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

November 12, 2025

- *Announced strategic collaboration and license agreement with ImmunoScape to develop breakthrough cell therapy approach for solid tumors – Company is entitled to receive upfront payments totaling $15M*

- *Announced strategic transition in leadership to further enable next stage of growth with disruptive autoimmune therapeutic candidates, most notably CUE-401, the Company's lead autoimmune asset*

BOSTON, Nov. 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 third quarter 2025.

"During the third quarter of 2025 and early in the fourth quarter, the Company made tremendous progress from having successfully implemented a plan of optionality and laying the necessary groundwork for future growth," said Usman Azam, M.D., president and chief executive officer of Cue Biopharma. "I am deeply proud of the Cue team and believe we are strategically positioned to further advance our differentiating Immuno-STAT® platform and lead autoimmune asset, CUE-401, toward the clinic to address a major unmet need in autoimmune disease treatment."

Business Highlights

- *Announced strategic transition in leadership to further enable next stage of growth with disruptive autoimmune therapeutic candidates, most notably CUE-401, the Company's lead autoimmune asset*
  - *Usman Azam, M.D., appointed President and Chief Executive Officer, effective as of September 29*
  - *CUE-401 is uniquely engineered and designed as a tolerogenic bifunctional molecule harnessing the power of transforming growth factor beta (TGF-β) and interleukin 2 (IL-2) to re-establish immune tolerance and balance*

- *Announced strategic collaboration and license agreement with ImmunoScape to develop breakthrough cell therapy approach for solid tumors*
  - *Upfront total payment of $15 million, $10 million in Q4 2025 and $5 million in November of 2026, as well as a 40% equity stake in ImmunoScape*
  - *Exclusive collaboration and license agreement focuses on advancing novel, T cell therapy "Seed-and-Boost" approach exploiting the mechanism of the CUE-100 series of Immuno-STATs®*

- *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. New data observed included 12-month overall survival of 88% and median overall survival (mOS) of 32.7 months*

Third Quarter 2025 Financial Results

The Company reported collaboration revenue of $2.1 million and $3.3 million for the three months ended September 30, 2025 and 2024, respectively. The decrease was due to the timing of revenue earned from the Company's collaboration and license agreement with Boehringer Ingelheim International GmbH (BI) in 2025 compared to the timing of revenue earned from the Company's Ono Collaboration and Option Agreement in 2024.

Research and development expenses were $4.8 million and $9.4 million for the three months ended September 30, 2025 and 2024, respectively. The decrease was primarily due to decreases in clinical trial costs for the Company's CUE-100 series, as well as decreases in employee compensation.

General and administrative expenses were $4.9 million and $2.9 million for the three months ended September 30, 2025 and 2024, respectively. The increase was primarily due to a one-time employee severance accrual in September of 2025, as well as an increase in professional fees.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Collaboration revenue	$ 2,149	$ 3,336	$ 5,524	$ 7,711
Operating expenses:				
General and administrative	4,939	2,867	12,792	10,564
Research and development	4,754	9,381	21,211	29,111
Loss (gain) on fixed asset disposal	51	(97)	51	(97)
Total operating expenses	9,744	12,151	34,054	39,578
Loss from operations	(7,595)	(8,815)	(28,530)	(31,867)
Other income (expense):				
Interest income	222	343	649	1,332
Interest expense	(75)	(188)	(306)	(643)
Total other income, net	147	155	343	689
Net loss	$ (7,448)	$ (8,660)	$ (28,187)	$ (31,178)
Unrealized gain from available-for-sale securities	1	-	1	-
Comprehensive loss	$ (7,447)	$ (8,660)	$ (28,186)	$ (31,178)
Net loss per common share – basic and diluted	$ (0.07)	$ (0.17)	$ (0.31)	$ (0.62)
Weighted average common shares outstanding – basic and diluted	100,869,349	51,229,701	90,271,072	50,292,983

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

	September 30, 2025	**December 31, 2024**
Assets		
Cash and cash equivalents	$ 11,701	$ 22,459
Marketable securities	6,971	-
Other assets	12,972	9,732
Total assets	$ 31,644	$ 32,191
Liabilities and stockholders' equity		
Liabilities	$ 18,398	$ 14,692
Stockholders' equity	13,246	17,499
Total liabilities and stockholders' equity	$ 31,644	$ 32,191

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. CUE-401, the company's lead autoimmune asset, is designed to act mechanistically as a master switch for regulatory T cell (Treg) differentiation and tolerance induction. It is a highly innovative bifunctional molecule combining a TGF-beta breathing-mask moiety with Cue Biopharma's clinically validated interleukin (IL-2) mutein in a single injectable biologic.

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 the company's plans to further advance its differentiating Immuno-STAT® platform and lead autoimmune asset, CUE-401, toward the clinic to address a major unmet need in autoimmune disease treatment; the company's business strategies, plans and prospects; and the potential benefits of the therapeutic approach to be developed pursuant to the collaboration and license agreement with ImmunoScape. 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 ability to maintain its collaboration with ImmunoScape; 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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