-Quarter 2022 Financial Results
The Company reported collaboration revenue of approximately $26 thousand and $2.7 million for the three months ended June 30, 2022 and 2021, respectively.

Research and development expenses were $9.6 million and $8.8 million for the three months ended June 30, 2022 and 2021, respectively. The increase in research and development expenses of $0.8 million was primarily due to an increase in laboratory and drug substance manufacturing costs, employee compensation, other professional fees, licensing fees, and rent.

General and administrative expenses were $3.8 million and $4.3 million for the three months ended June 30, 2022 and 2021, respectively. The decrease in general and administrative expense of $0.5 million was primarily due to a decrease in stock-based compensation expense related to executive management, professional and consulting fees, and employee and board compensation incurred in the second quarter of 2022 as compared to the same period in 2021.

Cue Biopharma, Inc.
Selected Consolidated Statement of Operations Data
(In thousands, except share data)

	Three Months Ended June 30,	
	2022	**2021**
Collaboration revenue	$ 26	$ 2,739
Operating expenses (income):		
General and administrative	3,782	4,280
Research and development	9,592	8,762
Gain on right-of-use asset termination	(258)	-
Total operating expenses	13,116	13,042
Loss from operations	(13,090)	(10,303)
Other (expense) income:		
Total other (expense) income, net	(118)	24
Net Loss	$ (13,208)	$ (10,279)
Net loss per common share – basic and diluted	$ (0.37)	$ (0.33)
Weighted average common shares outstanding – basic and diluted	35,357,343	31,233,794

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

	June 30, 2022	**December 31, 2021**
Cash and cash equivalents	66,126	64,371
Total current assets	69,004	68,468
Working Capital	60,681	55,680
Total assets	84,749	83,401
Total Stockholders' equity	59,756	65,492

About Cue Biopharma
Cue Biopharma, a clinical-stage biopharmaceutical company, is developing a novel class of injectable biologics to selectively engage and modulate tumor-specific T cells directly within the patient's body to transform the treatment of cancer. 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 Boston, Massachusetts, the company is led by an experienced management team and independent Board of Directors with deep expertise in immunology and immuno-oncology as well as the design and clinical development of protein biologics.

For more information, visit https://www.cuebiopharma.com and follow us on Twitter at 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. Such forward-looking statements include, but are not limited to, those regarding: the company's estimate of the period in which it expects to have cash to fund its operations; the company's belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective engagement of disease-relevant T cells; and the company's business strategies, plans and prospects. Forward-looking statements, which are based on certain assumptions and describe the company's 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, although not all forward-looking statements contain these identifying words. All statements other than statements of historical facts included in this press release regarding the company’s strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Important factors that could cause the company’s actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the company’s limited operating history, limited cash and a history of losses; the company’s ability to achieve profitability; potential setbacks in the company’s research and development efforts including negative or inconclusive results from its preclinical studies, its ability to secure required U.S. Food and Drug Administration (“FDA”) or other governmental approvals for its product candidates and the breadth of any approved indication; adverse effects caused by public health pandemics, including COVID-19, including possible effects on the company’s trials; negative or inconclusive results from the company’s clinical trials or preclinical studies or serious and unexpected drug-related side effects or other safety issues experienced by participants in clinical trials; delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications to the FDA; the company’s reliance on licensors, collaborators, contract research organizations, suppliers and other business partners; the company’s ability to obtain adequate financing to fund its business operations in the future; operations and clinical the company’s ability to maintain and enforce necessary patent and other intellectual property protection; competitive factors; general economic and market conditions 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 the company’s 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 the company in this press release is based only on information currently available to the company and speaks only as of the date on which it is made. The company undertakes 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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