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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2019

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-38327

Cue Biopharma, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**47-3324577**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
21 Erie Street Cambridge, MA	**02139**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

Securities registered pursuant to Section 12 (g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act): Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $160.4 million (based on the closing price of the registrant's common stock on June 28, 2019 of $8.99 per share).

As of March 6, 2020, the registrant had 26,575,959 shares of Common Stock $0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days after the end of the fiscal year ended December 31, 2019. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

CUE BIOPHARMA, INC.
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 and references to future periods. All statements other than statements of historical facts included in this Annual Report on Form 10-K 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, the following:

- our limited operating history, limited cash and a history of losses;
- our ability to achieve profitability;
- our ability to secure required 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;
- 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 this Annual Report on Form 10-K.

Any forward-looking statement made by us in this report 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.

PART I

Cue Biopharma, Inc. ("we," "us," "our," "Cue" and the "Company") was incorporated in the State of Delaware on December 31, 2014 under the name Imagen Biopharma, Inc., and completed its organization, formation and initial capitalization activities effective as of January 1, 2015. In October 2016, the Company changed its name to Cue Biopharma, Inc. The Company's corporate office and research facilities are located in Cambridge, Massachusetts.

Item 1. Business

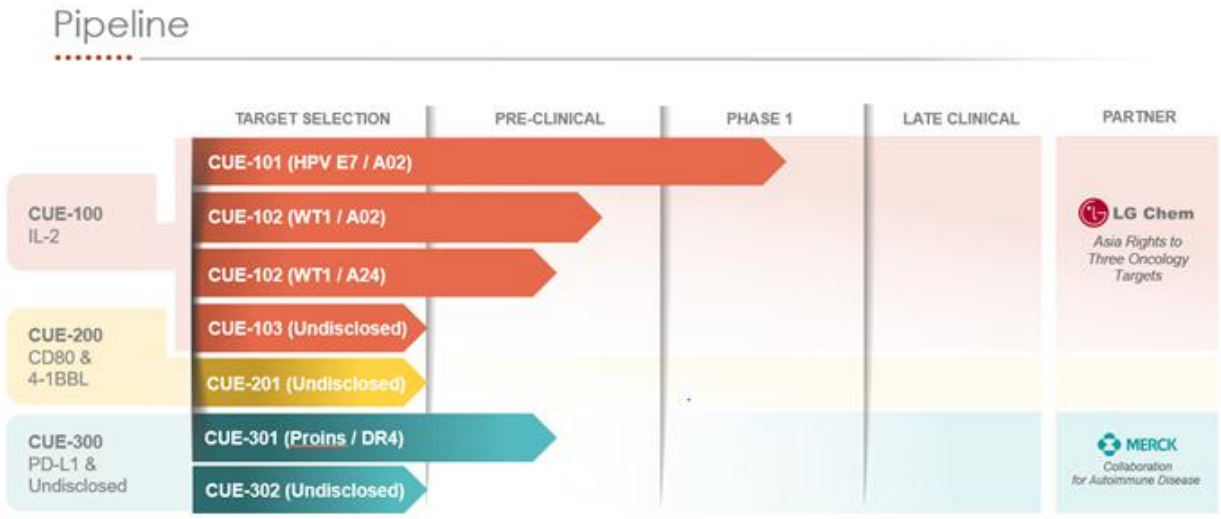
Overview

Cue Biopharma is a clinical-stage biopharmaceutical company engineering a novel class of injectable biologics to selectively engage and modulate targeted T cells within the body. Our proprietary Immuno-STAT™ (*Selective Targeting and Alteration of T Cells*) platform is engineered to selectively engage and modulate disease relevant T cells directly within the body which we believe will allow us to harness the fullest potential of an individual's intrinsic immune repertoire for restoring health while avoiding the deleterious side-effects of broad immune activation (for immuno-oncology or infectious immunity) or broad immune suppression (for autoimmunity and inflammation). In addition to the selective control of T cell activity, we believe Immuno-STATs offer several key points of potential differentiation over competing approaches, including modularity and versatility providing broad disease coverage, manufacturability, and convenient administration.

Through rational protein engineering, we leverage the modular and versatile nature of the Immuno-STAT platform to design therapeutics for selective immune modulation in cancer, chronic infectious disease, and autoimmune disease. To address the needs of these clinical indications, we have developed three biologic series, CUE-100, CUE-200, and CUE-300, each possessing distinct signaling modules that underscore unique biological mechanisms that may be applied across many diseases. The CUE-100 series exploits rationally engineered IL-2 in context of the core Immuno-STAT framework for activation of tumor-specific T cells, while the CUE-200 series is focused on cell surface receptors including CD80 and/or 4-1BBL. The CUE-300 series is being developed for autoimmune diseases for selective modulation of the autoreactive T cell repertoire.

The Company's product candidates are in various stages of clinical and preclinical development, and while we believe that these candidates hold tremendous potential value, the Company's activities are subject to significant risks and uncertainties. The Company has not yet commenced any commercial revenue-generating operations, has limited cash flows from operations, and will need to raise additional capital to fund its growth and ongoing business operations.

Our Immuno-STAT Pipeline



Cue Biopharma Immuno-STAT Pipeline: The pipeline snapshot above details our current portfolio assets and their stages of development. CUE-101 is our most advanced clinical stage asset, currently being dosed in a Ph 1 monotherapy trial for human papilloma virus (HPV)-driven head and neck cancer. CUE-102 focuses on Wilm's tumor-1 (WT1) as the tumor antigen.

We have made significant progress furthering the advancement of the CUE-100 series. We dosed the first patient in September 2019 in a Phase 1 clinical trial of CUE-101 for the treatment of HPV16-driven recurrent/metastatic head and neck squamous cell carcinoma (HNSCC). Enabled by the company's proprietary Immuno-STAT platform, CUE-101 is the company's lead biologic drug candidate, designed to directly engage and activate T cells in the body to target HPV-driven cancers. The CUE-101 program is representative of the IL2-based CUE-100 series for which we have generated a robust preclinical data package, including activation of HPV specific T cells from human blood. These data were recently published in a peer-reviewed journal (Quayle et al., *Clinical Cancer Research* 2019, *https://clincancerres.aacrjournals.org/content/early/2020/01/15/1078-0432.CCR-19-3354*).

We are currently advancing a pipeline of additional promising preclinical candidates that hold the potential to treat multiple cancers, and with recent advances with the CUE-300 series for autoimmune disorders, plan to be well poised with a growing pipeline of promising clinical candidates throughout the coming year. Furthermore, we also have the potential of developing a pipeline of Immuno-STATs for treating chronic infectious diseases with the CUE-200 series.

Our Business Strategy

Our primary objective is to become a leading biopharmaceutical company developing breakthrough, highly selective and differentiated biologics for safe and effective therapeutic immune modulation directly in patients having high unmet medical need. In order to achieve this objective, we are focused on the following strategies:

Advance our IL-2-based CUE-100 series, demonstrated with our lead Immuno-STAT program, CUE-101

- Execute clinical trials that are designed with a translational approach to determine CUE-101's ability to selectively activate and expand patients' own endogenous HPV16-specific T cell repertoire to target and attack tumor cells
- Build a clinical data set that demonstrates the safety, anti-tumor effect, and immunogenicity of CUE-101 as a monotherapy in patients with HPV16-driven recurrent/ metastatic head and neck squamous cell carcinoma (HNSCC)
- Expand patient access and address the significant unmet patient need in frontline therapy for HPV16-driven HNSCC in combination with anti-PD1 therapy, based on supporting monotherapy clinical data for HNSCC.

Leverage our modular and versatile Immuno-STAT platform to generate and advance a pipeline of Immuno-STATs and strategically partner to expand our global patient reach

- Beyond the IL-2-based CUE-100 series, as exemplified by CUE-101, for addressing a broad range of cancers, we have a growing pipeline of therapeutic frameworks and programs designed to address the significant, unmet medical need for treating serious, life threatening indications, such as autoimmune disease and chronic infectious disease
- We are working to develop robust data packages in the discovery stage for the CUE-200 series that demonstrates the ability to enhance T cell activation and/ or reverse T cell exhaustion, an area of critical need for chronic infectious diseases, and achieve proof of mechanism with the CUE-300 series, focused on autoimmune disease, through our Merck Collaboration
- We will continue to selectively explore other opportunities to create value from the platform and may pursue these with partners and/or as wholly owned Cue Biopharma assets

Expand and enhance our core capabilities and Immuno-STAT platform

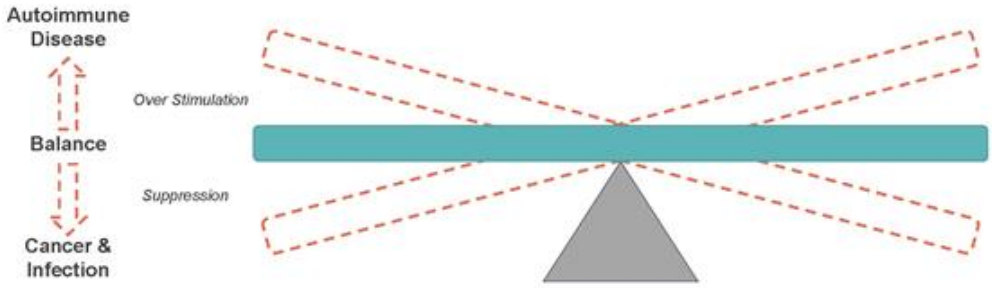
- We view protein engineering and translational immunology as our core competencies and to expand our competitive advantages, will continue to invest in these areas to further optimize the platform for rapid and cost-effective drug development. We may also in-license, acquire, or invest in complementary businesses, technologies, products or assets

Our Approach

The Immune System and T Cell Immunity

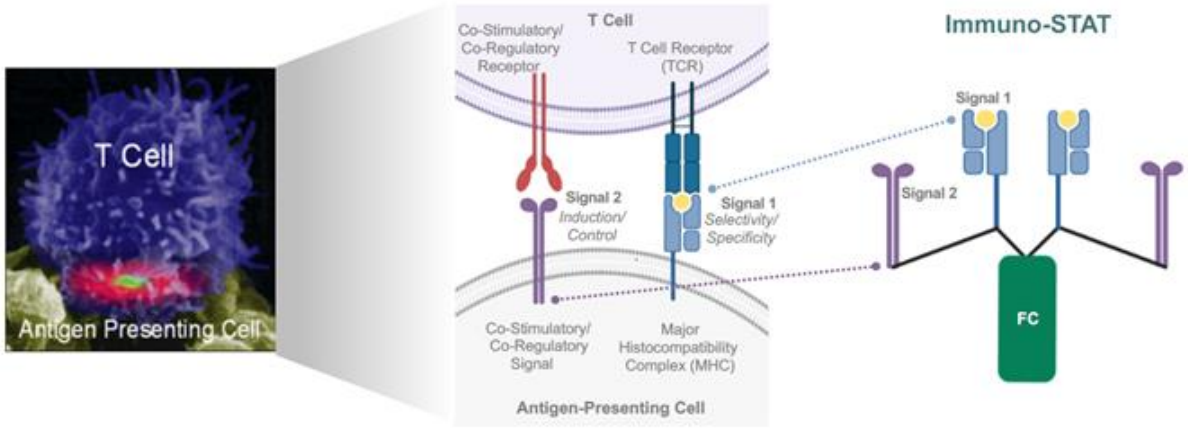
As highlighted in the figure below, a critical component of human health is achieving and maintaining a state of immune balance. Imbalance of the immune system underscores many diseased states: susceptibility to cancers and chronic infectious disease can be attributed to inadequate or attenuated immune responses, while autoimmune diseases result from an overactive immune system that reacts against the host.

