Cue Biopharma Reports Third Quarter 2026 Financial Results and Recent Business Highlights

November 16, 2026

- *CUE-221 Phase 2 chronic spontaneous urticaria (CSU) findings highlight differentiated clinical benefit and potential to expand the addressable patient population in CSU and food allergy*
- *CUE-401 enters clinical development with initiation of first-in-human dosing, achieving key 2026 milestone*
- *Operating results reflect expenditures related to initiation of clinical development program expenses and non-cash charges*

BOSTON, Nov. 16, 2026 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical stage biopharmaceutical company targeting transformative therapies for immune-mediated diseases, today reported third quarter 2026 financial results as well as recent business highlights.

“We are seeing exciting momentum across our portfolio,” said Pasha Sarraf, M.D., Ph.D., chairman of the board of Cue Biopharma. “We believe CUE-221 has the potential to redefine treatment of IgE-mediated diseases by delivering deeper, more durable disease control and expanding the population of patients who can benefit from anti-IgE therapy. The additional clinical and pharmacological findings shared today from our Phase 2 CSU study reinforce CUE-221’s differentiated profile in CSU and provide a strong foundation to advance our food allergy program. In addition, commencement of dosing in our CUE-401 Phase 1 trial marks a significant milestone for Cue Biopharma as our first autoimmune therapeutic candidate enters the clinic.”

“Our goal is to move beyond partial protection toward more complete, sustained protection for patients, including those with high baseline IgE who remain underserved by current therapies. In parallel, we are advancing half-life extension efforts for CUE-221, aimed at further enhancing patient convenience,” said Shao-Lee Lin, M.D., Ph.D., president and chief executive officer of Cue Biopharma. “CUE-401 is a potentially first-in-class dual-agonist, precision engineered by Cue scientists and designed to unlock the potential of TGF-β biology and restore immune tolerance. We believe this differentiated approach offers broad opportunities to address high unmet needs across autoimmune diseases. We look forward to sharing further progress as we advance our portfolio of therapies aimed at delivering durable, disease-modifying benefits across allergic and autoimmune diseases.”

Business Highlights
CUE-221: Phase 2 CSU Study Results
We announced positive Phase 2 CSU topline results demonstrating highly statistically significant dose responsive clinical impact on the primary endpoint of complete hives resolution (HSS7=0) and statistically significant improvement on the key secondary endpoint of complete response (UAS7=0).

Previously reported durable clinical benefit (HSS7=0) at week 28 (12 weeks after the last dose) in the 4mg/kg dose group persisted in the absence of clinically meaningful drug exposure, was not observed at lower doses, and was significantly greater than XOLAIR® (omalizumab) in a post-hoc analysis, implicating biological effects beyond IgE neutralization alone. These findings are consistent with CUE-221’s dual mechanism of action designed to both neutralize IgE and prevent the synthesis of new IgE.

The study enrolled patients across a broad range of baseline IgE (median of 427 ng/mL [178 IU/m], range up to 7860, ng/mL, with approximately one-third having high IgE ≥ 720 ng/mL (300 IU/mL).

In the study, CUE-221 demonstrated rapid, profound and dose-responsive free IgE suppression. At 4 mg/kg, all patients in the intensive PK subgroup achieved levels below the limit of quantification within hours of dosing with >90% of the overall population achieving these levels at the first post-dose assessment at week 1, including patients with baseline IgE exceeding the XOLAIR® food allergy dosing table. Median free IgE rose at the end of each 4-week dosing interval (26% of baseline at the end of the first dosing interval), with extent of return progressively diminishing at the end of each subsequent dosing interval.

In a prespecified subgroup analysis of patients with high baseline IgE ≥ 300 IU/mL, 78% of patients receiving 4 mg/kg achieved complete hive resolution (HSS7=0) at week 12 versus 0% with placebo ($P < 0.005$). A subsequent post-hoc analysis also demonstrated a statistically significant higher complete response (UAS7=0) rate of 67% versus 0% with placebo ($p < 0.05$). Together these data suggest that baseline IgE may predict response in CSU and highlight the clinical potential of CUE-221 in patients with high baseline IgE across disease states, including food allergy.

