



Cue Biopharma Reports Fourth Quarter and Full Year 2019 Financial Results and Recent Business Highlights

March 17, 2020

- *Extended cash runway with \$33.3 million from at-the-market equity offerings in Q4'19*
- *Focused and effective execution of clinical development of CUE-101 as a Phase 1 monotherapy dose escalation and expansion trial in HNSCC*
- *Immuno-STAT™ Platform for autoimmune disease featured in Merck presentation at the Antigen-Specific Immune Tolerance Drug Development Summit*
- *Published paper on preclinical and translational data supporting the therapeutic potential of CUE-101 in HPV16-related malignancies in peer-reviewed journal Clinical Cancer Research*

CAMBRIDGE, Mass., March 17, 2020 (GLOBE NEWSWIRE) -- [Cue Biopharma, Inc.](#) (NASDAQ: CUE), a clinical-stage biopharmaceutical company engineering a novel class of injectable biologics to selectively engage and modulate targeted T cells within the body, provided a business update for the fourth quarter and full year 2019.

"We continue to execute on our stated goals and objectives in a highly focused manner. The fourth quarter of 2019, as well as the beginning of 2020, has been marked by the successful opening of all 13 participating clinical centers and the associated enhancement of patient enrollment for our ongoing CUE-101 monotherapy Phase 1 trial," said Daniel Passeri, chief executive officer of Cue Biopharma. Mr. Passeri added, "Furthermore, we successfully accessed the capital markets in a highly effective and prudent manner through an At-the-Market ("ATM") instrument with Stifel Nicolaus & Company, Inc. ("Stifel") raising \$49M, net of commissions paid, in the second half of the year through strategically placed blocks of shares with targeted fundamental institutional investors. As a result of our successful execution of clearly defined corporate initiatives, we are now well positioned to focus upon the next stages of our strategic corporate development plan."

According to Anish Suri, Ph.D., president and chief scientific officer of Cue Biopharma, "We continue to make significant progress across the R&D organization on many fronts including expanding our oncology pipeline assets, evolving our platform and generating key datasets to support application of our platform in autoimmune diseases. To the last point, we are very pleased to have Merck, our collaborator in autoimmune disease, recently present advances in the Immuno-STAT platform for selective modulation of pathologic T cells involved in autoimmune type 1 diabetes."

Fourth-Quarter 2019 Financial Results

The Company reported collaboration revenue of approximately \$1.0 million and \$0.3 million for the three months ended December 31, 2019 and 2018, respectively.

Research and development expenses were \$6.9 million and \$7.3 million for the three months ended December 31, 2019 and 2018, respectively. The decrease in research and development expenses of \$0.4 million was primarily due to a decrease in manufacturing cost as our full clinical supply was manufactured during 2018. The decrease in these costs were offset by clinical trial expenses related to the CUE-101 monotherapy trial that was initiated in the latter part of the third quarter of 2019.

General and administrative expenses were \$3.1 million and \$5.3 million for the three months ended December 31, 2019 and 2018, respectively. The decrease in general and administrative expense of \$2.2 million was primarily due to a decrease in stock-based compensation expense and legal and accounting fees incurred in the fourth quarter of 2019 as compared to the same period in 2018.

Full Year 2019 Financial Results

The Company reported collaboration revenue of approximately \$3.5 million and \$1.1 million for the years ended December 31, 2019 and 2018, respectively.

Research and development expenses were \$27.5 million and \$28.5 million for the years ended December 31, 2019 and 2018, respectively. The decrease in research and development expenses of \$1.0 million was primarily due to a reduction in headcount and operational efficiencies realized during 2019.

General and administrative expenses were \$12.7 million and \$11.3 million for the years ended December 31, 2019 and 2018, respectively. The increase in general and administrative expense of \$1.4 million was primarily due to an increase in headcount and legal fees related to our patent filings in 2019.

As of December 31, 2019, the Company had approximately \$59.4 million in cash and cash equivalents compared with \$39.2 million as of December 31, 2018.