Immune Balance



The human immune system comprises a number of specialized cell types that collectively function to identify and defend the body against foreign threats. A human T cell is a subtype of a white blood cell that plays a central role in the immune system. During an immune response, T cells are activated via close encounters with a specialized cell type known as the antigen presenting cell ("APC"). Prominent APC types include dendritic cells, macrophages and B cells. The primary function of an APC is to uptake antigens, primarily proteins, catabolize them into peptides and display them on their cell-surface in complex with specialized molecules known as the major histocompatibility complex molecules or human leukocyte antigen ("MHC", or "HLA" in humans). This critical function of an APC, also referred to as "antigen processing and presentation", ultimately results in generation of the key molecular substrate – the peptide MHC complex (pMHC or pHLA in humans) – that is recognized by the T cell via its T cell receptor ("TCR"). The source of the antigenic world for the APC is vast and unlimited: antigens from pathogens such as viruses, bacteria and others activate T cells for protective immunity; antigens from tumor cells are key for robust anti-tumor T cell responses; and antigens from self-tissue are aberrantly recognized by autoreactive T cells. Hence, the nature of the pMHC complex on the APC sets the specificity of the T cell response. The intimate interactions between the T cells and APCs occur within a molecular interface known as the immunological or immune synapse (as shown in the figure below) wherein the TCR-pMHC engagement as well as additional accessary signals are sensed by T cells resulting in T cell activation or regulation. In essence, the immune synapse allows controlled engagement and selective activation of T cells through the presentation of two distinct signals: Signal 1, TCR engagement of the pMHC; and Signal 2, activating co-stimulatory or co-inhibitory signals. The core protein framework for the Immuno-STAT platform builds upon our ability to combine the key signals for T cell modulation (i.e. Signal 1 and Signal 2) into a singular molecular scaffold, as shown below.

The Immune Synapse

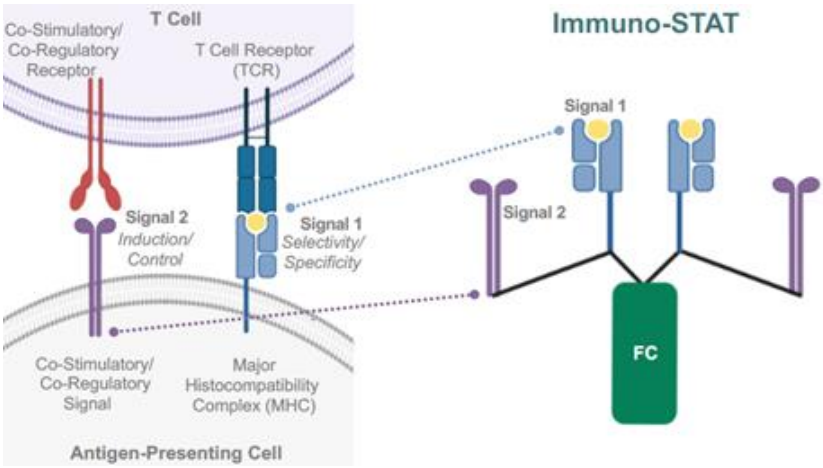


While the elegant and dynamic nature of T cell-APC interactions is an essential component of immunity or tolerance (i.e., not reactive to self), it is often encumbered by many considerations including: (i) antigen availability and release for presentation by APCs; (ii) antigen uptake and processing efficiencies of an APC that generate the appropriate pMHC complex for the T cell; (iii) stability, amount and turnover of pMHC complexes displayed on the cell surface of an APC; (iv) the "right" kind of the APC phenotype for the desired biological outcome – activating versus tolerogenic, for example; (v) effects of the local tissue/tumor microenvironment on the APC (e.g., immunosuppressive tumor microenvironments directly impede local APC function in the tumor lesion); and (vi) the absolute dependency on localization and encounter of the right T cell with the right APC in the individual. These challenges could be potentially circumvented if the essential components for T cell activation (i.e., pMHC complex and appropriate co-stimulatory signals), are provided to the T cells directly with no dependency on the APCs. This is the core focus of the Immuno-STAT platform, as described below.

The Immuno-STAT: "***Immune Responses, on Cue"***

Through rational protein engineering, we are developing a proprietary class of Immuno-STAT product candidates to selectively modulate the activity of antigen-specific T cells in a patient's body. Our Immuno-STATs direct T cell activity via two distinct signals presented naturally within the immune synapse by the body when mounting an immune response. We accomplish this by the fusion of a TCR targeting pMHC complex (i.e., Signal 1) with co-stimulatory signaling molecules (i.e., Signal 2). This co-engagement of signals through the TCR and co-stimulatory receptor mimics and recapitulates the very signals encountered in nature by T cells upon successful interactions with APCs. Hence, the Immuno-STATs harness "nature's cues" for antigen specificity, along with appropriate secondary activating or inhibitory signals, resulting in targeted T cell modulation.

The Immuno-STAT Framework Builds Upon Nature's Components for T cell Modulation



During the last decade, there has been substantial progress in therapeutically modifying the function of immune cells, such as T cells, to either enhance tumor killing in the context of oncology or protect tissue in the context of autoimmune disease. Much of the focus has centered on approaches that result in broad and non-specific immune modulation (e.g., cytokines, cytokine inhibitors, checkpoint inhibitors, and bi-specifics) with significant challenges remaining to be addressed regarding specificity, efficacy and patient safety.

More recently, adoptive cell therapies (e.g., CAR-Ts) have shown promise in removing T cells from patients, activating, stimulating, and expanding them outside the body (i.e., ex vivo) and then infusing large numbers of cells back into the patients for potential therapeutic benefit. While these approaches have demonstrated some encouraging and impressive clinical responses in several hematologic malignancies, they are also associated with significant toxicities, including life threatening cytokine release syndrome, inducement of autoimmune diseases, etc. Moreover, labor-intensive technical requirements and expense associated with individualized T cell extraction, ex vivo amplification /modification, and patient re-infusion represent significant scaling and cost challenges in addition to the rigorous procedures required to condition the patient prior to re-infusion might limit broad usage and eventual successful commercialization of this therapeutic modality.

We believe that our Immuno-STAT product candidates may offer important key features of potential clinical differentiation and advantages over competing immunotherapy approaches, including:

- "Ready-to-engage" biologics that specifically targets and selectively modulates disease relevant T cells
- Not dependent on barriers of natural antigen presentation via antigen presenting cells
- Ability to control specificity, quantity and quality of the modulating signal rather than systemic, non-selective signaling (e.g., rIL-2, bi-specifics, etc.)
- Administered directly to the patient and does not involve ex-vivo manipulation of T cells (e.g., cell therapy) or rigorous pre- and post- therapy conditioning of the patient

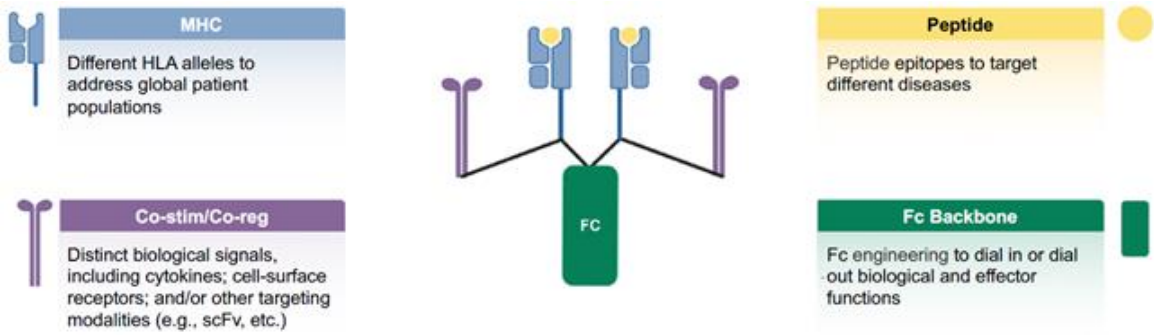
Therapeutic Applications

An insufficient T cell response may result in susceptibility to cancers or chronic infectious diseases. Conversely, an aberrant overactive T cell response against self-tissue results in autoimmune disease. In each of the above diseased states, the desired therapeutic approach should specifically target the dysregulated immune axis thereby providing the maximal potential for patient benefit.

- In the context of cancer and chronic infectious disease, Immuno-STATs are designed to selectively activate disease-specific T cells
- For the treatment of autoimmune disease, Immuno-STATs are designed to selectively inhibit pathogenic autoreactive T cells

We plan to leverage the modularity and versatility of the platform to design Immuno-STATs that address particular T cell modulation objectives/criteria, including different co-stimulatory/co-inhibitory signals across disease areas (e.g., cancer vs. autoimmune) and different targeting peptides across indications (e.g., head and neck cancer vs breast cancer); and different global patient populations via targeting distinct HLA alleles. The modularity of this unique platform provides us the opportunity to generate therapeutic molecules across many different indications to serve distinct patient populations.

Immuno-STAT Modularity



Potential Commercialization Advantages

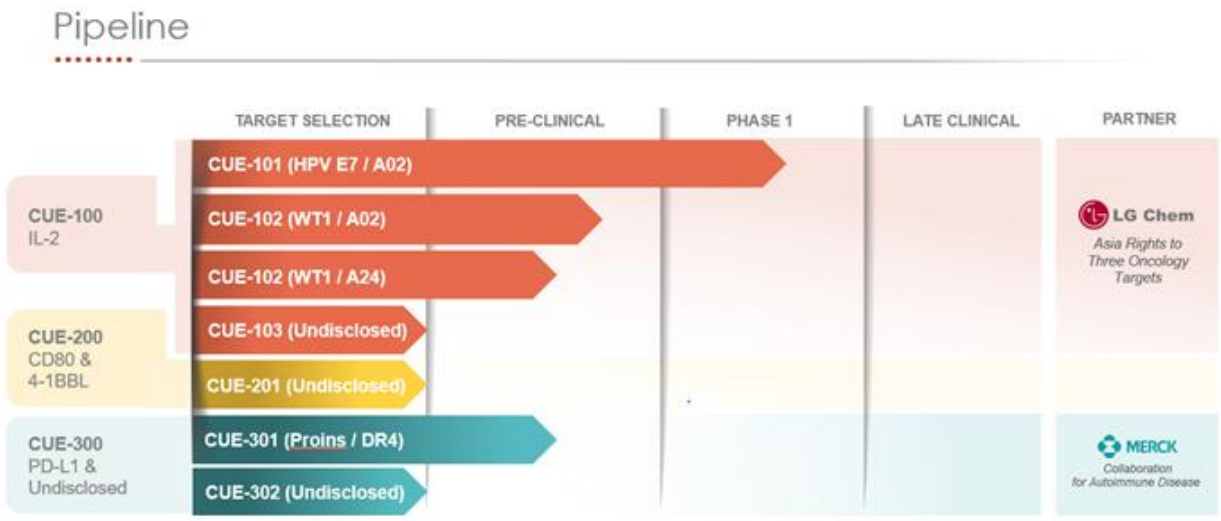
In addition to the selective control of T cell activity, we believe our Immuno-STAT platform offers several key points of potential differentiation over competing approaches:

- Access to a broad set of disease targets (extracellular and intracellular antigens) and patient populations (diverse HLA types)

- Utilizes industry standard development and production process to support a cost-of-goods and supply chain similar to monoclonal antibodies

- Standard delivery format (IV, SubQ) over a dosing schedule (weekly, monthly) that can be administered by specialists and community-based physicians

