UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): November 12, 2019

Cue Biopharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38327**	**47-3324577**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

21 Erie St., Cambridge, Massachusetts	**02139**
(Address of principal executive offices)	**(Zip Code)**

(Registrant's telephone number, including area code): (617) 949-2680

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	**CUE**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operations and Financial Condition

On November 12, 2019, Cue Biopharma, Inc. announced its financial results for the quarter ended September 30, 2019. A copy of the press release is being furnished as Exhibit 99 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

The exhibits required to be filed as a part of this Current Report on Form 8-K are listed below and incorporated herein by reference

Exhibit No.	Exhibit Description
99	Press release, dated November 12, 2019, issued by Cue Biopharma, Inc., furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Cue Biopharma, Inc.

Date: November 12, 2019

By: /s/ Daniel R. Passeri
Name: Daniel R. Passeri
Title: Chief Executive Officer

Cue Biopharma Reports Third Quarter 2019 Financial Results and Recent Business Highlights

- *Initiated patient dosing in Phase 1 clinical study of lead program CUE-101 in head and neck squamous cell carcinoma (HNSCC)*
- *Extended cash runway with $11.9 million from at-the-market equity offering in Q3*
- *Promoted Dr. Anish Suri to the role of president and chief scientific officer*

CAMBRIDGE, Mass., November 12, 2019 — 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, today provided a business update for the third quarter 2019.

“The third quarter was marked by the dosing of the first patient in our Phase 1 clinical study of CUE-101, which represents a transformative milestone for the company as we continue to grow and develop as a clinical stage company,” said Daniel Passeri, chief executive officer. “As part of this continued evolution, the promotion of Dr. Suri to President and CSO helps enhance our productivity and effectiveness by further integrating operational functions and fostering close coordination of preclinical translational studies with clinical development.”

Dr. Suri stated, “We have made significant progress on several key programs in addition to CUE-101, including CUE-102, a program selected with our collaboration partner, LG Chem Life Sciences, as well as our early-stage program in auto-immune disease, through our collaboration with Merck. With our first immuno-oncology candidate now in the clinic and additional candidates in lead optimization, Cue Biopharma is well positioned for the potential of significant value inflection over the coming months.”

Recent News & Business Updates

- Recently initiated dosing a Phase 1 clinical trial to investigate the safety and efficacy of CUE-101 in the treatment of HNSCC. The trial is a multi-center, open-label, Phase 1 dose escalation and expansion study evaluating the safety, anti-tumor effect, and

immunogenicity of CUE-101 as a monotherapy in approximately 50 patients with confirmed HPV16-driven recurrent/metastatic HNSCC and HLA-A*02:01 serotype.

- Extended cash runway through an at-the-market equity offering sales agreement for aggregate gross proceeds of up to $30 million with Stifel Nicolaus & Company, Inc. (“Stifel”), who acts as sales agent. As of September 30, 2019, the Company had sold 2,084,615 shares of common stock under the sales agreement for total proceeds of approximately $15.7 million, net of commissions paid, but excluding estimated transaction expenses.
- Promoted Anish Suri, Ph.D., to the role of president in addition to his current role as chief scientific officer. As president, Dr. Suri will assume operational and management oversight of corporate functions, as well as research and development activities. Building upon the recent success of entering clinical development with its lead drug candidate CUE-101, the company plans to augment its senior management team with a number of key hires through 2020.
- On Friday, November 8, 2019, Cue Biopharma presented a poster on its lead program, CUE-101, at the Society for Immunotherapy of Cancer 34th Annual Meeting (SITC 2019) titled, “CUE-101, a novel HPV16 E7:pMHC:IL-2:Fc fusion protein, enhances tumor antigen specific T cell activation for the treatment of HPV16-driven malignancies.”

Third-Quarter Results & Financial Highlights

The Company reported collaboration revenue of approximately $1.0 million and $0.4 million for the three months ended September 30, 2019 and 2018, respectively.

Research and development expenses were $5.3 million and $10.3 million for the three months ended September 30, 2019 and 2018, respectively. The decrease in research and development expenses of $5.0 million was primarily due to a reduction in headcount, operational efficiencies and a decrease in drug substance manufacturing cost as our full clinical supply for the CUE-101 Phase 1 monotherapy trial was manufactured during 2018.

General and administrative expenses were $2.8 million and $2.9 million for the three months ended September 30, 2019 and 2018, respectively. The decrease in general and administrative expense of $0.1 million was primarily due to a reduction in headcount.

As of September 30, 2019, the Company had approximately $31.3 million in cash and cash equivalents compared with $39.2 million as of December 31, 2018.

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

	Three Months Ended September 30,	
	2019	2018
Collaboration revenue	$ 984	$ 449
Operating expenses:		
General and administrative	2,776	2,895
Research and development	5,302	10,313
Total operating expenses	8,078	13,208
Loss from operations	(7,094)	(12,759)
Other income:		
Interest income	99	102
Other income, net	5	98
Loss before income taxes	$ (6,990)	$ (12,559)
Net loss	$ (6,990)	$ (12,559)
Net loss per common share – basic and diluted	$ (0.31)	$ (0.62)
Weighted average common shares outstanding – basic and diluted	22,450	20,132

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

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 31,379	$ 20,800
Marketable securities	—	18,413
Total current assets	32,990	40,610
Working capital	22,598	39,984
Total assets	45,209	45,363
Total Stockholders’ equity	27,022	33,972

About the CUE-100 Series

The CUE-100 series consists of Fc-fusion biologics that incorporate peptide-MHC (pMHC) molecules along with rationally engineered IL-2 molecules. This singular biologic is anticipated to selectively target, activate and expand a robust repertoire of tumor-specific T cells directly in the patient. The binding affinity of IL-2 for its receptor has been deliberately attenuated to achieve preferential selective activation of tumor-specific effector T cells while reducing potential for effects on regulatory T cells (Tregs) or broad systemic activation, potentially mitigating the dose-limiting toxicities associated with current IL-2-based therapies.

About CUE-101

CUE-101, our lead program from the CUE-100 series, contains IL-2 and a pMHC composed of HLA-A*02:01 complexed with a dominant peptide derived from the human papilloma virus 16 E7 protein (HPV16-E7). The drug is a fusion protein designed to target and activate antigen-specific T cells present in the patient's body to attack HPV16-driven cancers. CUE-101 is currently being tested in a Phase 1 clinical trial for the treatment of HPV16-driven recurrent or metastatic head and neck squamous cell carcinoma (HNSCC). For more information about the trial, please visit clinicaltrial.gov.

About Immuno-STAT

Immuno-STAT™ biologics are designed for targeted modulation of disease-associated T cells in the areas of immuno-oncology and autoimmune disease. Each of our biologic drugs is designed using our proprietary scaffold comprising: 1) a peptide-MHC complex (pMHC) to provide selectivity through interaction with the T cell receptor (TCR), and 2) a unique co-stimulatory signaling molecule to modulate the activity of the target T cells.

The simultaneous engagement of co-stimulatory molecules and pMHC binding mimics the signals delivered by antigen presenting cells (APCs) to T cells during a natural immune response. This design enables Immuno-STAT biologics to engage with the T cell population of interest, resulting in highly targeted T cell modulation. Because our drugs are delivered directly in the patient's body (in vivo), they are fundamentally different from other T cell therapeutic approaches that require the patients' T cells to be extracted, stimulated and expanded outside the body (ex vivo), and reinfused in an activated state.

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.cuebio.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 licensors, collaborations and strategic alliances; our ability to obtain adequate financing to fund our business operations in the future; 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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