



Cue Biopharma Reports Third Quarter 2020 Results and CUE-101 Phase 1 Dose Escalation Trial Updates

November 17, 2020

CAMBRIDGE, Mass., Nov. 17, 2020 (GLOBE NEWSWIRE) -- [Cue Biopharma, Inc.](#) (Nasdaq: CUE), a clinical-stage biopharmaceutical company engineering a novel class of injectable biologics designed to selectively engage and modulate targeted T cells within the patient's body, provided a business update for the third quarter of 2020.

"We are very pleased with the progress we continue to make advancing CUE-101 through the ongoing Phase 1 monotherapy dose escalation trial," said Daniel Passeri, chief executive officer of Cue Biopharma. "We are encouraged by the datasets to date from this ongoing study, have completed dosing cohort 6, at 4mg/kg and were recently cleared by the Safety Review Committee to begin dosing cohort 7, at 8mg/kg."

Anish Suri, chief scientific officer and president of Cue Biopharma, added, "We believe that we remain well-positioned for continued execution of our development plans for our lead asset CUE-101, which is representative of our IL-2 based CUE-100 series, and the continued build-out of our pipeline via our proprietary protein engineering approach, as also exemplified by recent scientific presentations at the SITC meeting last week."

Third Quarter 2020 Financial Results

Collaboration revenue was \$704,000 and \$984,000 for the three months ended September 30, 2020 and 2019, respectively.

Research and development expenses were \$7.5 million and \$5.3 million for the three months ended September 30, 2020 and 2019, respectively. This increase of approximately \$2.2 million was due primarily to an increase in clinical trial activity, drug manufacturing costs, and stock-based compensation expense, offset by a decrease in travel expenses during the third quarter of 2020 as the COVID-19 pandemic continued to hamper business travel throughout the quarter.

General and administrative expenses were \$3.3 million and \$2.8 million for the three months ended September 30, 2020 and 2019, respectively. This increase of approximately \$0.5 million was due primarily to increases in stock-based compensation and legal fees offset by a decrease in travel expenses for the third quarter of 2020.

"As of September 30, 2020, we had approximately \$91.8 million in cash, cash equivalents and marketable securities, which we believe will allow us to support the clinical development of our lead asset CUE-101 into the second quarter of 2022," said Kerri-Ann Millar, chief financial officer of Cue Biopharma.

Recent News & Business Updates

- Presented three posters highlighting the company's clinical and pipeline progress at the Society for Immunotherapy of Cancer's 35th Anniversary Annual Meeting (SITC 2020). The posters include a clinical update on CUE-101, the lead drug candidate from the IL-2 based CUE-100 series and data supporting the potential of the Immuno-STAT™ (*Selective Targeting and Alteration of T cells*) platform to selectively engage and modulate targeted T cells within the body in a manner that could address a broad range of indications.
- Entered into an amendment to the Global License and Collaboration agreement with LG Chem that extended the deadline for LG Chem to exercise its option for an additional Immuno-STAT program from November 6, 2020 to April 30, 2021.
- Appointed Tamar Howson to the board of directors. Ms. Howson brings broad corporate and business development experience to the board, having held executive leadership positions in several global biopharmaceutical and pharmaceutical companies as well as her extensive board service.
- Presented preclinical data focused on the in vivo detection of tumor antigen-specific T cells in a peer-reviewed paper published in *Nature Methods* titled, "In vivo detection of antigen-specific CD8 T cells by immuno-positron emission tomography." The study was co-authored by Steven C. Almo, Ph.D., co-founder of Cue Biopharma, professor and chair of biochemistry, professor of physiology & biophysics and the Wollowick Family Foundation chair in multiple sclerosis and immunology at Albert Einstein College of Medicine and Hidde Ploegh, Ph.D., a renowned expert in molecular immunology and a member of the program in cellular and molecular medicine at Boston Children's Hospital.
- Extended cash runway during the third quarter of 2020 through sales of shares of common stock under an ATM equity offering sales agreement for aggregate proceeds of \$14.3 million, net of commissions paid, with Stifel Nicolaus & Company, Inc., who acted as sales agent.

Members of the Cue Biopharma executive management team will provide an update on the ongoing Phase 1 clinical trial of CUE-101 for the treatment of HPV+ HNSCC, technology platforms and pipeline progress, as well as updates on its strategic objectives and anticipated milestones today,

Tuesday, November 17 at 4:30 p.m. EST.

Investors: 877-407-9208

International: 201-493-6784

Conference
ID: 13712195

Webcast: <http://public.viavid.com/index.php?id=142111>

About Cue Biopharma

Cue Biopharma, a clinical-stage biopharmaceutical company, is engineering a novel class of injectable biologics to selectively engage and modulate targeted T cells within the patient's body to transform the treatment of cancer, infectious diseases and autoimmune diseases. The company's proprietary platform, Immuno-STAT™ (*Selective Targeting and Alteration of T cells*) is designed to harness the body's intrinsic immune system without the need for ex vivo manipulation.

Headquartered in Cambridge, Massachusetts, we are led by an experienced management team and independent Board of Directors with deep expertise in the design and clinical development of protein biologics, immunology and immuno-oncology treatments.

For more information, visit www.cuebiopharma.com and follow us on Twitter <https://twitter.com/CueBiopharma>.

Cautionary Note Regarding 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 development plans for CUE-101 and the continued buildout of its pipeline; the sufficiency of the company's cash, cash equivalents and marketable securities to support the clinical development of CUE-101; the anticipated results of the company's drug development efforts, including study results; and the company's expectations regarding regulatory developments and expected future operating results. 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 operations and clinical 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; 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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Cue Biopharma, Inc.
Selected Consolidated Statement of Operations
(in thousands)

	Three Months Ended September 30,	
	2020	2019
Collaboration revenue	\$ 704	\$ 984
Operating expenses:		

General and administrative	3,318	2,776
Research and development	7,517	5,302
Total operating expenses	<u>10,835</u>	<u>8,078</u>
Loss from operations	<u>(10,131)</u>	<u>(7,094)</u>
Other income:		
Interest income	123	99
Other income / (expense) net	<u>(23)</u>	<u>5</u>
Net Loss	\$ (10,031)	\$ (6,990)
Net loss per common share – basic and diluted	\$ (0.34)	\$ (0.31)
Weighted average common shares outstanding – basic and diluted	<u>29,651</u>	<u>22,450</u>

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

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Cash and cash equivalents	\$ 71,729	\$ 44,290
Marketable securities	20,074	15,120
Total current assets	93,563	61,025
Working Capital	79,336	49,370
Total assets	106,617	71,605
Total Stockholders' equity	87,553	54,584



Source: Cue Biopharma, Inc.