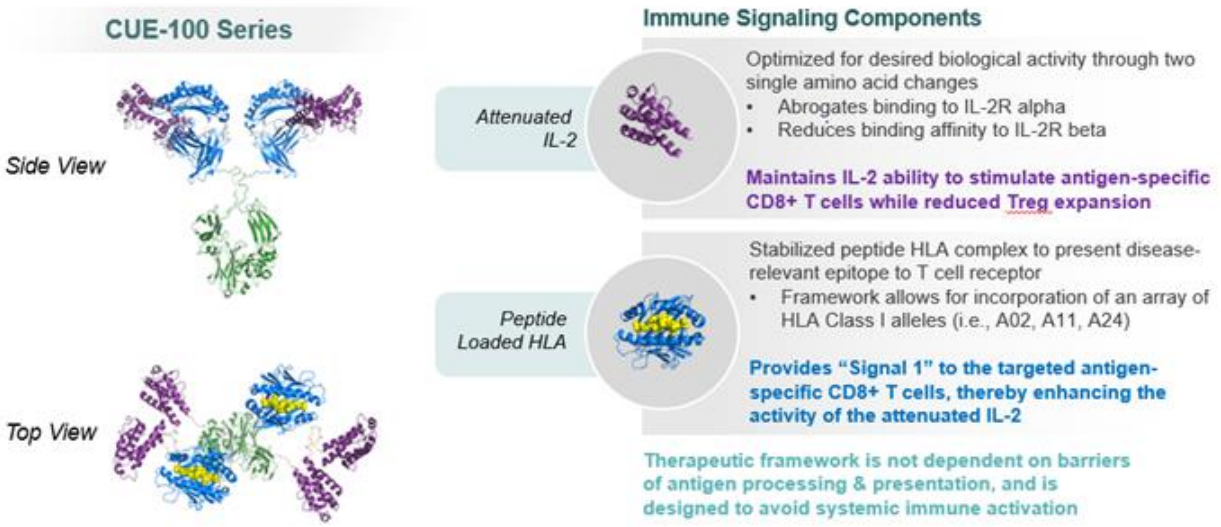
Our Pipeline



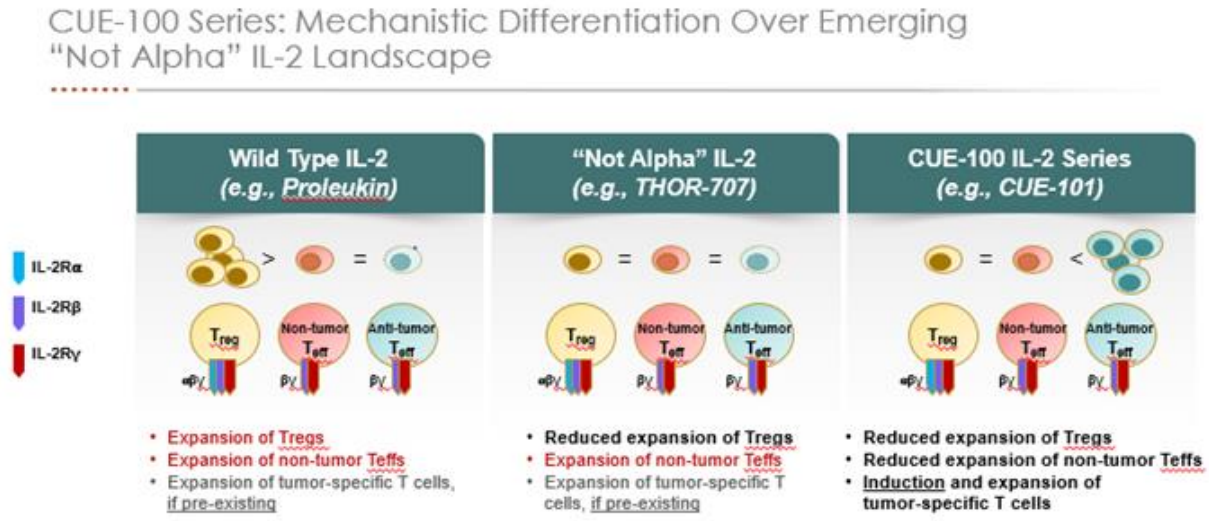
Immuno-Oncology

CUE-100 Series

Product candidates developed within our CUE-100 framework selectively stimulate the interleukin 2 (IL-2) receptor, a potent activator of the pathway critical to the growth, expansion and survival of T cells. We have engineered the framework to activate specific T cell populations through peptide-MHC complex (pMHC) targeting of T cell receptors (TCRs) and selective deployment of the IL-2 signal. The IL-2 has been modified to minimize engagement of the high affinity IL-2 receptor alpha chain and reduce the affinity on the beta chain while retaining potency. This enables our Immuno-STATs to preferentially activate tumor specific T-cells without systemically activating other T cell populations, thereby potentially mitigating the dose-limiting toxicities associated with current IL-2-based therapies.



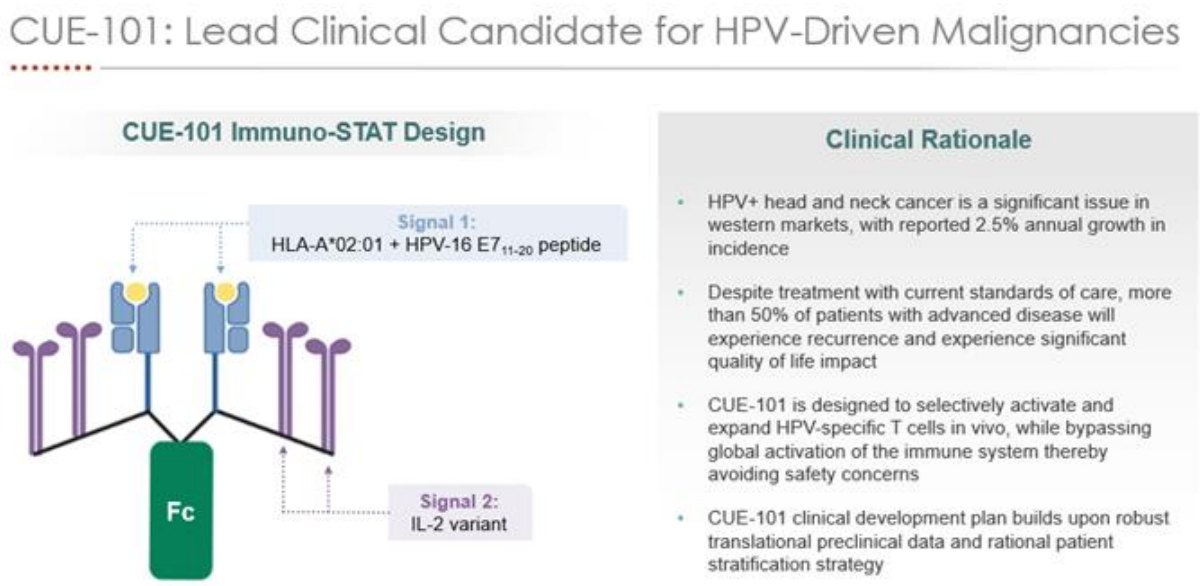
We believe the selective deployment of our uniquely engineered IL-2 molecules in context of the Immuno-STAT framework may provide superior differentiation over competing approaches that are focused on IL-2. The table below summarizes some of the key biological factors and considerations of the different approaches.



CUE-101

Our lead product candidate from the CUE-100 framework, CUE-101, contains IL-2 and a pMHC composed of HLA-A*02:01 complexed with a dominant peptide derived from the human papilloma virus E7 protein (HPV-E7), as shown in the figure below. It is a fusion protein biologic designed to target and activate antigen-specific T cells to fight HPV-driven cancers.

HPV cancers account for more than 20,000 deaths each year in the US and Europe. The majority of these cancers are driven by HPV-16 which carries the E7 antigen targeted by CUE-101. Despite treatment with current standards of care, approximately 50% of patients with advanced disease will experience recurrence and significant quality of life impact. Patients with HPV-driven head and neck, cervical and genitoanal cancers represent an important unmet clinical need and underscore the opportunity for promising new therapeutics.



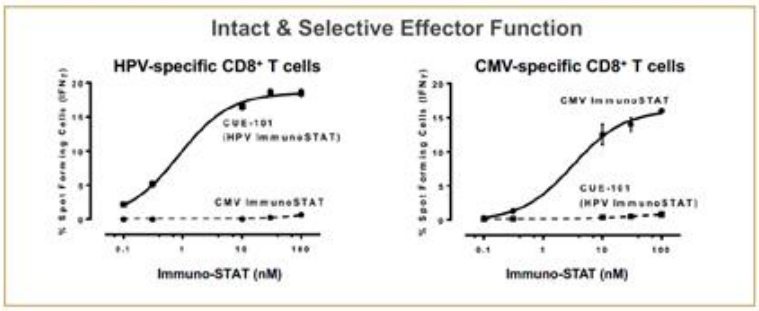
We have performed extensive in vitro and in vivo pre-clinical studies with CUE-101, which have been recently published in *Clinical Cancer Research (Quayle et. al. CUE-101, a Novel HPV16 E7-pHLA-IL-2-Fc Fusion Protein, Enhances Tumor Antigen Specific T Cell Activation for the Treatment of HPV16-Driven Malignancies https://clincancerres.aacrjournals.org/content/early/2020/01/15/1078-0432.CCR-19-3354)*

Some of the key highlights and findings are shown below.

In Vitro Activity with CUE-101

In preclinical studies, we have demonstrated selective targeting and engagement of specific T cells by Immuno-STATs generated within the CUE-100 series, including CUE-101.

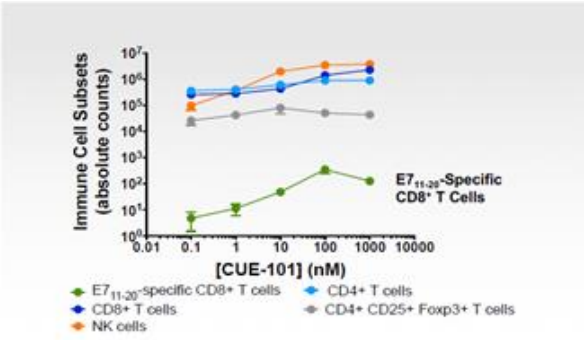
CUE-101 Selectivity and Specificity



Activation of HPV-specific human CD8+ T cells (left-panel) or CMV-specific human CD8+ T cells (right panel) in response to CUE-101 or a CMV Immuno-STAT. CUE-101 harbors a peptide from HPV E7 protein while the CMV Immuno-STAT contains a peptide derived from cytomegalovirus (CMV); both molecules contain the same engineered IL-2 molecules as described earlier in the CUE-100 series. Activation of T cells was measured via production of interferon-g (IFN-g). As shown, CUE-101 selectively activates HPV-specific CD8+ T cells and not the CMV T cells, and vice versa, the CMV Immuno-STAT preferentially activates CMV T cells and not the HPV-specific T cells. The specificity and selectivity of the biological response is a direct reflection of the strength of rational protein engineering that underscores the CUE-100 framework.

Furthermore, in ex vivo assays with primary human peripheral blood mononuclear cells ("PBMCs"), CUE-101 demonstrated selective expansion of the anti-tumor CD8+ T cells over other immune cell types, as shown in the figure below.

CUE-101 Selective Expansion of HPV-Specific T Cells



CUE-101 specifically expands HPV-specific CD8+ T cells. PBMCs from a healthy individual were treated ex vivo with CUE-101 and the antigen-specific T cells were quantitated and analyzed post stimulation. Selective expansion of E7-specific T cells was noted with minimal perturbations of other T cell subsets.

CUE-101 Clinical Development Plan

In September 2019, we dosed the first patient in a Phase 1 clinical trial of CUE-101 for the treatment of HPV16-driven recurrent/metastatic head and neck squamous cell carcinoma (HNSCC). This program is representative of the CUE-100 series for which we have generated a robust preclinical data package, including activation of human HPV specific T cells from human blood, as noted above. Our initial CUE-101 Phase 1 trial focuses on recurrent/metastatic ("R/M") HNSCC, where patients will likely have received several lines of systemic therapy including checkpoint inhibition. In addition, in the second half of 2020, we plan to run a trial in combination with a checkpoint inhibition therapy for locally advanced HNSCC patients. This combination study will offer the opportunity to assess relevant biomarkers of CUE-101 activity in peripheral blood when administered as a front line therapy.

We view R/M HNSCC as an important first market opportunity for CUE-101 with the potential for accelerated approval. Head and neck cancer was the seventh most common cancer worldwide in 2018 (650,000 new cases and 330,000 deaths), accounting for 3% of all cancers (51,540 new cases) and just over 1.5% of all cancer deaths (10,030 deaths) in the United States alone. Cases of HPV-associated oropharyngeal cancer, induced primarily by HPV type 16, are increasing, in North America and western Europe. The fraction of head and neck cancers diagnosed as HPV-positive oropharyngeal cancers in the United States rose from just 16% in the 1980s to more than 70% in the 2000s. In addition to HNSCC, we also intend to pursue expansion studies for cervical cancers which we view as an attractive opportunity with significant unmet need and potentially other HPV-driven cancers (e.g., anal, vulvar, etc.). Outside of the US and EU, we will work with our partner LG Chem to commercialize CUE-101 in Asia.

