Cue Biopharma Reports First Quarter 2022 Financial Results

May 10, 2022

BOSTON, May 10, 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 targeted T cells directly within the patient's body, today reported first quarter 2022 financial results. The Company will not host a business update call in conjunction with its financial results press release.

Recent Business Updates

- Extended cash runway with an aggregate of $23.6 million from the sale of 3,593,407 shares of our common stock pursuant to our at-the-market (ATM) equity offering sales agreement with Jefferies LLC. As of March 31, 2022, the Company sold 2,396,013 shares of common stock under the October 2021 ATM Agreement for proceeds of approximately $17.6 million net of commissions paid, excluding transaction expenses, and in April 2022 sold an additional 1,197,394 shares of common stock for proceeds of approximately $6.0 million, net of commissions paid, excluding transaction expenses.

- Completed enrollment of 20 patients at the recommended Phase 2 dose of 4mg/kg of the Phase 1b monotherapy trial of CUE-101 for the treatment of HPV16-driven recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC) in second line and beyond treatment-refractory patients. To date, CUE-101 has demonstrated a favorable tolerability profile as well as encouraging anti-tumor clinical activity and what appears to be an emerging trend of enhanced overall survival (OS).

- Completed dose escalation phase of CUE-101 in combination with Merck's KEYTRUDA ®, an anti-PD-1 biologic agent, as first-line therapy in patients with advanced HPV16+ HNSCC. Patient enrollment has begun in the expansion phase at the recommended Phase 2 dose of 4mg/kg of CUE-101.

"Through a focused and strategic deployment of resources during the first quarter of 2022, we have made significant progress advancing the IL-2-based CUE-100 series for oncology, as well as strengthening our financial position," said Daniel Passeri, chief executive officer of Cue Biopharma. "As reported, we recently completed the patient expansion phase of the monotherapy Phase 1b clinical trial of CUE-101 and the dose escalation phase of the CUE-101 Phase 1 combination trial with KEYTRUDA®. We are very pleased with our clinical trial progress to date and have enhanced confidence in the emerging data supporting the potential of our CUE-100 series pipeline in immuno-oncology through targeted and selective stimulation of the patient's immune system against cancer."

Kerri-Ann Millar, chief financial officer of Cue Biopharma, added, "We continue to be in a solid financial position as we remain disciplined in our resource deployment and adroit in our response to the challenges of the current biotech capital markets. Accessing our ATM common stock facility during the first four months of 2022 allowed us to extend the anticipated operational runway further into the third quarter of 2023 which we anticipate will enable us to assess the data readouts from both our Phase 1 monotherapy and combination clinical trials of CUE-101."

First-Quarter 2022 Financial Results

The Company reported collaboration revenue of approximately $1.0 million and $1.6 million for the three months ended March 31, 2022 and 2021, respectively.

Research and development expenses were $10.1 million and $9.8 million for the three months ended March 31, 2022 and 2021, respectively. The increase in research and development expenses of $0.3 million was primarily due to an increase 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 $5.2 million and $4.3 million for the three months ended March 31, 2022 and 2021, respectively. The increase in general and administrative expense of $0.9 million was primarily due to an increase in stock-based compensation expense, professional and consulting fees, and employee and board compensation incurred in the first 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 March 31,	
	2022	**2021**
Collaboration revenue	$ 1,000	$ 1,553
Operating expenses:		
General and administrative	5,156	4,255
Research and development	10,082	9,816

Total operating expenses	15,238	14,071
Loss from operations	(14,238)	(12,518)
Other income:		
Interest (expense) income, net	(17)	13
Net Loss	$ (14,255)	$ (12,512)
Net loss per common share – basic and diluted	$ (0.44)	$ (0.41)
Weighted average common shares outstanding – basic and diluted	32,436,316	30,434,525

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

	March 31, 2022	December 31, 2021
Cash and cash equivalents	67,927	64,371
Total current assets	75,947	68,469
Working Capital	64,536	55,680
Total assets	90,704	83,402
Total Stockholders' equity	64,673	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 targeted T cells directly within the patient's body to transform the treatment of cancer, infectious diseases and autoimmune diseases. The company's proprietary Immuno-STAT ™*(Selective Targeting and Alteration of T cells)* platform, is designed to harness the body's intrinsic immune system 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 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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