Cue Biopharma Reports Third Quarter 2023 Financial Results and Recent Business Highlights

November 9, 2023

BOSTON, Nov. 09, 2023 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of T cell engagers to selectively modulate tumor-specific T cells, provided a business and financial update for the third quarter of 2023.

Recent Business Highlights

- Presented positive data from ongoing Phase 1 trials of CUE-101 and CUE-102 at the Society for Immunotherapy of Cancer's 38th Anniversary Annual Meeting (SITC 2023) held November 1-5.
    - *Updated Phase 1 data of CUE-101 monotherapy for second line (2L) and beyond recurrent/metastatic HPV+ head and neck squamous cell carcinoma demonstrating an estimated median overall survival (mOS) of 20.8 months compared with the historical mOS of 8.4 months for KEYTRUDA® (pembrolizumab) observed in Merck's KEYNOTE-040 trial.*
    - *Completed enrollment of 20 patients for the ongoing Phase 1b study of CUE-101 in combination with pembrolizumab. Of 17 evaluable patients at the September 27 SITC data cutoff, an overall response rate (ORR) of 47% was reported for CUE-101 + pembrolizumab vs. 19% historic ORR for pembrolizumab alone in Merck's KEYNOTE-048 trial, with median progression free survival (mPFS) and mOS still maturing and trending positively. In patients with low levels of PD-L1 expression in the tumor tissue that are historically low responders to anti-PD-1 therapy, CUE-101 + pembrolizumab demonstrated an ORR of 56% vs. 14.5% for pembrolizumab alone.*
    - *Reported initial data from CUE-102 Phase 1 monotherapy trial for the treatment of Wilms' Tumor 1 (WT1)-expressing tumors with early observations of anti-tumor activity and tolerability.*
- Demonstrated disease control rate (DCR) of 75% and 80% at the 4mg/kg and 2mg/kg doses of CUE-102 respectively and observed tumor reductions of -30% and -29% in two patients, one with gastric cancer and one with ovarian cancer.
- Advanced preclinical programs from the CUE-100 series including additional alleles, such as A11, A24 and A03 and tumor epitopes, such as KRAS and MAGE A4, as well as CUE-401 in collaboration with Ono Pharmaceutical.

"The continued advancements of our programs and platform have positioned us as a potential industry- leading solutions provider for immuno-oncology and autoimmune disease," said Daniel Passeri, chief executive officer of Cue Biopharma. "Importantly, we believe the positive data from our ongoing clinical trials has placed us in a sound position to continue developing our platform for selective and targeted modulation of disease relevant T cells in broader applications across many cancers and autoimmune diseases."

Third Quarter 2023 Financial Results

The Company reported collaboration revenue of approximately $2.1 million and $68,000 for the three months ended September 30, 2023 and 2022, respectively. Revenue in the third quarter of 2023 was primarily due to work related to the recent collaboration and option agreement with Ono Pharmaceutical Co., Ltd.

Research and development expenses were $9.9 million and $7.6 million for the three months ended September 30, 2023 and 2022, respectively. The increase was due to higher clinical expenses, stock-based compensation and research and laboratory expenses in the third quarter of 2023 as compared to the same period in 2022.

General and administrative expenses remained steady at $3.6 million and 3.5 million for the three months ended September 30, 2023 and 2022, respectively.

The Company reported collaboration revenue of approximately $3.7 million and $1.1 million for the nine months ended September 30, 2023 and 2022, respectively. Revenue for the nine months ended September 30, 2023 was primarily due to work related to the recent collaboration and option agreement with Ono Pharmaceutical Co., Ltd.

Research and development expenses were $30.0 million and $27.2 million for the nine months ended September 30, 2023 and 2022, respectively. This increase was primarily due to increased clinical costs in 2023 related to the initiation of the Phase 1 monotherapy clinical trial of CUE-102.

General and administrative expenses were $12.1 million and $12.5 million for the nine months ended September 30, 2023 and 2022, respectively. This decrease was primarily due to lower stock-based compensation for executive management.

As of September 30, 2023, the Company had approximately $54.7 million in cash and cash equivalents compared with $76.3 million in cash, cash equivalents and marketable securities as of December 31, 2022. We expect our current cash and cash equivalents to fund operations through 2024.

Cue Biopharma, Inc.
Selected Consolidated Statement of Operations and Other Comprehensive Loss Data
(In thousands, except share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration revenue	$ 2,100	$ 68	$ 3,669	$ 1,094
Operating expenses:				
General and administrative	3,645	3,528	12,071	12,465
Research and development	9,874	7,571	29,915	27,246
Gain on right-of-use asset termination	-	-	-	(258)
Total operating expenses	13,519	11,009	41,986	39,453
Loss from operations	(11,419)	(11,031)	(38,317)	(38,359)
Other income (expense):				
Interest income	700	200	1,756	296
Interest expense	(286)	(124)	(738)	(355)
Total other income (expense)	414	76	1,018	(59)
Net loss	$ (11,005)	$ (10,955)	$ (37,299)	$ (38,418)
Unrealized gain (loss) from available-for-sale securities	5	(92)	96	(92)
Comprehensive loss	$ (11,000)	$ (11,047)	$ (37,203)	$ (38,510)
Net loss per common share – basic and diluted	$ (0.24)	$ (0.31)	$ (0.82)	$ (1.11)
Weighted average common shares outstanding – basic and diluted	46,358,555	35,383,430	45,274,124	34,471,499

Cue Biopharma, Inc.
Selected Consolidated Balance Sheet Data
(In thousands)

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 54,691	$ 51,614
Marketable securities	-	24,675
Total current assets	57,517	77,187
Working capital	40,310	65,639
Total assets	68,888	91,283
Total stockholders' equity	42,666	65,683

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 body's intrinsic immune system as T cell engagers without the need for ex vivo manipulation or 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 Twitter at https://twitter.com/CueBiopharma.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the safe harbor created by those sections. Such forward-looking statements include, but are not limited to, those regarding: the company's belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective engagement 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 potential corporate development and partnership opportunities; and the cash runway of the company and the sufficiency of the company's cash, cash equivalents, and marketable securities 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 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 the recent COVID-19 pandemic, 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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