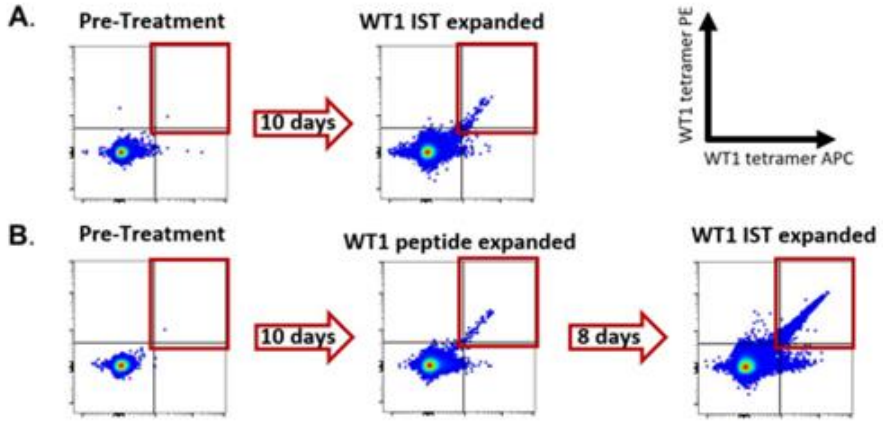
CUE-102

CUE-102 leverages the CUE-100 framework and a pMHC derived from the Wilms' Tumor protein (WT1), an onco-fetal viral antigen known to be over-expressed in a number of cancers, including solid tumors and hematologic malignancies. This program is focused on generation of two distinct therapeutic molecules – one, deploys HLA-A02 (dominant in the US and western EU) and the other deploys HLA-A24 (dominant in the Asian patient populations). Developing CUE-102 with two

different HLA alleles allows us to target a broader global patient population. Early data with ex vivo human T cell activation and expansion demonstrates the activity of WT1 Immuno-STATs, as noted below. In 2020, we plan to initiate Investigational New Drug ("IND") enabling studies for this program in collaboration with our partner LG Chem Life Sciences. Similar to CUE-101, CUE-102 is a fusion protein biologic designed to target and activate antigen-specific T cells to fight cancers overexpressing WT1.

WT1 is known to be expressed in more than 20 different cancers, including both solid tumors (i.e., Ovarian, pancreatic, lung) and hematologic malignancies (i.e., acute myeloid leukemia, multiple myeloma,, myelodysplastic syndromes). Patients with WT1 associated cancers represent an important unmet clinical need and underscore the opportunity for promising new therapeutics.

Biological activity of WT1 Immuno-STATs



A. **WT1-specific Immuno-STATs can induce expansion of WT1-specific T cell from an unprimed T cell repertoire**. Healthy donor PBMCs were stimulated for 10 days with a WT1 126-134 R126Y-specific Immuno-STAT. Cells were stained with WT1 126-134 R126Y tetramers and analyzed by flow cytometry. WT1 IST expanded cells show expansion of WT1-specific T cells compared to the pre-treatment control.

B. **WT1-specific Immuno-STATs can induce expansion of WT1-specific T cell from a primed T cell repertoire**. Healthy donor PBMCs were primed for 10 days with a WT1 126-134 peptide in the presence of IL-2. Primed T cells were re-stimulated for 8 days with a WT1 126-134 R126Y Immuno-STAT. Re-stimulated cells were stained with WT1 126-134 R126Y tetramers and analyzed by flow cytometry. WT1 IST expanded cells show expansion of WT1-specific T cells compared to the pre-treatment control and WT1 peptide-expanded T cells.

CUE-103

CUE-103 will also leverage the CUE-100 framework and target an antigen to be selected in collaboration with LG Chem Life Sciences. We are currently evaluating several attractive candidate tumor antigens for CUE-103.

CUE-200 Framework

The CUE-200 framework utilizes co-stimulatory cell surface receptors, including CD80 and/or 4-1BBL to reactivate exhausted T cells and is designed to promote enhanced antigen-specific T cell activation and function for the treatment of chronic infectious diseases. Both CD80/CD28 and 4-1BBL/4-1BB pathways have been implicated in enhancing anti-tumor T cell responses, including re-invigorating exhausted T cells. We see this as a unique opportunity to potentially harness and deploy these co-stimulatory signaling molecules to selectively modulate anti-tumor T cells. We continue to evaluate these mechanisms within the CUE-200 series via discovery-stage programs and generate datasets that further our understanding.

Autoimmune Disease

CUE-300 Framework

The CUE-300 framework has been focused on class II HLA alleles that are recognized by CD4+ T cells. It has the potential to target a broad range of addressable autoimmune diseases by selectively modulating disease-associated CD4+ T cells so that healthy cells and tissue are protected from immune attack.

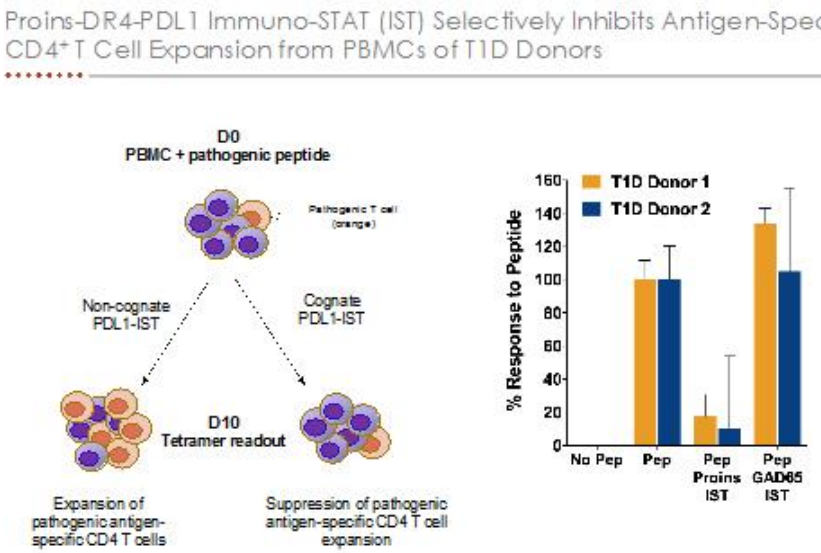
To inhibit autoimmune disease associated T cells, Immuno-STATs are engineered to work via two general strategies:

- Inhibition (or selective ablation) of autoreactive T cells by selectively delivering inhibitory signals; or
- Selective expansion of antigen specific regulatory T cells ("Tregs") to control aberrant activation of autoreactive T cells

Immuno-STAT frameworks for autoimmune disease will be designed to influence a subset of T cells known as CD4 T cells. CD4 T cells recognize peptides in the context of MHC class II proteins. Therefore, prototypic Immuno-STAT frameworks in autoimmunity would rely on MHC class II recognition by CD4 T cells. This is distinct from the MHC class I recognition by CD8 T cells that is the basis of our current oncology pipeline.

Consistent with our plan to establish strategic partnerships with leading pharmaceutical or biotechnology organizations to further our development efforts, in November 2017 we entered into a Collaboration Agreement with Merck Sharp & Dohme Corp. ("Merck") for a partnership to research and develop proprietary biologics that target certain autoimmune diseases. We view this Collaboration Agreement as a component of our development strategy since it will allow us to advance our autoimmune programs in partnership with a world class pharmaceutical company, while also continuing our focus on our more advanced cancer programs.

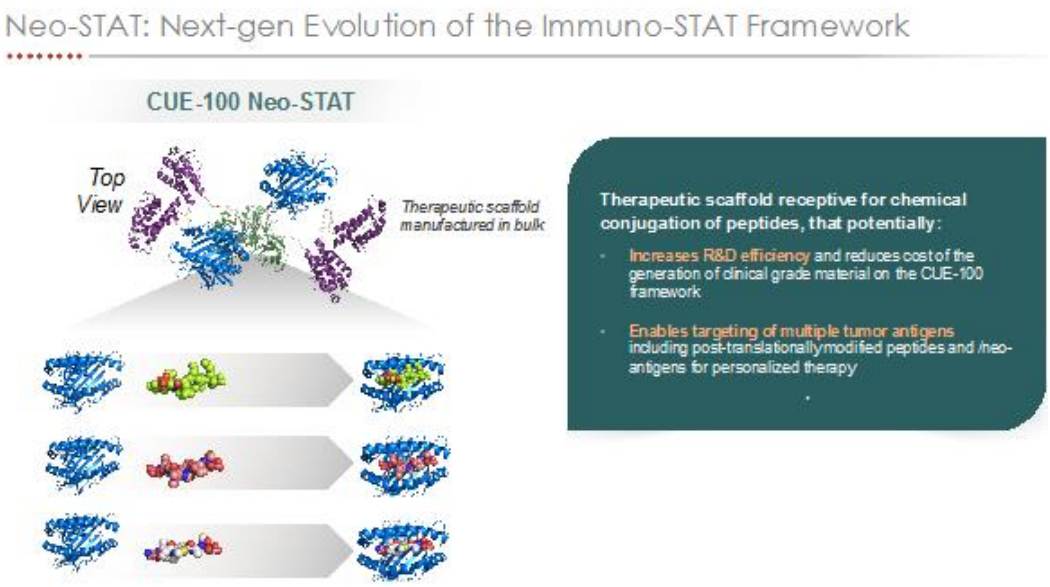
Pursuant to the Collaboration Agreement, in July 2018, we generated molecules that provided proof-of-concept and feasibility for this program. During 2019, we will continue to generate data to support proof-of-mechanism and inform the path forward for this program. An example of the activity of Immuno-STATs for modulation of CD4+ T cells is shown in the figure below. In this instance Immuno-STATs with the human class II MHC molecule, HLA-DR0401 ("DR4"), were generated along with an epitope from pro-insulin (a known autoantigen in type 1 diabetes) and PD-L1 molecule for selective down-modulation of CD4+ T cells reactive to the pro-insulin peptide. The Pro-Insulin-DR4-PD-L1 Immuno-STATs selectively inhibited the activation and expansion of specific T cells. In contrast, Immuno-STAT molecules harboring a peptide from glutamic acid decarboxylase (GAD, another autoantigen in type 1 diabetes) had no effect, hence demonstrating selectivity and specificity.



PBMCs from type 1 diabetes (T1D) donors were stimulated for 10 days with Proins78-90 K88S peptide and indicated Immuno-STATs in Immunocult™ media. Cultures were replenished with fresh media and supplemented with recombinant human IL-2 on days 3, 5, 7 and 9. On day 10, expansion of Proins78-90 K88S-specific CD4+ T cells was assessed by staining with Proins78-90 K88S tetramer and flow cytometry analysis. Cells cultured with peptide in the presence of the Proins-DR4-PDL1 Immuno-STAT showed significant reduction in antigen-specific CD4+ T cell expansion compared to controls.

Evolution of the Neo-STAT platform

In addition to the Immuno-STATs described above that are engineered as fusion protein biologics, we are developing the next generation platform, termed Neo-STAT, that will significantly enhance our continued productivity. A key focus of the Neo-STAT platform is to generate a "peptide-less" or "empty" Immuno-STAT scaffold of the CUE-100 series. In parallel, we have identified peptide-conjugation chemistries that can be deployed to covalently attach peptides to the Neo-STAT scaffold. To that end, we will have the ability to generate therapeutic molecules targeting multiple tumor antigens; be able to target post-translationally modified antigens (e.g., targeting of phospho-peptides from tumor cells); and to develop future strategies to deploy the Neo-STAT platform for personalized tumor neo-antigens. Importantly, the Neo-STAT framework allows us to maximize our efficiencies – both from a cost- and timing-perspective.



Our License Agreement with Einstein

On January 14, 2015, we entered into a license agreement, as amended and restated on July 31, 2017 (the "Einstein License"), with Albert Einstein College of Medicine "Einstein" for certain patent rights (the "Patents") relating to the Company's core technology platform for the engineering of biologics to control T cell activity, precision, immune-modulatory product candidates, and two supporting technologies that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides. The Company holds an exclusive worldwide license, with the right to sublicense, import, make, have made, use, provide, offer to sell, and sell all products, processes and services that use the Patents, including certain technology received from Einstein related thereto (the "Licensed Products").

The Einstein License is a royalty-bearing license obligating us to pay a percentage of proceeds received from sales of categories of Licensed Products at low single digit rates. We have also agreed to share a portion of our proceeds that we derive from other agreements, like sublicense agreements, relating to Licensed Products that we may enter into. The percentage of such proceeds that we are required to pay Einstein ranges from the low to high teens, depending on how far we have developed a Licensed Product before we enter into an agreement relating to the Licensed Product. These percentages are reduced for sales of Licensed Products in countries where a competing product exists and for products or services involving the use or incorporation of technology received from Einstein relating to synapse for targeted T cell activation molecules, receptor ligand identification or platforms for T cell monitoring. In addition to our obligation to pay royalties based upon a percentage of proceeds from sales of Licensed Products, we have also agreed to pay Einstein annual maintenance fees. The maintenance payments are creditable against any royalty payments we pay under the Einstein License. As of December 31, 2019, we had paid to Einstein an aggregate amount of $565,659 in license and license maintenance fees under the Einstein License.

