



Cue Biopharma Reports Second Quarter 2025 Financial Results and Recent Business Highlights

August 12, 2025

- Received FDA feedback on Pre-IND Briefing Document reinforcing Company's intention to advance investigational new drug (IND) submission for CUE-401 to address unmet need in the treatment of autoimmune disease.
- Announced strategic research collaboration and license agreement with Boehringer Ingelheim to develop and commercialize CUE-501, a differentiated B cell depletion therapy for autoimmune and inflammatory diseases.
 - Upfront payment of \$12 million and ~\$345 million in potential milestone payments
- Raised approximately \$20 million through a public offering.

BOSTON, Aug. 12, 2025 (GLOBE NEWSWIRE) -- [Cue Biopharma, Inc.](#) (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of therapeutic biologics to selectively engage and modulate disease-specific T cells for the treatment of autoimmune disease and cancer, today provided a business and financial update for the second quarter 2025.

"We made significant progress during the second quarter with highly encouraging clinical data from our ongoing Phase 1b clinical trial, supporting our belief that CUE-101, representative of the CUE-100 series, has the potential to establish a new standard of care for HPV+ HNSCC patients," said Daniel Passeri, chief executive officer of Cue Biopharma. "These maturing data, together with the continued advancements of our lead autoimmune programs, reinforces our commitment to provide patients with more effective and well tolerated therapies to treat serious disease."

Business Highlights

- Received FDA feedback on Pre-IND Briefing Document reinforcing Company's intention to advance IND submission for CUE-401 to address unmet need in the treatment of autoimmune disease.
- Announced strategic research collaboration and license agreement with Boehringer Ingelheim to develop and commercialize CUE-501, a differentiated B cell depletion therapy for autoimmune and inflammatory diseases.
 - Upfront payment of \$12 million and ~\$345 million in potential milestone payments
- Raised approximately \$20 million through a public offering.
- Hosted virtual investor event, *Mobilizing the Immune System: Cue Biopharma's Novel Biologics Portfolio*, featuring key opinion leaders, Richard DiPaolo, PhD, and Andrew Cope, MD PhD.
- Poster presentation delivered by Dana-Farber Cancer Institute at the American Society of Gene & Cell Therapy Annual Meeting presented proof-of-concept data on CUE-101 and its potential to control CAR-T cell expansion and persistence in vivo.
- Reported new complete response and confirmed 50% overall response rate (ORR) in ongoing Phase 1 trial of CUE-101 and pembrolizumab (KEYTRUDA®) in recurrent/metastatic HPV+ head and neck cancer. Data observed included 12-month overall survival of 88% and median overall survival (mOS) of 32 months.

Second Quarter 2025 Financial Results

The Company reported collaboration revenue of \$3.0 million and \$2.7 million for the three months ended June 30, 2025 and 2024, respectively. The increase was due to the timing of revenue earned from the collaboration and license agreement with Boehringer Ingelheim International GmbH (BI).

Research and development expenses were \$7.9 million and \$9.5 million for the three months ended June 30, 2025 and 2024, respectively. The decrease was primarily due to decreases in clinical trials costs and employee compensation.

General and administrative expenses were \$3.7 million and \$3.5 million for the three months ended June 30, 2025 and 2024, respectively. The increase was primarily due to an increase in professional fees.

Cue Biopharma, Inc.
Condensed Consolidated Statement of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Collaboration revenue	\$ 2,954	\$ 2,658	\$ 3,374	\$ 4,375
Operating expenses:				
General and administrative	3,679	3,511	7,852	7,697
Research and development	7,910	9,530	16,457	19,729
Total operating expenses	11,589	13,041	24,309	27,426
Loss from operations	(8,635)	(10,383)	(20,935)	(23,051)
Other income (expense):				
Interest income	198	427	368	989
Interest expense	(45)	(215)	(172)	(456)
Total other income, net	153	212	196	533
Net loss	\$ (8,482)	\$ (10,171)	\$ (20,739)	\$ (22,518)
Comprehensive loss	\$ (8,482)	\$ (10,171)	\$ (20,739)	\$ (22,518)
Net loss per common share – basic and diluted	\$ (0.09)	\$ (0.20)	\$ (0.24)	\$ (0.45)
Weighted average common shares outstanding – basic and diluted	95,459,401	50,174,756	84,857,051	49,822,689

Cue Biopharma, Inc.
Condensed Consolidated Balance Sheets
(Unaudited, In thousands)

	June 30, 2025	December 31, 2024
Assets		
Cash and cash equivalents	\$ 27,492	\$ 22,459
Other assets	13,215	9,732
Total assets	<u>\$ 40,707</u>	<u>\$ 32,191</u>
Liabilities and stockholders' equity		
Liabilities	\$ 22,548	\$ 14,692
Stockholders' equity	18,159	17,499
Total liabilities and stockholders' equity	<u>\$ 40,707</u>	<u>\$ 32,191</u>

About Cue Biopharma

Cue Biopharma, a clinical-stage biopharmaceutical company, is developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body. The company's proprietary platform, Immuno-STAT[®] (*Selective Targeting and Alteration of T cells*), and biologics are designed to harness the curative potential of the body's intrinsic immune system without the adverse effects of broad systemic immune modulation.

Headquartered in Boston, Massachusetts, we are led by an experienced management team with deep expertise in immunology and immuno-oncology as well as the design and clinical development of protein biologics.

For more information please visit www.cuebiopharma.com and follow us on [X](#) and [LinkedIn](#).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, those regarding: the company's belief regarding the potential benefits and applications of its drug candidates and programs, including CUE-101's potential to control CAR-T cell expansion and persistence in vivo and that CUE-101 has the potential to establish a new standard of care for HPV+ HNSCC patients; the company's plans to submit an IND for CUE-401; the company's business strategies, plans and prospects; and the company's potential receipt of future milestone-based payments. 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," "promise" 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 obtain adequate financing to fund its business operations in the near term and successfully remediate its current "going concern" determination that it does not have sufficient capital on hand to continue operations beyond the next twelve months; 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 or clinical trials or the company's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; serious and unexpected drug-related side effects or other safety issues experienced by participants in clinical trials; 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 possible effects on the company's operations and 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 and ability to continue as a going concern; 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 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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