Cue Biopharma Reports Fourth Quarter and Full Year 2022 Financial Results and Recent Business Highlights

March 21, 2023

- *Received U.S. Food and Drug Administration (FDA) acceptance of Investigational New Drug (IND) application for CUE-102 in Wilms' Tumor 1 (WT1)-expressing cancers and initiated dosing in a Phase 1 dose escalation monotherapy trial at 1mg/kg.*
- *Granted FDA Fast Track Designation for CUE-101 for the treatment of HPV+ recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC) as a monotherapy and in combination with pembrolizumab (KEYTRUDA®).*
- *Presented new positive data from the ongoing Phase 1 trials of CUE-101 in combination with pembrolizumab and as a monotherapy for HPV+ (R/M HNSCC) at the Society for Immunotherapy of Cancer's (SITC) 37th Annual Meeting on November 10, 2022.*
- *Entered into securities purchase agreements with accredited investors for a $30 million private investment in public equity (PIPE) financing. The transaction closed on November 16, 2022.*
- *Entered into a strategic collaboration and option agreement with Ono Pharmaceutical for CUE-401, a bispecific protein designed to induce and expand regulatory T cells (Tregs) for the treatment of autoimmune and inflammatory diseases.*

BOSTON, March 21, 2023 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body, today reported fourth quarter and full year 2022 financial results.

"2022 was a strategically important and significant year for Cue Biopharma with the emergence of positive clinical data from our ongoing trials with CUE-101 – our lead oncology drug product candidate from the CUE-100 series – validating and derisking our Immuno-STAT™ platform, and having accessed opportunities to secure a strong financial position that enable us to further execute on our corporate and clinical goals throughout 2023 and well into 2024," said Daniel Passeri, chief executive officer of Cue Biopharma. "Importantly, we plan to present updated clinical data from our representative programs from the CUE-100 series oncology programs at an upcoming scientific conference with the aim of further demonstrating the potential significance of our platform and clinical development approach for the treatment of multiple cancers. Additionally, we look forward to advancing our lead autoimmune disease asset, CUE-401, toward the clinic through our recent partnership with Ono Pharmaceutical and will continue to seek similar partnerships that support building out our promising pipeline of potential breakthrough therapeutics."

Fourth Quarter 2022 Financial Results

The Company reported collaboration revenue of approximately $0.15 million and $8.3 million for the three months ended December 31, 2022 and 2021, respectively. The decrease was primarily due to the completion of the research phase of the LG Chem collaboration in the first quarter of 2022.

Research and development expenses were $11.3 million and $11.5 million for the three months ended December 31, 2022 and 2021, respectively. The decrease was due to the completion of enrollment in the CUE-101 Phase 1 monotherapy clinical trial in the first half of 2022.

General and administrative expenses were $3.7 million and $4.7 million for the three months ended December 31, 2022 and 2021, respectively. The decrease was due primarily to recording lower stock-based compensation expense during the fourth quarter of 2022 versus the same period in 2021.

Full Year 2022 Financial Results

The Company reported collaboration revenue of approximately $1.2 million and $14.9 million for the years ended December 31, 2022 and 2021, respectively. The decrease was primarily due to completion of the research phase of the LG Chem collaboration during the first quarter of the year.

Research and development expenses were $38.6 million and $41.3 million for the years ended December 31, 2022 and 2021, respectively. The decrease was primarily due to a decrease in costs related to the CUE-101 Phase 1 monotherapy clinical trial as enrollment was completed in the first half of 2022, a decrease in CUE-101 combination clinical trial costs and lower manufacturing costs for CUE-101 and CUE-102 clinical material during 2022, as compared to 2021.

General and administrative expenses were $16.2 million and $17.3 million for the years ended December 31, 2022 and 2021, respectively. The decrease in general and administrative expense was due primarily to lower professional and consulting fees, stock-based compensation and rent in 2022.

As of December 31, 2022, the Company had approximately $76.3 million in cash, cash equivalents and marketable securities compared with $64.4 million as of December 31, 2021. We expect our current cash, cash equivalents, and marketable securities to fund operations into the second half of 2024.

Cue Biopharma, Inc.
Condensed Consolidated Statement of Operations
(In thousands, except per share information)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Collaboration revenue	$ 151	$ 8,254	$ 1,245	$ 14,941
Operating expenses:				
General and administrative	3,704	4,647	16,169	17,306
Research and development	11,332	11,501	38,578	41,347
Gain on right-of-use asset termination	(19)	-	(277)	-
Total operating expenses	15,017	16,148	54,470	58,653
Loss from operations	(14,866)	(7,894)	(53,225)	(43,712)
Other income:				
Interest income	632	4	928	46
Interest expense	(359)	-	(713)	-
Loss before income taxes	$ (14,593)	$ (7,890)	$ (53,010)	$ (43,666)
Provision for income taxes	-	(495)	-	(495)
Net loss	$ (14,593)	$ (8,385)	$ (53,010)	$ (44,161)
Unrealized loss from available-for-sale securities	(4)	-	(96)	(7)
Comprehensive loss	(14,597)	(8,385)	(53,106)	(44,168)
Net loss per common share – basic and diluted	$ (0.37)	$ (0.26)	$ (1.49)	$ (1.41)
Weighted average common shares outstanding – basic and diluted	39,171,994	31,941,699	35,649,134	31,285,418

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

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 51,614	$ 64,371
Marketable securities	24,675	-
Total current assets	77,187	68,468
Working Capital	65,639	55,680
Total assets	91,283	83,401
Total Stockholders' equity	65,683	65,492

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 potential benefits and results that may be achieved through the collaboration with Ono; the company's belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective engagement of disease-relevant T cells; 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 "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, 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 COVID-19, including possible effects on the company's trials; negative or inconclusive results from the company's clinical trials or preclinical studies or serious and unexpected drug-related side effects or other safety issues experienced by participants in 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; operations and clinical 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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