Under the Einstein License, we are also obligated to make milestone payments corresponding to: (i) approval of the first IND by the FDA or foreign equivalent for a Licensed Product; (ii) approval of any subsequent IND application or foreign equivalent for a "new indication" for a Licensed Product; (iii) initiation of Phase 2 clinical trials or foreign equivalent on a Licensed Product; (iv) initiation of Phase 2 clinical trials or foreign equivalent for a "new indication" for a Licensed Product; (v) initiation of Phase 3 clinical trials or foreign equivalent on a Licensed Product; (vi) initiation of Phase 3 clinical trials or foreign equivalent for a "new indication" for a Licensed Product, (vii) the first commercial sale of a Licensed Product; (viii) the first commercial sale of each "new indication" for one of our previously approved Licensed Products; and (ix) cumulative sales of certain Licensed Products reaching certain threshold amounts. The aggregate amount of milestone payments made under the Einstein License may equal up to $1.85 million for each Licensed Product and up to $1.85 million for each new indication of a Licensed Product. Additionally, the aggregate amount of one-time milestone payments based on cumulative sales of all Licensed Products may equal up to $5.75 million.

In addition to our obligations to make the cash payments to Einstein described above, under the Einstein License we issued Einstein 671,572 shares of our Common Stock immediately prior to completion of the initial public offering of our common stock completed on December 27, 2017.

The Einstein License expires upon the expiration of our last obligation to make royalty payments to Einstein, unless terminated earlier under the provisions thereof. Under the Einstein License, we will be obligated to make royalty payments to Einstein, with respect to certain Licensed Products, for the longer of 15 years from the first sale of such products in each country or for the duration of any market exclusivity period granted by a regulatory agency for such product and, with respect to certain Licensed Products sold by sublicensees, the longer of 10 years from the first sale of such products in each country or for so long as the sublicensee agrees to pay royalties on such products. We have the right to terminate the Einstein License at any time upon sixty (60) days' written notice to Einstein; provided, however, that we will lose intellectual property rights related to the Patents if we choose to terminate the Einstein License in this manner. Each party has the right to terminate the Einstein License if the other party is in default or breach of any condition of the Einstein License with a right to cure any such breach within sixty (60) days from receipt of notice of such default or breach, unless the other party has disputed the alleged breach in good faith. Either party can also terminate the Einstein License if the other party voluntarily files for bankruptcy or other similar insolvency proceedings, makes a general assignment for the benefit of creditors, or is the subject of an involuntary bankruptcy petition that is not dismissed within ninety (90) days. If we fail to pay any sum that is due and payable to Einstein within thirty (30) days after receiving written notice of our default from Einstein, then Einstein has the option of terminating the Einstein License unless we pay within forty-five (45) days of such notice all delinquent sums with interest.

Einstein may also terminate the Einstein License in the event we are convicted of certain felonies relating to the manufacture or use of Licensed Products.

The Einstein License also obligates us to meet certain due diligence requirements (the "Diligence Milestones") as follows:

- update our research and development plan annually;
- submit an IND application to the FDA or similar foreign regulatory agency within a number of years from the Effective Date;
- initiate Phase 1 clinical trials on a Licensed Product within a number of years from the Effective Date;
- initiate Phase 2 clinical trials on a Licensed Product within a number of years from the Effective Date;
- initiate Phase 3 clinical trials on a Licensed Product within a number of years from the Effective Date;
- submit an application for FDA approval to market and sell a Licensed Product within a number of years from the Effective Date;
- have our first commercial sale of an FDA Licensed Product within a number of years from the Effective Date; and
- spend a minimum amount per year on product development until our first commercial sale of a Licensed Product.

If we fail to meet any of the Diligence Milestones, Einstein will have the right to terminate the Einstein License if such Diligence Milestone is not satisfied within thirty (30) days from receiving a written notice of default from Einstein. Under certain circumstances and upon prior notice to Einstein, we may have the right to an additional extension of our Diligence Milestones if, despite our commercially reasonable efforts we are not able to satisfy the Phase 2 clinical trial Diligence Milestone or any subsequent Diligence Milestone. As of the date of this prospectus, we have met all required Diligence Milestones.

Our Collaboration Agreement with Merck

On November 14, 2017, we entered into an Exclusive Patent License and Research Collaboration Agreement (the "Merck Agreement") with Merck Sharp & Dohme Corp. ("Merck") for a partnership to research and develop certain of the Company's proprietary biologics that target certain autoimmune disease indications (the "Initial Indications"). We view this Merck Agreement as a component of our development strategy since it will allow us to advance our autoimmune programs in partnership with a world class pharmaceutical company, while also continuing our focus on our more advanced cancer programs. The research program outlined in the Merck Agreement entails (1) our research, discovery and development of certain Immuno-STAT drug candidates up to the point of demonstration of certain biologically relevant effects ("Proof of Mechanism") and (2) the further development by Merck of the Immuno-STAT product candidates that have demonstrated Proof of Mechanism (the "Proposed Product Candidates") up to the point of demonstration of all or substantially all of the properties outlined in such Proposed Product Candidates' profiles as described in the Merck Agreement.

For the purposes of this collaboration, we granted to Merck under the Merck Agreement an exclusive license under certain of our patent rights, including a sublicense of patent rights licensed from Einstein, to the extent applicable to the specific Immuno-STAT product candidates that are elected to be developed by Merck. In addition, so long as Merck continues product development on a Proposed Product Candidate, we are restricted from conducting any development activities within the Initial Indication covered by such Proposed Product Candidate other than pursuant to the Merck Agreement.

In exchange for the licenses and other rights granted to Merck under the Merck Agreement, we received a $2.5 million nonrefundable up-front payment and may be eligible to receive additional funding in developmental milestone payments, as well as tiered royalties if all research, development, regulatory and commercial milestones agreed upon by both parties are successfully achieved. Excluding the upfront payment described above, we are eligible to earn up to $101 million for the achievement of certain research and development milestones, $120 million for the achievement of certain regulatory milestones and $150 million for the achievement of certain commercial milestones, in addition to tiered royalties on sales, if all pre-specified milestones associated with multiple products across the primary disease indication areas are achieved. The Merck Agreement requires us to use the first $2.7 million of milestone payments we receive under the agreement to fund contract research. The amount of the royalty payments is a percentage of product sales ranging in the single digits based on the amount of such sales. As of December 31, 2019, the Company recorded approximately $2 million in collaboration revenue related to this agreement.

The term of the Merck Agreement extends until the expiration of all royalty obligations following a product candidate's receipt of marketing authorization, at which point Merck's licenses and sublicenses granted under the agreement shall become fully paid-up, perpetual licenses and sublicenses, as applicable. Royalties on each product subject to the Merck Agreement shall continue on a country-by-country basis until the expiration of the later of: (1) the last-to-expire patent claiming the compound on which such product is based and (2) a period of ten years after the first commercial sale of such product in such country.

Notwithstanding the foregoing, Merck may terminate the Merck Agreement at any time upon 30 days' notice to the Company. The Merck Agreement may also be terminated by either party if the other party is in breach of its obligations thereunder and fails to cure such breach within 90 days after notice or by either party if the other party files for bankruptcy or other similar insolvency proceedings.

Our Collaboration Agreement with LG Chem

Effective November 6, 2018, we entered into a Collaboration, License and Option Agreement (the "LG Chem Agreement") with LG Chem, Ltd. ("LG Chem"), related to the development of Immuno-STATs focused in the field of oncology.

Pursuant to the LG Chem Agreement, we granted LG Chem an exclusive license to develop, manufacture and commercialize our lead product, CUE-101, as well as Immuno-STATs that target T-cells against two additional cancer antigens ("Product Candidates"), in Australia, Japan, Republic of Korea, Singapore, Malaysia, Vietnam, Thailand, Philippines, Indonesia, China (including Macau and Hong Kong) and Taiwan (collectively, the "LG Chem Territory"). We retain rights to develop and commercialize all assets included in the LG Chem Agreement in the United States and in global markets outside of the LG Chem Territory. Under the LG Chem Agreement, we will engineer the selected Immuno-STATs for up to three alleles, which are expected to include the predominant alleles in the LG Chem Territory, thereby enhancing Cue's market reach by providing for greater patient coverage of populations in global markets, while LG Chem will establish a chemistry, manufacturing and controls ("CMC") process for the development and commercialization of selected Product Candidates. In addition, LG Chem has the option to select one additional Immuno-STAT for an oncology target (an "Additional Immuno-STAT") within two years of the effective date of the LG Chem Agreement for an exclusive worldwide development and

commercialization license. If LG Chem exercises this option, then the parties will execute a license and collaboration agreement ("Global License and Collaboration Agreement") setting forth the terms and conditions relating to such arrangement. We will retain an option to co-develop and co-commercialize the additional program worldwide.

Under the terms of the LG Chem Agreement, LG Chem paid us a $5.0 million non-refundable, non-creditable upfront payment and purchased approximately $5.0 million of shares of our common stock at a price per share equal to a twenty percent (20%) premium to the volume weighted-average closing price per share over the thirty (30) trading day period immediately prior to the effective date of the LG Chem Agreement. We are also eligible to receive additional aggregate payments of approximately $400 million if certain research, development, regulatory and commercial milestones are successfully achieved. In addition, the LG Chem Agreement also provides that LG Chem will pay us tiered single-digit royalties on net sales of commercialized Product Candidates ("Collaboration Products") in the LG Chem Territory on a product-by-product and country-by-country basis, until the later of expiration of patent rights in a country, the expiration of regulatory exclusivity in such country, or ten years after the first commercial sale of a Collaboration Product in such country, subject to certain royalty step-down provisions set forth in the LG Chem Agreement.

Pursuant to the LG Chem Agreement, the parties will share research costs related to Collaboration Products, and LG Chem will provide chemical manufacturing and controls ("CMC") process development for selected Product Candidates and potentially additional downstream manufacturing capabilities, including clinical and commercial supply for Collaboration Products. In return for performing CMC process development, LG Chem is eligible to receive low-single digit percentage royalty payments on the sales of Collaboration Products sold in all countries outside the LG Chem Territory. Furthermore, should the parties enter into a Global License and Collaboration Agreement for an Additional Immuno-STAT, LG Chem will pay us a one-time, non-refundable, non-creditable upfront payment and we will be eligible to receive up to approximately $470 to $675 million in fees and milestone payments as well as tiered royalty payments on future global sales that range from high-single digit to mid-double digit percentages in the United States and mid-single to low-double digit percentages outside of the United States. The amount of fees and milestone payments, as well as whether we receive royalty payments, will depend on when LG Chem nominates the Additional Immuno-STAT, the number of alleles selected by LG Chem and whether we exercise our option to co-develop and co-commercialize the additional program worldwide, in which case we would share costs and profits instead of receiving royalties and post-option-exercise milestones. As of December 31, 2019, the Company recorded approximately $2.6 million in collaboration revenue related to this agreement.

The LG Chem Agreement includes various representations, warranties, covenants, indemnities and other customary provisions. LG Chem may terminate the LG Chem Agreement for convenience or change of control of the Company on a program-by-program, product-by-product or country-by-country basis, or in its entirety, at any time following the notice period set forth in the LG Chem Agreement. Either party may terminate the LG Chem Agreement, in its entirety or on a program-by-program, product-by-product or country-by-country basis, in the event of an uncured material breach. The LG Chem Agreement is also terminable by either party (i) upon the bankruptcy, insolvency or liquidation of the other party or (ii) for certain activities involving the challenge of certain patents controlled by the other party. Unless earlier terminated, the LG Chem Agreement will expire on a product-by-product and country-by-country basis upon the expiration of the applicable royalty term.

Our Intellectual Property

We believe that our current patents and patent applications and any future patents and other proprietary rights that we own, or control through licensing, are and will be essential to our business. We believe that these intellectual property rights will affect our ability to compete effectively with others. We also rely and will rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants, advisors and other parties. Our success will depend in part on our ability, and the ability of our licensor, to obtain, maintain (including making periodic filings and payments) and enforce patent protection for our/their intellectual property, including those patents and patent applications to which we have secured exclusive rights.

