Cue Biopharma Reports Fourth Quarter and Full Year 2023 Financial Results and Updated Business Highlights

April 8, 2024

BOSTON, April 08, 2024 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of therapeutic biologics to selectively modulate disease-specific T cells, today reported fourth quarter and full year 2023 financial results.

- *Presented additional positive data from the ongoing Phase 1 trials of CUE-101 in first line (1L) human papillomavirus positive (HPV+) recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC) in combination 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 CUE-102 in Wilms' Tumor 1 (WT1) positive cancers at the Society for Immunotherapy of Cancer's (SITC) 38th Annual Meeting in November 2023.*

- *Completed enrollment of 25 patients in the 1L Phase 1b dose expansion trial of CUE-101 in combination with SOC CPI pembrolizumab.*

- *Presented notable updates from the ongoing Phase 1 clinical trials of CUE-101 and CUE-102 at the 2024 Oppenheimer Annual Healthcare Life Sciences Conference in February:*
    - *CUE-101 monotherapy in 2L HPV+ R/M HNSCC demonstrated median overall survival (mOS) of 20.8 months vs. historical third-party mOS of 7.5 and 8.4 months with two different CPIs: OPDIVO® (nivolumab) and pembrolizumab, respectively*
    - *CUE-101 in combination with pembrolizumab in 1L R/M HNSCC showed an overall response rate (ORR) of 46% vs. 19% with pembrolizumab alone in a third-party trial and median progression free survival (mPFS) of 8.3 months vs. 3.2 months with pembrolizumab alone in a third-party trial*
    - *CUE-101 continued to demonstrate favorable tolerability in the monotherapy and combination trials*
    - *CUE-102 monotherapy in late-stage refractory metastatic cancers demonstrated tumor reductions and stable disease in multiple patients in the dose escalation Phase 1 trial*

- *Concluded Type B meeting with FDA receiving guidance for potential paths for CUE-101 registrational trials in both monotherapy and combination settings.*

- *Advanced preclinical program CUE-401 in collaboration with Ono Pharmaceutical for the treatment of autoimmune and inflammatory diseases. Preclinical activity demonstrated in disease models supported moving toward selection of an Investigational New Drug (IND) candidate.*

- *Deployed the Immuno-STAT™ platform to develop a therapeutic biologics candidate, CUE-501, a bispecific Immuno-STAT that is designed to direct selective memory T cells to deplete B cells, to address autoimmune and inflammatory diseases.*

"Cue Biopharma continues to make measurable progress advancing its clinical oncology programs CUE-101 and CUE-102, as well as its lead preclinical autoimmune and inflammatory disease candidate CUE-401, partnered with Ono Pharmaceutical," said Daniel Passeri, chief executive officer of Cue Biopharma. "We also accomplished an important milestone earlier this year with guidance received from the FDA for potential CUE-101 registrational trials both in the monotherapy and combination settings providing further risk-reduction and defined resource requirements for achieving the next phase of our strategic corporate objectives. I believe that these key milestones, including progress addressing additional therapeutic approaches for the treatment of autoimmune and inflammatory diseases with CUE-401 and CUE-501, bolster our competitive positioning in securing value for our shareholders and most importantly, patients suffering from these debilitating and life-threatening diseases."

Fourth Quarter 2023 Financial Results

The Company reported collaboration revenue of approximately $1.8 million and $0.15 million for the three months ended December 31, 2023 and 2022, respectively. The increase was due to revenue earned from the strategic collaboration agreement entered into with Ono Pharmaceutical in the first quarter of 2023.

Research and development expenses were $10.9 million and $11.3 million for the three months ended December 31, 2023 and 2022, respectively. The decrease was primarily due to drug substance manufacturing projects for CUE-101 and CUE-102 completed in 2022.

General and administrative expenses were $4.6 million and $3.7 million for the three months ended December 31, 2023 and 2022, respectively. The increase was primarily due to an increase in professional and consulting fees.

Full Year 2023 Financial Results

The Company reported collaboration revenue of approximately $5.5 million and $1.2 million for the years ended December 31, 2023 and 2022, respectively. The increase was due to revenue earned from our strategic collaboration agreement entered into with Ono Pharmaceutical in the first quarter of 2023.

Research and development expenses were approximately $40.8 million and $38.6 million for the years ended December 31, 2023 and 2022, respectively. The increase was primarily due to increases in clinical development costs and research and laboratory expenses, offset by decreases in employee costs and rent expense.

General and administrative expenses were approximately $16.7 million and $16.2 million for the years ended December 31, 2023 and 2022, respectively. The increase was primarily due to an increase in professional and consulting fees.

As of December 31, 2023, the Company had approximately $48.5 million in cash, cash equivalents and marketable securities compared with $76.3 million as of December 31, 2022. We expect our current cash, cash equivalents, and marketable securities to fund operations into the first quarter of 2025.

Cue Biopharma, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share information)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Collaboration revenue	$ 1,821	$ 151	$ 5,490	$ 1,245
Operating expenses (income):				
General and administrative	4,609	3,704	16,680	16,169
Research and development	10,887	11,332	40,802	38,578
Loss (gain) on fixed asset disposal and right-of-use asset termination	157	(19)	157	(277)
Total operating expenses	15,653	15,017	57,639	54,470
Loss from operations	$ (13,832)	$ (14,866)	$ (52,149)	$ (53,225)
Other income (expense):				
Interest income	905	632	2,661	928
Interest expense	(507)	(359)	(1,245)	(713)
Loss before income taxes	$ (13,434)	$ (14,593)	$ (50,733)	$ (53,010)
Provision for income taxes	-	-	-	-
Net loss	$ (13,434)	$ (14,593)	$ (50,733)	$ (53,010)
Unrealized gain (loss) from available-for-sale securities	-	(4)	96	(96)
Comprehensive loss	(13,434)	(14,597)	(50,637)	(53,106)
Net loss per common share – basic and diluted	$ (0.28)	$ (0.37)	$ (1.11)	$ (1.49)
Weighted average common shares outstanding – basic and diluted	47,181,633	39,171,994	45,754,794	35,649,134

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

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 48,514	$ 51,614
Marketable securities	-	24,675
Total current assets	51,454	77,187
Working capital	34,373	65,639
Total assets	61,530	91,283
Total stockholders' equity	37,085	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 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 (Twitter) 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 Immuno-STAT platform stimulates targeted immune modulation through the selective engagement of disease-relevant T cells and the applicability of the company's platform across many cancers and autoimmune diseases; the company's business strategies, plans and prospects, including potential paths for CUE-101 registrational trials in both monotherapy and combination settings; its beliefs regarding its competitive positioning to secure value for shareholders and patients; 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 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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Source: Cue Biopharma, Inc.