Collectively, the Phase 1 and Phase 2 CSU studies of CUE-221 demonstrated favorable and well-tolerated safety profiles, up to 10 mg/kg. No neutralizing antibodies have been observed. The phase 2 study identified 4 mg/kg as the dose at which differentiated clinical benefit emerged relative to lower doses and XOLAIR. Bioavailability was approximately 50% subcutaneous

(SC) compared with intravenous (IV). Taken together, this enables the evaluation of higher exposures aimed at further optimizing efficacy in CSU and expanding the addressable food allergy population to include the 20-30% of patients currently ineligible for treatment with XOLAIR®.

The CUE-221 Investigational New Drug (IND) application for food allergy has been cleared by the Food and Drug Administration (FDA), enabling advancement of the clinical development program.

CUE-401 Advancing a Potentially First-in-Class Precision Engineered Dual-Agonist for Autoimmune Disease

- Initiated the first-in-human Phase 1 trial, with dosing underway in the first cohort.
- CUE-401, Cue's lead autoimmune candidate, is designed to regulate inflammation and drive Treg-mediated tolerance.

Third Quarter 2026 Financial Results

Third quarter revenue was $0.1 million, compared to $2.1 million in the third quarter of 2025. The decrease in 2026 was due to less revenue recognized under our BI Collaboration and License Agreement during the three months ended September 30, 2026, compared to the same period in 2025, reflecting the planned progression of activities under the agreement.

Research and development expenses were $17.0 million for the three months ended September 30, 2026, compared to $4.8 million in the third quarter of 2025. The increase was primarily attributable to an increase in clinical trial costs associated with the start-up and initiation of clinical development, as well as non-cash stock-based compensation expense recognized in the quarter, related to long term, performance-based, company-wide incentive equity grants made following the Company's strategic transformation in the second quarter of 2026.

General and administrative expenses were $29.8 million for the three months ended September 30, 2026, compared to $4.9 million for the same period in 2025. The increase was primarily attributable to non-cash stock-based compensation expense allocated to general and administrative expense in the quarter as described above.

Other income and expense for the three months ended September 30, 2026, primarily comprised a net non-cash loss related to the revaluation of the top-up share obligation for shares the Company may be required to issue to Ascendant under the license agreement upon the achievement of certain milestones.

Net loss for the three months ended September 30, 2026, was $50.0 million, compared to $7.4 million in the third quarter of 2025.

As of September 30, 2026, the Company had $57.9 million in cash and cash equivalents. Additionally, pursuant to a Second Amendment to the License Agreement with ImmunoScape, in November 2026, the Company's right to receive a $5.0 million payment was increased to a total of $5.5 million, payable as follows: $3.0 million in the fourth quarter of 2026, $1.5 million in third quarter of 2027, and $1.0 million in the fourth quarter of 2027.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Collaboration revenue	$ 132	$ 2,149	$ 13,695	$ 5,524
Operating expenses:				
General and administrative	29,826	4,939	80,543	12,792
Research and development	17,015	4,754	72,919	21,211
Loss on fixed asset disposal	—	51	—	51
Gain on lease termination	(110)	—	(120)	—
Loss on write-off of lease security deposit	498	—	498	—
Total operating expenses	47,229	9,744	153,840	34,054
Loss from operations	(47,097)	(7,595)	(140,145)	(28,530)
Other income (expense):				
Interest income	483	222	819	649
Interest expense	(2)	(75)	(11)	(306)
Loss on issuance of liability-classified warrants and related issuance costs	—	—	(90,011)	—
Changes in fair value of financial instruments	(3,400)	—	21,087	—
Total other income (expense), net	(2,919)	147	(68,116)	343
Net loss	$ (50,016)	$ (7,448)	$ (208,261)	$ (28,187)

Unrealized gain from available-for-sale securities	—	1	—	1
Comprehensive loss	$ (50,016)	$ (7,447)	$ (208,261)	$ (28,186)
Net loss per common share – basic and diluted	$ (4.74)	$ (2.22)	$ (28.70)	$ (9.37)
Weighted average common shares outstanding – basic and diluted	10,561,814	3,362,311	7,255,392	3,009,035