As of December 31, 2019, we owned or had licensed seven patents, twenty-three pending patent applications in the United States (including twelve pending U.S. provisional patent applications), twelve pending international PCT applications and 125 pending foreign patent applications intended to protect the intellectual property underlying our technology. Our patent applications describe certain features of our technologies, including our Immuno-STAT platform, our Neo-STAT platform, CAR-T and ex-vivo applications of our Immuno-STAT platform, as well as specific biologic molecules, product candidates, and methods of treatment using our Immuno-STATs. We plan to spend considerable resources and focus in the future on obtaining U.S. and foreign patents. We have and will continue to actively protect our intellectual property. No assurances can be given that any of our patent applications will result in the issuance of a patent or that the examination process will not require us to narrow our claims. In addition, any issued patents may be contested, circumvented, found unenforceable or

invalid, and we may not be able to successfully enforce our patent rights against third parties. No assurance can be given that others will not independently develop a similar or competing technology or design around any patents that may be issued to us. We intend to expand our international operations in the future and our patent portfolio, copyright, trademark and trade secret protections may not be available or may be limited in foreign countries.

Each of our patents, if and when granted, will generally have a term of 20 years from its respective U.S. non-provisional priority filing date, subject to available extensions. They are thus set to expire no earlier than dates ranging from 2033 to 2040, although there can be no assurance that any of the patent applications will be granted.

Competition

While we believe that our product candidates, technology, knowledge and experience provide us with competitive advantages, we face competition from established and emerging pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

Furthermore, immunotherapy technologies are advancing at a rapid pace and we anticipate competing with companies developing bi-specific antibodies (e.g., Amgen, Inc., Hoffmann-La Roche and Sutro Biopharma), CAR-T therapies (e.g., Novartis A.G., Juno Therapeutics and Kite Pharma, Inc.), checkpoint inhibitors (e.g., Bristol-Myers Squibb, Merck & Co. and Pfizer, Inc.), antibody drug conjugates (e.g., Seattle Genetics, Inc., ImmunoGen, Inc. and Sorrento Therapeutics), and targeted cytokines (e.g., Nektar/Bristol Myers Squibb, Synthorax and Hoffmann-La Roche) many of which have significantly greater financial and other resources than we have.

Government Regulation and Product Approval

Biological products are subject to rigorous regulation by the U.S. Food and Drug Administration (the “FDA”) and other governmental agency regulations in the United States and in foreign countries. Noncompliance with applicable requirements can result in warning letters, import detentions, fines, civil penalties, injunctions, suspensions or losses of regulatory approvals or clearances, recall or seizure of products, operating restrictions, denial of export applications, and criminal prosecution. Failure to obtain regulatory approvals or the restriction, suspension or revocation of regulatory approvals or clearances, as well as any other failure to comply with regulatory requirements, would have a material adverse effect on our business, financial condition and results of operations. In connection with regulatory approval, we will have to comply with the many requirements associated with preclinical and clinical trials, the FDA Biologics License Application (“BLA”) process and FDA manufacturing requirements. Upon approval of a BLA by the FDA and similar approvals in foreign countries, there will be additional regulation relating to the manufacturing, packaging, distribution, labeling, marketing and promotion of our potential products. These latter regulations are not only found in federal regulation but many states and, of course, foreign countries.

U.S. Biologic Product Development Process

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act (the “FDCA”), the Public Health Services Act (the “PHSA”) and implementing regulations. The FDCA, PHSA and their implementing regulations govern, among other things, the research, development, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distributing, marketing and promotion of biologic products. Biologic products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal (in vivo) studies in accordance with the FDA’s Good Laboratory Practices (“GLPs”) and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an Investigational New Drug Application (an “IND”), which must become effective before human clinical trials may begin;

- approval by an independent institutional review board, or IRB, reviewing each clinical site before each clinical trial may be conducted;

- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as Good Clinical Practices ("GCPs"), and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the biological product candidate for its intended use;

- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current Good Marketing Practices ("cGMP") to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current Good Tissue Practices ("cGTPs") for the use of human cellular and tissue products;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

- payment of applicable user fees and FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board (an "IRB") at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Clinical trials also must be reviewed by an institutional biosafety committee (an "IBC"), a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- ***Phase 1.*** The biological product candidate is initially introduced into human subjects to test for safety (adverse effects), determine recommended Phase 2 dosing and evaluate any signals of efficacy for specific targeted diseases. The initial human testing is often conducted in patients, rather than in healthy volunteers, in the case of products for severe or life-threatening diseases, especially when the product is inherently toxic.

- ***Phase 2.*** The biological product candidate is evaluated in a limited patient population to identify safety risks, optimize dosing and preliminarily evaluate the efficacy of the product for specific targeted diseases.

- ***Phase 3.*** Clinical trials are undertaken in an expanded patient population at geographically dispersed clinical trial sites to further evaluate dosage, clinical efficacy, potency, and safety. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the National Institutes of Health and the investigators for serious and unexpected adverse events, as well as any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Cancer immunotherapy products are a relatively new category of biologic products for the FDA. As a result, there can be no assurance as to the length of the clinical trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the biologic product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. FDA BLA Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended (the "PDUFA"), each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each approved prescription biological product. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no application fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication, and such orphan products may also qualify for an exemption from the annual program fees if the FDA determines that the exemption is necessary to protect the public health and the applicant's gross annual revenues are less than $50 million.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to assure the

safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the cGTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products ("HCT/Ps"), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the cGTP requirements is to ensure that cellular tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP, cGTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives FDA regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act (the "PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, the PREA does not apply to any product for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Expedited Development and Review Programs

The FDA has various programs, including Fast Track, Breakthrough Therapy Designation, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing products, and/or provide for approval on the basis of surrogate endpoints. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, products that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of products to treat serious diseases and fill an unmet medical need. A Fast Track designation provides access to more frequent meetings with the FDA, potential rolling review of the application, and eligibility for priority review. The request may be made at the time of IND submission and generally no later than the pre-BLA meeting. The FDA will respond within 60 calendar days of receipt of the request. Breakthrough Therapy Designation is available for products that are intended to treat a serious condition where preliminary clinical evidence indicates that the product may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. The request may be made at the time of IND submission and generally no later than the end-of-Phase 2 meeting. The FDA will respond within 60 calendar days of receipt of the request. Breakthrough Therapy Designation conveys all of the Fast Track program features along with more intensive FDA guidance and organizational commitment. Priority review, which is requested at the time of BLA or NDA submission, is designed to give products that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track, Breakthrough Therapy Designation and priority

review do not affect the standards for approval, the FDA will attempt to expedite review of the application. Accelerated approval provides an earlier approval of products to treat serious diseases, and that fill an unmet medical need based on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. Discussions with the FDA about the feasibility of an accelerated approval typically begin early in the development of the product in order to identify, among other things, an appropriate endpoint. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use will be disclosed publicly by the FDA; the posting will also indicate whether the drug or biologic is no longer designated as an orphan drug. More than one product candidate may receive an orphan drug designation for the same indication. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to seven years of orphan product exclusivity. During the seven-year exclusivity period, the FDA may not approve any other applications to market a product containing the same active moiety for the same disease, except in very limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Thus, orphan drug exclusivity could block the approval of one of our potential products for seven years if a competitor obtains approval of the same product as defined by the FDA and we are not able to show the clinical superiority of our product candidate or if our product candidate's indication is determined to be contained within the competitor's product orphan indication. In addition, if the FDA grants orphan drug designation, based on a plausible hypothesis that a proposed drug may be clinically superior to a previously approved same drug for the same use, after the drug receives marketing approval for the designated use, in order to receive orphan drug exclusive approval for such use, the sponsor must demonstrate that the drug is actually clinically superior to any previously approved same drug for the same use. Any claims for clinical superiority could require a head-to-head clinical trial between such drugs.

U.S. FDA Post-Approval Requirements

Any potential biologic products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, cGMP regulations, including record-keeping and documentation requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe FDA approved products for off-label uses that, they deem to be appropriate in their professional medical judgment, it is FDA's position that manufacturers may not market or promote products for such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the quality and long-term stability of the product. We expect to rely on third parties for the manufacturing of clinical and commercial quantities of our potential products in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and

approval. The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our potential products under development.

Failure to comply with the applicable U.S. FDA requirements at any time during the biologic product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal actions and adverse publicity. These actions could include refusal to approve pending applications or supplemental applications, withdrawal of an approval, clinical hold, suspension or termination of clinical trials by an IRB, warning or untitled letters, recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines or other monetary penalties, refusals of government contracts, mandated corrective advertising and promotion or communications to healthcare professionals or patients, debarment, restitution, disgorgement of profits or other civil or criminal penalties.

U.S. Patent Term Restoration and Marketing Exclusivity

The Biologics Price Competition and Innovation Act (the "BPCIA") amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. This 12-year period of data exclusivity may be extended by six months, for a total of 12.5 years, if the FDA requests that the innovator company conduct pediatric clinical investigations of the product.

Depending upon the timing, duration and specifics of the FDA approval of the use of our drug candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patent applications, if granted, to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA. Similar types of extensions for patent term lost during product development and the regulatory review process in foreign countries also may be available for foreign patents in our portfolio that cover marketed products in foreign countries.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Other Health Care Laws and Regulations

In the United States, among other things, the research, manufacturing, distribution, sale and promotion of biologic products are potentially subject to regulation and enforcement by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, state Attorneys General and other state and local government agencies. Our current and future business activities, including for example, sales, marketing and scientific/educational grant programs must comply with health care regulatory laws, as applicable, which may include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for, or to induce, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for

which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers on the other;

- the federal False Claims Act or FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent. Federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, also may implicate the FCA;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, other healthcare professionals and teaching hospitals, and ownership and investment interests held by physicians and other healthcare professionals and their immediate family members;

- Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to: items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare professionals and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Violation of any of the laws described above or any other governmental laws and regulations may result in penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, refusal to allow us to enter into supply contracts, including government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees

As of December 31, 2019, we had 45 full-time employees and two part-time employees. Substantially all of our employees are in Cambridge, Massachusetts. None of our employees are represented by a labor union or covered by a collective bargaining agreement, and we believe our relationship with our employees is good. Additionally, we utilize independent contractors and other third parties to assist with various aspects of our drug and product development.

Status as an Emerging Growth Company

We are an "emerging growth company" as that term is defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until. private companies (*i.e.*, those that have not had a registration statement declared effective under the Securities Act of 1933, as amended (the "Securities Act"), or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are required to comply with such new or revised financial accounting standards. The JOBS Act also provides that an emerging growth company can elect to opt out of the extended transition period provided by Section 102(b)(1) of the JOBS Act and comply with the requirements that apply to non-emerging growth companies, but any such election to opt out is irrevocable. We have irrevocably elected to opt out of this extended transition period provided by Section 102(b)(1) of the JOBS Act. Even though we have elected to opt out of the extended transition period, we may still take advantage of all of the other provisions of the JOBS Act, which include, but are not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, the reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and the exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Item 1A. Risk Factors

We are subject to various risks that may materially harm our business, prospects, financial condition and results of operations. This discussion highlights some of the risks that may affect future operating results. These are the risks and uncertainties we believe are most important for you to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, our business may not grow, our stock price may suffer, and we may be unable to stay in business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business, prospects, results of operations and financial condition. The risks discussed below include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements.

Risks Related to Our Business

We are a clinical stage biopharmaceutical company, have no history of generating commercial revenue, have a history of operating losses, and we may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company. We have a limited operating history, have never generated revenue from product sales, and have a history of losses from operations. As of December 31, 2019, we had an accumulated deficit of approximately $108.5 million. Our ability to achieve commercial revenue-generating operations and, ultimately, achieve profitability will depend on whether we can obtain additional capital when we need it, complete the development of our technology, receive regulatory approval of our planned product candidates and find strategic collaborators that can incorporate our planned products candidates into new or existing drugs which can be successfully commercialized. There can be no assurance that we will ever generate commercial revenues or achieve profitability.

We currently do not have, and may never develop, any FDA-approved or commercialized products.

We currently do not have any products approved by the FDA or any other regulatory agency or any commercialized products and thus have never generated commercial revenue from product sales. We have not yet sought to obtain any regulatory approvals for any planned product candidates in the United States or in any foreign market. Therefore, any estimated timing for our planned product candidates to be commercialized would be highly speculative.