Recent News & Business Updates

- Extended cash runway through an ATM equity offering sales agreements for aggregate proceeds of \$49 million, net of

commissions paid, with Stifel, who acted as sales agent. As of December 31, 2019, the Company had sold 5,314,055 shares of common stock under the sales agreements.

- Immuno-STAT (*Selective Targeting and Alteration of T cells*) platform was featured in a Merck presentation at the *Antigen-Specific Immune Tolerance Drug Development Summit* in February 2020. The presentation highlights an Immuno-STAT that was made to selectively deliver a PD-L1 inhibitory signal to CD4 T cells reactive to the proinsulin protein, which is associated with type 1 diabetes. This Immuno-STAT selectively inhibited the expansion of proinsulin reactive T cells isolated from the blood of type 1 diabetes patients, and also selectively inhibited the functional response of proinsulin-specific CD4 T cells when the Immuno-STAT was administered to transgenic mice.
- Published research demonstrating the ability of the Company's lead biologic candidate CUE-101 to activate tumor antigen specific antitumor immunity in the peer-reviewed medical journal *Clinical Cancer Research*, a journal of the American Association for Cancer Research. The manuscript by Steven Quayle et al. is titled "[CUE-101, a Novel HPV16 E7 pHLA-IL-2-Fc Fusion Protein, Enhances Tumor Antigen Specific T Cell Activation for the Treatment of HPV16-Driven Malignancies.](#)"

The research highlights the ability of our proprietary Immuno-STAT (*Selective Targeting and Alternation of T cells*) platform to selectively engage and modulate targeted T cells within the body. CUE-101 is the Company's lead drug candidate from the IL-2 based CUE-100 series designed to directly engage and activate T cells to target HPV16-driven recurrent/metastatic head and neck squamous cell carcinoma (HNSCC).

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Collaboration revenue	\$ 1,049	\$ 331	\$ 3,458	\$ 1,143
Operating expenses:				
General and administrative	3,100	5,305	12,740	11,295
Research and development	6,965	7,261	27,487	28,544
Total operating expenses	10,065	12,566	40,227	39,839
Loss from operations	(9,016)	(12,235)	(36,769)	(38,696)
Other income:				
Interest income	110	105	419	376
Other income / (expense) net	(12)	86	64	165
Loss before income taxes	\$ (8,918)	\$ (12,044)	\$ (36,286)	\$ (38,155)
Provision for income taxes	-	-	(412)	(825)
Net loss	\$ (8,918)	\$ (12,044)	\$ (36,698)	\$ (38,980)
Net loss per common share – basic and diluted	\$ (0.37)	\$ (0.60)	\$ (1.66)	\$ (1.94)
Weighted average common shares outstanding – basic and diluted	24,147	20,201	22,042	20,134

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

	December 31, 2019	December 31, 2018
Cash and cash equivalents	44,290	20,800
Marketable securities	15,120	18,413

Total current assets	61,025	40,610
Working Capital	49,370	34,393
Total assets	71,605	45,363
Total Stockholders' equity	54,584	33,972

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 body to transform the treatment of cancer 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 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>.

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. Forward-looking statements, which are based on certain assumptions and describe our 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. All statements other than statements of historical facts included in this press release regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding anticipated results of our drug development efforts, including study results, our expectations regarding regulatory developments and expected future operating results. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, our limited operating history, limited cash and a history of losses; our ability to achieve profitability; our ability to secure required U.S. Food and Drug Administration ("FDA") or other governmental approvals for our product candidates and the breadth of any approved indication; negative or inconclusive results from our clinical studies or serious and unexpected drug-related side effects or other safety issues experienced by participants in our clinical trials; delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications to the FDA; our reliance on third parties to conduct our clinical trials as well as licensors, collaborations and strategic alliances; our ability to obtain adequate financing to fund our business operations in the future; uncertainties associated with COVID-19 or coronavirus, including its possible effects on our operations and clinical trial; 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 our 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 us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake 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.