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

August 19, 2024

BOSTON, Aug. 19, 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, provided a business and financial update for the second quarter 2024.

Recent Business Highlights

- *Delivered oral presentation on updated data from ongoing Phase 1(b) trial of CUE-101 as a first line (1L) therapy in human papillomavirus positive (HPV+) recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC), with standard of care (SOC) checkpoint inhibitor (CPI) KEYTRUDA® (pembrolizumab) and as a monotherapy in second line and beyond (2L+) HPV+ R/M HNSCC, as well as a poster presentation on CUE-102 in Wilms' Tumor 1 (WT1) positive cancers at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting held in June.*

- *Further advanced autoimmune program CUE-401, partnered with Ono Pharmaceutical, Ltd., and CUE-501, our lead CUE-500 series asset.*
    - *Programs are designed to address significant unmet medical need in large patient populations across numerous autoimmune and inflammatory diseases*
    - *Preclinical data has progressed well with consistent positive activity in multiple disease models*

- *Initiated strategic prioritization of autoimmune programs to focus upon near-term and intermediate value creation potential, to enable optimization and reduction of capital requirements, while retaining oncology programs, CUE-101 and CUE-102, as promising clinical data further matures.*

- *Positive observations as updated data continues to mature from ongoing oncology clinical trials, CUE-101 and CUE-102.*
    - *CUE-101 in combination with pembrolizumab in 1L R/M HNSCC, as of August 4, 2024, demonstrated an objective response rate (ORR) of 46% in all patients with combined positive score (CPS) ≥1 and 50% ORR with CPS <20, median progression free survival (mPFS) of 5.8 months and median overall survival (mOS) of 21.8 months*
    - *CUE-101 monotherapy in 2L+ HPV+ R/M HNSCC demonstrated mOS of 20.8 months vs. mOS of 7.5 and 8.4 months observed in trials in 2L patients with two different CPIs: OPDIVO® (nivolumab) and pembrolizumab, respectively*
    - *CUE-102 monotherapy in late-stage refractory metastatic cancers has been well tolerated and to date, has demonstrated dose-dependent increases in exposure and activation and expansion of WT1-specific T cells with observed anti-tumor activity in two gastric and ovarian patients, as well as disease control in several tumor types in multiple patients in the dose escalation Phase 1 trial*

"We had a highly productive second quarter with promising clinical data continuing to mature from our ongoing oncology trials further supporting our belief that CUE-101, as our lead representative CUE-100 program, has the potential to establish a new standard of care for HPV+ HNSCC patients," said Daniel Passeri, chief executive officer of Cue Biopharma. "These observations, combined with the ongoing advancements of our prioritized autoimmune programs and the recent implementation of a highly focused, strategic business model underscoring our objectives to proactively manage and mitigate capital access risk, support the transformational potential of our Immuno-STAT™ platform to accomplish our mission of developing breakthrough immunotherapies to establish a new standard of care in the treatment of cancer and autoimmune disease."

Second Quarter 2024 Financial Results

The Company reported collaboration revenue of $2.7 million and $1.4 million for the three months ended June 30, 2024 and 2023, respectively. The increase was due to the timing of revenue earned from the collaboration and option agreement with Ono Pharmaceutical Co., Ltd.

Research and development expenses were $9.5 million and $10.7 million for the three months ended June 30, 2024 and 2023, respectively. The decrease was primarily due to a decrease in research and laboratory costs and compensation expense.

General and administrative expenses were $3.5 million and $4.2 million for the three months ended June 30, 2024 and 2023, respectively. The decrease was primarily due to decreases in professional fees, employee compensation, overhead, and stock-based compensation expense.

The Company reported collaboration revenue of $4.4 million and $1.6 million for the six months ended June 30, 2024 and 2023, respectively. The increase was due to the timing of revenue earned from the collaboration and option agreement with Ono Pharmaceutical Co., Ltd.

Research and development expenses were $19.7 million and $20.0 million for the six months ended June 30, 2024 and 2023, respectively. The decrease was primarily due to a decrease in research and laboratory costs and stock-based compensation expense, partially offset by an increase in clinical expenses.

General and administrative expenses were $7.7 million and $8.4 million for the six months ended June 30, 2024 and 2023, respectively. The decrease was primarily due to decreases in professional fees and employee compensation.

As of June 30, 2024, the Company had $30.0 million in cash and cash equivalents compared with $48.5 million as of June 30, 2023. We expect our current cash, cash equivalents, and marketable securities to fund operations through the second quarter of 2025.

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,	
	2024	**2023**	**2024**	**2023**
Collaboration revenue	$ 2,658	$ 1,382	$ 4,375	$ 1,570
Operating expenses:				
General and administrative	3,511	4,249	7,697	8,425
Research and development	9,530	10,650	19,729	20,041
Total operating expenses	13,041	14,899	27,426	28,466
Loss from operations	(10,383)	(13,517)	(23,051)	(26,896)
Other income (expense):				
Interest income	427	564	989	1,056
Interest expense	(215)	(232)	(456)	(454)
Total other income, net	212	332	533	602
Net loss	$ (10,171)	$ (13,185)	$ (22,518)	$ (26,294)
Unrealized gain from available-for-sale securities	—	34	—	91
Comprehensive loss	$ (10,171)	$ (13,151)	$ (22,518)	$ (26,203)
Net loss per common share – basic and diluted	$ (0.20)	$ (0.29)	$ (0.45)	$ (0.59)
Weighted average common shares outstanding – basic and diluted	50,174,756	44,798,760	49,822,689	44,725,875

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

	June 30, 2024	**December 31, 2023**
Assets		
Cash and cash equivalents	$ 30,029	$ 48,514
Other assets	12,300	13,016
Total assets	$ 42,329	$ 61,530
Liabilities and stockholders' equity		
Liabilities	$ 20,707	$ 24,445
Stockholders' equity	21,622	37,085
Total Liabilities and stockholders' equity	$ 42,329	$ 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 regarding the potential benefits and applications of its drug candidates and programs, including the transformational potential of the company's Immuno-STAT™ platform to accomplish its mission of developing breakthrough immunotherapies to establish a new standard of care in the treatment of cancer and autoimmune disease; the near-term and intermediate value creation potential of its autoimmune programs; the company's intention to preserve the value of its oncology programs; the company's business strategies, plans and prospects, including those related to the prioritization of CUE-401 and CUE-501, and the potential benefits of the company's program prioritization and realignment on its burn rate; 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," "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 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 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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