To date, we have invested substantial resources in an exclusive license with Einstein that forms the foundation for our planned product candidates and potential applications. For us to develop any products that might ultimately be commercialized, we will have to invest further time and capital in research and product development, regulatory compliance and market development. Therefore, we and our licensor, prospective business partners and other collaborators may never develop any products that can be commercialized. All of our development efforts will require substantial additional funding, none of which may result in any commercial revenue. Our efforts may not lead to commercially successful products for a number of reasons, including:

- we and our licensor, prospective business partners and other collaborators may not be able to complete research regarding, and nonclinical and clinical development of, our planned product candidates;
- regulatory approvals and marketing authorizations may not be achieved for our planned product candidates, or the scope of the approved indication may be narrower than sought;
- we and our licensor, prospective business partners and other collaborators may experience delays in our development program, clinical trials and the regulatory approval process;
- our technology may not prove to be safe and effective in clinical trials or preclinical studies and our planned product candidates may have adverse side effects which outweigh any potential benefit to patients;
- we may not be able to identify suitable collaborators to complete development or commercialization of our potential products;
- we may not be able to maintain, protect or expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;

- any future products that are ultimately approved by the FDA or other regulatory bodies may not be commercially accepted in the marketplace by physicians or patients;

- any future products that are ultimately approved by the FDA or other regulatory bodies may not be able to be manufactured in commercial quantities or at an acceptable cost;

- physicians may not receive any reimbursement from third-party payors, or the level of reimbursement may be insufficient to support widespread adoption of any of our future products once approved by the FDA or other regulatory bodies; and

- rapid technological change may make our technology and future products obsolete.

We are substantially dependent on the success of our product candidates, only one of which is currently being tested in a clinical trial, and significant additional research and development and clinical testing will be required before we can potentially seek regulatory approval for or commercialize any of our product candidates.

Our main focus and the investment of a significant portion of our efforts and financial resources has been in the development of our lead product candidate, CUE-101, for which we are currently actively conducting a Phase 1 clinical trial. Our other product candidates are all at a pre-clinical stage. We expect that additional trials of CUE-101 will be required in order to gain approval by the FDA. Therefore, significant additional research and development activity and clinical testing are required before we and our collaborators will have a chance to achieve a commercially viable product from such candidates. Our research and development efforts remain subject to all of the risks associated with the development of new biopharmaceutical products and treatments based on immune modulation. Development of the underlying technology may be affected by unanticipated technical or other problems, among other research and development issues, and the possible insufficiency of funds needed in order to complete development of these product candidates. Safety, regulatory and efficacy issues, clinical hurdles or other challenges may result in delays and cause us to incur additional expenses that would increase our losses. If we and our collaborators cannot complete, or if we experience significant delays in developing, our potential therapeutics or products for use in potential commercial applications, particularly after incurring significant expenditures, our business may fail and investors may lose the entirety of their investment.

We have limited experience in conducting clinical trials and no history of commercializing biologic products, which may make it difficult to evaluate the prospects for our future viability.

Our operations to date have been limited to financing and staffing our company, conducting research and developing our core technologies, and identifying and optimizing our lead product clinical candidates. Additionally, we have conducted limited clinical testing of one of our product candidates. Although we have recruited a team that has experience with clinical trials in the United States, as a company, we have limited experience conducting clinical trials and have not had previous experience commercializing product candidates or submitting an IND or a BLA to the FDA or similar submissions to initiate clinical trials or obtain marketing authorization to foreign regulatory authorities. We cannot be certain that current clinical trials will begin or be completed on time, if at all, that our planned clinical trials will begin on time, if at all, or that our planned development programs would be acceptable to the FDA or other regulatory authorities, or that, if regulatory approval is obtained, our product candidates can be successfully commercialized. Clinical trials and commercializing our product candidates will require significant additional financial and management resources, and reliance on third-party clinical investigators, contract research organizations (“CROs”), consultants and collaborators. Relying on third-party clinical investigators, CROs or collaborators may result in delays that are outside of our control.

Furthermore, we may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- negative or inconclusive results from our IND-enabling studies, clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;

- delays in submitting INDs or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;

- conditions imposed by the FDA or a foreign regulatory authority regarding the number, scope or design of our clinical trials;
- delays in enrolling patients in clinical trials;
- high drop-out rates of patients;
- inadequate supply or quality of clinical trial materials or other supplies necessary to conduct our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness or unacceptable side effects of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- difficulty in establishing or managing relationships with contract research organizations, or CROs, and clinical investigators;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- serious and unexpected drug-related side effects or other safety issues experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and foreign regulatory authorities.

Business interruptions, including any interruptions resulting from COVID-19, could cause a disruption of our current or future clinical trials or development and commercialization of our product candidates, including CUE-101, and we may not carry adequate business interruption insurance to cover any such losses.

All of our employees are located in the U.S. Our headquarters is located in Cambridge, Massachusetts. In addition to our employees, we rely on third-party clinical investigators, CROs, consultants and collaborators insider and outside of the U.S., including LG Chem, which is located in Korea. If we, or any of these third-party partners encounter any disruptions to our or their respective operations or facilities, or if we or any of these third-party partners were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute, pandemic, health emergencies, outbreaks of disease or other unforeseen disruption, then we or they may be prevented or delayed from effectively operating our or their business, respectively.

The coronavirus (COVID-19) that was reported to have surfaced in Wuhan, China in December 2019 and that has now spread to countries all over the world could adversely impact our operations or those of our third-party partners. Additionally, the continued spread of the virus could negatively impact the development of our product candidates, our clinical trial timelines and our financial results. The extent to which the coronavirus impacts our operations or those of our third-party partners, including LG Chem in Korea, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. While we carry insurance for certain business interruption events, we do not carry sufficient business interruption insurance to compensate us for all losses that may occur during significant business interruptions. Any losses or damages we incur could have a material adverse effect on our financial results and our ability to conduct business as expected.

Our current or planned clinical trials or those of our collaborators may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

In order to obtain marketing approval for any of our biologic product candidates, we must demonstrate the safety, purity, and efficacy of the product candidate for the relevant clinical indication or indications through preclinical studies and

clinical trials as well as additional supporting data. If our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

We have initiated a Phase 1 clinical trial for our lead product candidate, CUE-101, but otherwise we have not conducted any clinical trials. We have conducted various preclinical studies of our product candidates, but we do not know the predictive value of these studies for humans, and we cannot guarantee that any positive results in preclinical studies will successfully translate to human patients. It is not uncommon to observe results in human clinical trials that are unexpected based on preclinical testing, and many product candidates fail in clinical trials despite promising preclinical results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Human patients in clinical trials may suffer significant adverse events or other side effects not observed in our preclinical studies, including, but not limited to, immunogenic responses, organ toxicities such as liver, heart or kidney or other tolerability issues or possibly even death. The observed potency and kinetics of our planned product candidates in preclinical studies may not be observed in human clinical trials. If clinical trials of our planned product candidates fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our planned product candidates.

If significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to the clinical trial, patients may drop out of our trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA or other applicable regulatory authorities, or an Institutional Review Board ("IRB") may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or clinical testing. However, any such event, were it to occur, would cause substantial harm to our business and financial condition and would result in the diversion of our management's attention.

Success in preclinical studies or early clinical trials may not be indicative of results obtained in later trials.

Results from preclinical studies or early clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite demonstrating positive results in preclinical studies or having successfully advanced through initial clinical trials or preliminary stages of clinical trials. There can be no assurance that the results seen in preclinical studies for any of our product candidates ultimately will result in success in clinical trials or that results seen in Phase 1 or 2 trials will be replicated in Phase 3 trials.

There is a high failure rate for drugs and biologic products proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy or requirements during the period of our product candidate development. Any such delays could materially and adversely affect our business, financial condition, results of operations and prospects.

We plan to seek collaborations or strategic alliances. However, we may not be able to establish such relationships, and relationships we have established may not provide the expected benefits.

On November 14, 2017, we entered into the Merck Agreement under which Merck will partner with us in the development of our Immuno-STATs targeting certain autoimmune diseases. Pursuant to the Merck Agreement, Merck will acquire rights to develop, commercialize and sell Immuno-STATs relating to autoimmune disease and, in exchange for such rights, has agreed to make payments to us that include a licensing fee, milestone payments and sales royalties.

Effective November 6, 2018, we entered into the LG Chem Agreement, for the development of the Company's Immuno-STATs focused in the field of oncology. Pursuant to the LG Chem Agreement, we have granted certain exclusive license rights to LG Chem in Australia and in certain countries in Asia and LG Chem has agreed to provide certain services to us and to make payments to us that include a licensing fees, milestone payments and sales royalties. These agreements do not commit Merck or LG Chem to a long-term relationship, and they may disengage with us at any time.

Additionally, we plan to seek strategic alliances or collaborations with other third parties that we believe will complement or augment our development and commercialization efforts with respect to our planned product candidates and any future product candidates that we may develop. In addition, we currently do not have sales, marketing, manufacturing or distribution capabilities or arrangements. In order to commercialize our potential products, we plan to seek development and marketing partners or sublicensees to obtain necessary marketing, manufacturing and distribution capabilities.

Any of these relationships may require us to incur non-recurring and other charges, give up certain rights relating to our intellectual property and research and development activities, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, issue debt which may require liens on our assets and which will increase our monthly expense obligations, or disrupt our management and business. Moreover, we may not be successful in our efforts to establish additional strategic partnerships or other alternative arrangements for our planned product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our planned product candidates as having the requisite potential to demonstrate safety, purity, and efficacy. If we are unable to establish additional strategic partnerships or other alternative arrangements to develop our product candidates, the costs for us to independently develop our product candidates may be higher than we currently anticipate, which could materially harm our business prospects, financial condition and results of operation.

Further, collaborations involving our planned product candidates are subject to numerous risks, which may include the following:

- our collaborators may have significant discretion in determining the efforts and resources that they will apply to our collaboration as compared to their other then-existing collaborations;
- our collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- our collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- our collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates; a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of each of our potential products;
- our collaborators may not properly maintain or defend our intellectual property rights in accordance with the terms of our contractual arrangements with them or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to other potential liability;

- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts our managements' attention and our other resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and

- our collaborators may own or co-own intellectual property covering our potential products that results from our collaboration with them, and in such case, we would not have the exclusive right to commercialize such intellectual property without our collaborators' involvement and consent.

As a result, we may not be able to realize the benefit of collaboration agreements, strategic partnerships or licenses of our technology or potential products, which could delay our product development timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve sufficient revenue or net income to justify such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our planned product candidates could delay the development and commercialization of our planned product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

Our collaboration agreements with Merck and LG Chem contain exclusivity provisions that restrict our research and development activities.

We have granted to Merck under the Merck Agreement an exclusive license under certain of our patent rights, including a sublicense of patent rights licensed from Einstein, to the extent applicable to the specific Immuno-STAT™ that are elected to be developed by Merck. So long as Merck continues product development on a CUE product candidate that has demonstrated certain biologically relevant effects (a "Proposed Product Candidate"), we are restricted from conducting any development activities within the initial indication covered by such Proposed Product Candidate other than pursuant to the Merck Agreement.

Additionally, we have granted to LG Chem under the LG Chem Agreement an exclusive license to develop, manufacture and commercialize CUE-101, as well as Immuno-STATs that target T cells against two additional cancer antigens ("LG Chem Product Candidates"), in Australia and certain Asian countries (the "LG Chem Territory"). Under the LG Chem Agreement, the Company will engineer the selected Immuno-STAT for up to three alleles, which are expected to include the predominant alleles in the LG Chem Territory, while LG Chem will establish a CMC process for the development and commercialization of LG Chem Product Candidates. In addition, LG Chem has the option to select one additional Immuno-STAT for an oncology target within two years of the effective date of the Agreement for an exclusive worldwide development and commercialization license.

These restrictions on our development, manufacturing, and commercialization activities could impact our ability to successfully develop certain product candidates, which could harm our future business prospects for commercializing drugs for those product candidates.

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates; these decisions may prove to be wrong and may adversely affect our business.

Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify successful product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;

- our key platform technology, Immuno-STAT Biologics™, may not adequately enable us to design, discover and validate product candidates;

- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or

- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our drug portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than our product candidates. Our competitors may include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources than we have, such as a larger research and development staff and experienced marketing and manufacturing organizations, established relationships with CROs and other collaborators, as well as established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection and, in turn, exclude us from technologies that we may need for the development of our technologies and potential products.

Immunotherapy technologies are advancing at a rapid pace and we anticipate competing with companies developing bi-specific antibodies (e.g., Amgen, Inc., Hoffmann-La Roche and Sutro Biopharma), CAR-T therapies (e.g., Novartis A.G., Juno Therapeutics and Kite Pharma, Inc.), checkpoint inhibitors (e.g., Bristol-Myers Squibb, Merck & Co. and Pfizer, Inc.), antibody drug conjugates (e.g., Seattle Genetics, Inc., ImmunoGen, Inc. and Sorrento Therapeutics), and targeted cytokines (e.g., Nektar/Bristol Myers Squibb, Sythorax and Hoffmann-La Roche) many of which have significantly greater financial and other resources than we currently have.