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

	September 30, 2026	December 31, 2025
Assets		
Cash and cash equivalents	$ 57,939	$ 27,136
Other assets	9,316	15,076
Total assets	$ 67,255	$ 42,212
Liabilities and stockholders' equity		
Liabilities	$ 28,857	$ 15,780
Stockholders' equity	38,398	26,432
Total liabilities and stockholders' equity	$ 67,255	$ 42,212

About CUE-221
CUE-221 (Ascendant-221, UB-221) is a humanized anti-IgE IgG1 monoclonal antibody designed with a precision engineered dual mechanism of action. CUE-221 binds to IgE at sites that are distinct from the binding sites for XOLAIR® or other similar anti-IgE monoclonal antibodies. In doing so, it maintains the capacity of total IgE to bind the CD23 receptor at the surface of B cells, resulting in reduced IgE synthesis. Therefore, CUE-221 is a functionally distinct novel anti-IgE antibody designed to not only neutralize free IgE with high potency, but also to prevent the synthesis of new IgE with the possibility to achieve b-cell quiescence through crosslinking of CD23 which could ultimately result in sustained disease control beyond drug exposure. The CUE-221 Phase 2 clinical trial in CSU produced positive topline results and clinical evidence providing initial validation of the clinical potential of a precision engineered anti-IgE dual mechanism of action. The study also demonstrated fundamental biological differences compared to XOLAIR®.

About CUE-401
CUE-401 is a bispecific fusion protein of 2 human cytokines: IL-2 and TGFβ, each engineered in an attenuated form so as to decrease their affinity for their respective cognate receptor to limit the potential for broader off-target or adverse immunomodulatory effects. The design of CUE-401 stemmed from the Nobel Prize winning discovery of the role of regulatory T cells (Tregs) in autoimmunity, granted in 2025, and the recognition that the cytokines IL-2 and TGF-beta, when acting in concert are essential components in establishing immune tolerance by fostering the development of Tregs.

About Cue Biopharma
Cue Biopharma (Nasdaq: CUE) is a clinical stage biopharmaceutical company focused on advancing a portfolio of potentially transformative therapies aimed at delivering durable, potentially disease-modifying benefits across immunological disorders. Its lead asset, CUE-221, is a novel anti-IgE antibody with a dual mechanism of action, currently in Phase 2 development for allergic diseases. In addition, Cue developed the Immuno-STAT® platform which selectively targets disease-specific T cells in vivo without broad immune modulation. Its lead autoimmune candidate, CUE-401, is currently the subject of a Phase 1 clinical trial and is designed to regulate inflammation and drive Treg-mediated tolerance.

Cue is led by an experienced management team with deep expertise in identifying, acquiring, and advancing promising drug candidates. For more information, please visit www.cuebiopharma.com and follow us on X and LinkedIn.

Cautionary Note Regarding 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, the company's belief regarding the potential benefits and applications of its drug candidates and programs, including its potential benefits to patients suffering from allergic and autoimmune diseases; the company's plans to further advance its differentiating Immuno-STAT platform and its lead asset, CUE-221, and its lead autoimmune candidate, CUE-401, including expected timing of clinical trial initiation and data readout; the expected benefits from the company's license agreement with Ascendant; and expectations regarding the company's growth, 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 "aim,"

“believe,” “expect,” “may,” “will,” “should,” “would,” “could,” “seek,” “intend,” “plan,” “goal,” “project,” “estimate,” “anticipate,” “strategy,” “future,” “likely,” “promise,” “potential” 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 and establish collaboration, licensing and other arrangements; 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; the company’s ability to achieve profitability; potential setbacks in the company’s research and development efforts for its current and future drug product candidates, 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; potential challenges associated with clinical trials conducted in China and the company’s access to, and acceptability of, the data therefrom; its ability to secure required FDA or other governmental approvals for its product candidates and the breadth of any approved indication; 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 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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