Cue Biopharma Reports Third Quarter 2024 Financial Results and Recent Business Highlights

November 14, 2024

BOSTON, Nov. 14, 2024 (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 cancer and autoimmune disease, today provided a business and financial update for the third quarter of 2024.

Recent Business Highlights

- Presented positive updated data from the Phase 1 trials of CUE-101 and CUE-102 at the Society for Immunotherapy of Cancer's 39th Annual Meeting (SITC 2024) November 6-10
  - *Updated data from Phase 1 trial of CUE-101 in combination with KEYTRUDA® (pembrolizumab) continued to demonstrate enhanced benefit versus historical studies with pembrolizumab alone. Key findings included an objective response rate (ORR) of 46%, 12-month overall survival (OS) of 91.3% and a median overall survival (mOS) of 21.8 months in first line (1L) HPV+ R/M HNSCC patients, as well as an ORR of 50% in the subset of 1L patients with low PD-L1 expression (combined positive score (CPS) 1-19)*
  - *Updated data from Phase 1 monotherapy trial of CUE-102 included evidence of selective expansion of WT1-specific T cells and anti-tumor activity, as well as a favorable tolerability profile with no dose limiting toxicities (DLTs) in patients with Wilms' Tumor 1 (WT1)-expressing colorectal, gastric, ovarian and pancreatic cancers*
- Demonstrated disease control rate (DCR) of 67% in late-stage pancreatic cancer patients treated with CUE-102 monotherapy, including an unconfirmed partial response (PR) with a 40% decrease in tumor burden
- Announced pricing of $12.0 million public offering
- Appointed industry veteran Lucinda Warren as Chief Business Officer
- Continued advancement of preclinical programs, CUE-401 for induction and expansion of regulatory T cells, in collaboration with Ono Pharmaceutical, and CUE-501 for B cell depletion, positioning both programs towards drug candidate selection

"We are very pleased with the validating updated clinical data from our Phase 1 trials for both CUE-101 and CUE-102," said Daniel Passeri, chief executive officer of Cue Biopharma. "Importantly, we believe the maturing data further supports and strengthens our competitive differentiation and positioning for selective modulation of disease-specific T cells. This data further bolsters our confidence that the CUE-100 series, exemplified by CUE-101 and CUE-102, represents the potential of establishing a new standard of care for cancer patients. We are also very pleased with the continued progress of our preclinical autoimmune programs, both of which have moved closer towards drug candidate selection."

Third Quarter 2024 Financial Results

Collaboration revenue increased by $1.2 million to $3.3 million for the three months ended September 30, 2024, from $2.1 million for the three months ended September 30, 2023. The increase was due to revenue earned from the Ono Collaboration and Option Agreement, which was executed in February 2023.

Research and development expenses decreased by $0.5 million to $9.4 million for the three months ended September 30, 2024, from $9.9 million for the three months ended September 30, 2023. The decrease was primarily due to lower clinical trial costs and employee compensation, which includes stock-based compensation, partially offset by an increase in drug substance manufacturing costs related to the continued advancement of CUE-401.

General and administrative expenses decreased by $0.7 million to $2.9 million for the three months ended September 30, 2024, from $3.6 million for the three months ended September 30, 2023. The decrease was primarily due to a decrease in employee compensation, which includes stock-based compensation.

Collaboration revenue increased by $4.0 million to $7.7 million for the nine months ended September 30, 2024, from $3.7 million for the nine months ended September 30, 2023. The increase was due to revenue earned from the Ono Collaboration and Option Agreement, which was executed in February 2023.

Research and development expenses decreased by $0.8 million to $29.1 million for the nine months ended September 30, 2024, from $29.9 million for the nine months ended September 30, 2023. The decrease was primarily due to lower clinical trial costs and employee compensation, which includes stock-based compensation, partially offset by an increase in professional outside services related to the continued advancement of CUE-401.

General and administrative expenses decreased by $1.5 million to $10.6 million for the nine months ended September 30, 2024, from $12.1 million for the nine months ended September 30, 2023. The decrease was primarily due to a decrease in employee compensation, which includes stock-based compensation.

As of September 30, 2024, the Company had approximately $32.4 million in cash and cash equivalents compared with $48.5 million in cash and cash

equivalents as of December 31, 2023. The Company expects its current cash and cash equivalents to fund operations into the fourth quarter of 2025.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Collaboration revenue	$ 3,336	$ 2,100	$ 7,711	$ 3,669
Operating expenses:				
General and administrative	2,867	3,645	10,564	12,071
Research and development	9,381	9,874	29,111	29,915
Gain on fixed asset disposal	(97)	-	(97)	-
Total operating expenses	12,151	13,519	39,578	41,986
Loss from operations	(8,815)	(11,419)	(31,867)	(38,317)
Other income (expense):				
Interest income	343	700	1,332	1,756
Interest expense	(188)	(286)	(643)	(738)
Total other income, net	155	414	689	1,018
Net loss	$ (8,660)	$ (11,005)	$ (31,178)	$ (37,299)
Unrealized gain from available-for-sale securities	-	5	-	96
Comprehensive loss	$ (8,660)	$ (11,000)	$ (31,178)	$ (37,203)
Net loss per common share – basic and diluted	$ (0.17)	$ (0.24)	$ (0.62)	$ (0.82)
Weighted average common shares outstanding – basic and diluted	51,229,701	46,358,555	50,292,983	45,274,124

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

	September 30, 2024	**December 31, 2023**
Assets		
Cash and cash equivalents	$ 32,420	$ 48,514
Other assets	12,390	13,016
Total assets	$ 44,810	$ 61,530
Liabilities and stockholders' equity		
Liabilities	$ 19,444	$ 24,445
Stockholders' equity	25,366	37,085
Total Liabilities and stockholders' equity	$ 44,810	$ 61,530

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 through the selective modulation of disease-specific T cells without the adverse effects of broad systemic immune modulation.

Headquartered in Boston, Massachusetts, we are 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 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 that the CUE-100 series represents the potential of establishing a new standard of care for cancer patients; the company's belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective modulation of disease-relevant T cell and the applicability of the company's platform across many cancers and autoimmune diseases; the company's business strategies, plans and prospects, including the advancement of the company's preclinical autoimmune programs toward drug candidate selection ; and the cash runway of the company and the sufficiency of the company's cash and cash equivalents to fund its operations. 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 ability to shift its focus to its autoimmune assets and achieve the cost savings that it is projecting; 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 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 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; 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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