Cue Biopharma Reports Third Quarter 2022 Financial Results

November 14, 2022

BOSTON, Nov. 14, 2022 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of injectable biologics to selectively engage and modulate tumor-specific T cells directly within the patient's body, reported today third quarter 2022 financial results. The Company will host a business update call in conjunction with its financial results press release on November 14, 2022.

Recent Business Updates

- Announced a $30 million private investment in public equity (PIPE) financing with certain accredited investors in which the company agreed to sell 7,656,966 shares of its common stock and, in lieu of shares of common stock to certain investors, pre-funded warrants to purchase an aggregate of 1,531,440 shares of common stock, and, in each case, accompanying warrants to purchase an aggregate of up to 9,188,406 additional shares of common stock (or Pre-Funded Warrants). The transaction is expected to close on or about November 16, 2022, subject to the satisfaction of customary closing conditions.

- Presented new positive data from the ongoing Phase 1 trials of CUE-101 in combination with pembrolizumab (KEYTRUDA®) and as a monotherapy for recurrent/metastatic HPV+ head and neck squamous cell carcinoma (r/m HNSCC) at the Society for Immunotherapy of Cancer's (SITC) 37th Annual Meeting on November 10, 2022.

- Key data highlights from the dose escalation and patient expansion portion of the Phase 1 trial evaluating CUE-101 at the recommended Phase 2 dose in combination with pembrolizumab include a 40% overall response rate (ORR) and a 70% clinical benefit rate (CBR) in first line (1L) r/m HNSCC patients treated with CUE-101, with 16 evaluable patients to date.

- Median overall survival (mOS) approaching greater than 12 months in third line and beyond (3L+) patients treated with CUE-101 monotherapy, which is 50% greater than current standard of care (SOC) with anti-PD-1 therapy in second line (2L) patients.

"With our anticipated strengthened financial position and with bolstered confidence from the recently reported clinical update at SITC, we are able to focus on core strategic initiatives to further enhance our competitive positioning to optimize shareholder value," said Daniel Passeri, chief executive officer of Cue Biopharma.

Kerri-Ann Millar, chief financial officer of Cue Biopharma, added, "We are pleased to have announced our private placement, which would extend our cash runway into 2024 upon closing and further strengthen our ability to assess the CUE-101 data readouts from both the Phase 1 monotherapy and combination clinical trials and remain on track to define a potential registrational CUE-101 monotherapy trial by mid-2023."

Third-Quarter 2022 Financial Results
The Company reported collaboration revenue of approximately $68 thousand and $2.4 million for the three months ended September 30, 2022 and 2021, respectively.

Research and development expenses were $7.6 million and $11.3 million for the three months ended September 30, 2022 and 2021, respectively. The decrease in research and development expenses of $3.7 million was primarily due to a decrease in laboratory and drug substance manufacturing costs, employee and Scientific and Clinical Advisory Board compensation, other professional fees, licensing fees, and rent.

General and administrative expenses were $3.5 million and $4.1 million for the three months ended September 30, 2022 and 2021, respectively. The decrease in general and administrative expense of $0.6 million was primarily due to a decrease in stock-based compensation expense related to executive management, professional and consulting fees, and employee and board compensation incurred in the third quarter of 2022 as compared to the same period in 2021.

Cue Biopharma, Inc.
Selected Consolidated Statement of Operations Data
(in thousands, except share data)

	Three Months Ended September 30,	
	2022	**2021**
Collaboration revenue	$ 68	$ 2,395
Operating expenses:		
General and administrative	3,528	4,125

Research and development	7,571	11,288
Total operating expenses	11,099	15,413
Loss from operations	(11,031)	(13,018)
Other income:		
Total other income, net	76	25
Net Loss	$ (10,955)	$ (12,993)
Net loss per common share – basic and diluted	$ (0.31)	$ (0.41)
Weighted average common shares outstanding – basic and diluted	35,383,430	31,315,178

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

	September 30, 2022	December 31, 2021
Cash and cash equivalents	29,726	64,371
Marketable securities	29,457	-
Total current assets	61,700	68,469
Working Capital	51,478	55,681
Total assets	76,300	83,401
Total Stockholders' equity	50,764	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 tumor-specific T cells directly within the patient's body to transform the treatment of cancer. 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.

Headquartered in Boston, Massachusetts, the company is 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, visit https://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 statements about the expected closing of the PIPE financing; the company's anticipated use of proceeds from the PIPE financing; whether the conditions for the closing of the PIPE financing will be satisfied; the company's estimate of the period in which it expects to have cash to fund its operations; 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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