Even if we obtain regulatory approval of any of our product candidates, we may not be the first to market and that may negatively affect the price or demand for our product candidates. Additionally, we may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Furthermore, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor’s product. If such competitor product is determined to be the same product as one of our product candidates, we may be prevented from obtaining approval from the FDA for such product candidate for the same indication for seven years, except in limited circumstances, and we may be subject to similar restrictions under non-U.S. regulations.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify and develop new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

We are highly dependent upon the principal members of our management team, including Daniel Passeri, M.Sc., our Chief Executive Officer, Anish Suri, our President and Chief Scientific Officer, Kenneth Pienta, our Acting Chief Medical Officer, and other members of our scientific and clinical advisory team, including Steven Almo, Ph.D., the Chairman of our Scientific and Clinical Advisory Board. Our team has significant experience and knowledge of oncology drug discovery and development, T cell modulation, protein biochemistry and immunological assays, and the loss of any current or future team member could impair our ability to design, identify, and develop new intellectual property and product candidates and new scientific or product ideas. Additionally, if we lose the services of any of these persons, we would likely be forced to expend

significant time and money in the pursuit of replacements, which may result in a delay in the development of our product candidates and the implementation of our business plan and plan of operations and diversion of our management's attention. We can give no assurance that we could find satisfactory replacements for our current and future key scientific and management employees on terms that would not be unduly expensive or burdensome to us.

To induce valuable personnel to remain at our Company, in addition to salary and cash incentives, we have granted stock options and restricted stock units that vest over time. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that these employees could leave our employment at any time, for or without cause. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical and scientific personnel.

Our internal computer systems, or those used by third-party CROs, manufacturers or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs, manufacturers and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber-intrusions, loss of funds or information from phishing or other fraudulent schemes, attachments to emails, persons inside our organization, or persons with access to systems inside our organization or those with whom we do business. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Increased security threats and more sophisticated cybercrimes and cyberattacks pose a potential risk to the security and availability of our internal computer systems, networks and services, including those used by third-party CROs, manufacturers or other contractors or consultants, as well as the confidentiality, availability and integrity of our data and the data of potential trial participants or patients, employees and others. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information (such as individually identifiable health information), we could incur significant liabilities and the further development and commercialization of our product candidates could be delayed. In addition, the foreign, federal and state regulatory environment surrounding information security and privacy is increasingly demanding, with frequent imposition of new and changing requirements. Compliance with changes in privacy and information security laws and standards may result in significant expense due to increased investment in technology and the development of new operational processes.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely upon and plan to continue to rely upon third-party CROs for execution of our clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs, including Catalent, are required to comply with FDA laws and regulations regarding current good clinical practice, or GCP, for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. While we work closely with our CROs on the manufacturing process for our product candidates, including quality audits, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our CROs for compliance with GMP regulatory requirements and for manufacture of both active drug substances and finished drug products. In addition, portions of the clinical trials for our product candidates may

be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies for our product candidates.

We rely completely on third parties to manufacture clinical drug supplies for our product candidates. If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience disruptions in supply or delays, suspensions or terminations of clinical trials or regulatory submissions. We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers or other third-party manufacturers to manufacture our product candidates, including Catalent, must obtain and maintain approval by the FDA. While we work closely with our third-party manufacturers on the manufacturing process for our product candidates, including quality audits, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our contract manufacturers or other third-party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both active drug substances and finished drug products. If our contract manufacturers or other third-party manufacturers cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities and we may not have sufficient access to supplies, which could significantly and adversely affect our operations.

In addition, we have no control over the ability of our contract manufacturers or other third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve, or withdraws approval for, these facilities for the manufacture of our products and product candidates, we may need to find alternative manufacturing facilities, which would significantly impact our ability to commercialize, develop, or obtain or maintain regulatory approval for our products and product candidates.

We also rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our products and product candidates and we may need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a contract manufacturer or other third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

Reliance on third-party manufacturers entails additional risks, including the possible breach of manufacturing agreements by the third party, the possible misappropriation of our proprietary information -- further discussed below under "*Risks Related to Intellectual Property and Other Legal Matters*" -- and the possible termination or non-renewal of an agreement by a third party at a time that is costly or inconvenient for us.

We expect to continue to depend on contract manufacturers or other third-party manufacturers for the foreseeable future. We may, however, be unable to enter into agreements or do so on commercially reasonable terms for potential future product candidates, which could have a material adverse impact upon our business.

We rely on certain sole sources of supply for our product candidates and any disruption in the chain of supply may cause delays in developing, obtaining approval for, and commercializing our product candidates.

Currently, we use Catalent Pharma Solutions, LLC as a sole source of supply for manufacturing clinical supply of our lead product candidate, CUE-101. If we experience multiple successive batch failures, or if supply from Catalent is otherwise interrupted, there could be a significant disruption in our product candidate supply. Any alternative vendor would need to be qualified through an IND supplement, which could result in delay of our clinical trials of CUE-101. rely on sole sources of supply for the preclinical and clinical supply of materials.

The manufacturing processes for CUE-101 and our other product candidates are complex, and it may difficult or impossible to finalize appropriate processes for the scaled manufacture of the product candidates. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of any of our product candidates; cause us to incur higher costs; or prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required clinical or commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed.

Risks Related to Intellectual Property and Other Legal Matters

If we or our licensor are unable to protect our or its intellectual property, then our financial condition, results of operations and the value of our technology and potential products could be adversely affected.

Patents and other proprietary rights are essential to our business, and our ability to compete effectively is dependent upon the proprietary nature of our technologies. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants and other parties. Our success will depend in part on the ability of ourselves and our licensor(s) to obtain, to maintain (including making periodic filings and payments) and to enforce patent protection for its intellectual property, particularly those patent applications and other intellectual property to which we have secured exclusive rights. We and our licensor(s) may not successfully prosecute or continue to prosecute the patent applications which we have licensed. Even if patents are issued in respect of pending patent applications, we or our licensor(s) may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such enforcement less aggressively than we ordinarily would. Without adequate protection for the intellectual property that we own or license, others may be able to offer substantially identical products for sale, which could unfavorably affect our competitive business position and harm our business prospects. Even if issued, patents may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of the term of patent protection that we may have for our potential products.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and potential products could be adversely affected.

In addition to our licensed technology, we rely (and will continue to rely) upon, among other things, unpatented proprietary technology, processes, trade secrets, trademarks, and know-how. Any involuntary disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff

was previously employed by other pharmaceutical, medical technology or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their former employee's therapeutic development activities for us. Any dispute involving such employees may result in liabilities to us.

If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are important to our business.

We hold an exclusive license from Einstein to intellectual property relating to identification of novel immunomodulators, novel epitopes, and novel immunotherapy drugs. This license imposes various developmental milestone obligations on us. If we fail to comply with any obligations under the license agreement and fail to cure such noncompliance, Einstein will have the right to terminate the agreement and our license. The existing patent applications or future patents to which we have rights based on our agreements with Einstein may be too specific and narrowly construed to prevent third parties from developing or designing around the protection provided by these patents. Additionally, we may lose our rights to the patents and patent applications we license in the event of termination of the license agreement. There is no assurance that we will be successful in meeting all of the milestones in the future on a timely basis or that this important license agreement will not be terminated for other reasons, depriving us of significant rights. The termination of this license agreement would have a material adverse effect on our financial condition, results of operations, and prospects.

If we are unable to patent and protect the intellectual property used in our potential products, others may be able to copy our innovations, which may impair our ability to compete effectively in our markets.

The strength of our anticipated patents will involve complex legal and scientific matters and can be uncertain. As described above under "Business - Our Intellectual Property" we own or license a number of pending patent applications. Our anticipated patents may be challenged or fail to result in issued patents and anticipated patents may be too specific and narrowly construed to prevent third parties from developing or designing around the protections provided by our intellectual property and in that event we may lose competitive advantage and our business may suffer. Further, the patent and patent applications that we license or have filed may fail to result in issued patents or the claims may need to be amended. Even after amendment, a patent may not issue. In that event, we may not obtain the exclusive use of the intellectual property that we seek, and we may lose competitive advantage, which could result in harm to our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some non-U.S. countries can have a different scope and strength than do those in the United States. In addition, the laws of certain non-U.S. countries do not protect intellectual property rights to the same extent as U.S. federal and state laws do. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing drugs made using our inventions in and into the United States or non-U.S. jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to non-U.S. jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in the United States. These drugs may compete with our product candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many U.S.-based companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Litigation or third-party claims of intellectual property infringement or challenges to the validity of our anticipated patents would require us to use resources to protect our technology and may prevent or delay our development, regulatory approval or commercialization of our product candidates.

If we are the target of claims by third parties asserting that our potential products or intellectual property infringe upon the rights of others, we may be forced to incur substantial expenses or divert substantial employee resources from our business.

If successful, those claims could result in our having to pay substantial damages or could prevent us from developing one or more product candidates. Further, if a patent infringement suit is brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

If we or our collaborators experience patent infringement claims, or if we elect to avoid potential claims others may be able to assert, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into license agreements on acceptable terms. This could harm our business significantly. The cost to us of any litigation or other proceeding, regardless of its merit, and even if resolved in our favor, could be substantial. Some of our competitors may be able to bear the costs of such litigation or proceedings more effectively than we can because of their having greater financial and human resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement, the therapeutic industry is characterized by many suits regarding patents and other intellectual property rights. Other parties may in the future allege that our activities infringe upon their patents or that we are employing their proprietary technology without authorization. We may not have identified all the patents, patent applications or published literature that affect our business either by blocking our ability to commercialize our potential products, by preventing the patentability of one or more aspects of our potential products or those of our licensor or by covering the same or similar technologies that may affect our ability to market our potential products. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain future licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

Some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

The majority of the intellectual property rights we have licensed are generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to

manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the normal statutory term of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Further, normal statutory patent terms may be limited in the U.S. in the event there is a determination that the claims in different patents are directed to obvious variants of the same invention, which can negatively impact the normal statutory patent term. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and the scope of protection is not the full scope of the claims but is instead limited to the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects could be materially harmed.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We will face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any drugs. For example, we may be sued if our product candidates cause or are perceived to cause injury or death or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under state or foreign consumer protection laws. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our potential drugs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;

- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- financial cost;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize any product candidate.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of drugs we develop, alone or with collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our insurance coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We may be subject to securities litigation, which is expensive and could divert management attention.

The price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their common stock have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Risks Related to Government Regulation

We are subject to regulation in respect of our research and federal funding.

Because our licensor has conducted research under federal grants and we may conduct further research under federal grants, we will be subject to federal regulation in how we conduct our research and the agreement terms relating to those grants. There are also ethical guidelines promulgated by various governments and research institutions that we are required to follow in respect of our research. These guidelines are orientated towards research and experimentation involving humans and animals. Failure to follow the regulations, agreement terms and accepted scientific practices would jeopardize our grants and our results and the use of the results in further research and approval circumstances. Because our licensor has used federal funding, the government retains a "march-in" right in connection with these grants, which is the right to grant additional licenses to practice inventions developed from grant funding. The exercise of these "march-in" rights could result in decreased demand for our future products, which could have a material adverse effect on our results of operations and financial condition. In addition, any failure to comply with applicable laws or regulations could harm our business and divert our management's attention.

We will be subject to stringent domestic and foreign regulation in respect of any potential products. The regulatory approval processes of the FDA and other comparable regulatory authorities outside the United States are lengthy, time-consuming and inherently unpredictable. Any unfavorable regulatory action may materially and adversely affect our future financial condition and business operations.

Our potential products, further development activities and manufacturing and distribution, once developed and determined, will be subject to extensive and rigorous regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, and the safety and effectiveness of our drugs. The process of obtaining marketing approval from the FDA and comparable foreign bodies for new products, or for enhancements, expansion of the indications or modifications to existing products, could:

- take a significant, indeterminate amount of time;

- require the expenditure of substantial resources;
- involve rigorous preclinical and clinical testing, and possibly post-market surveillance;
- involve modifications, of our potential products;
- result in limitations on the indicated uses of our potential products; or
- result in our never being granted the regulatory approval we seek.

Any of these occurrences may cause our operations or potential for success to suffer, harm our competitive standing and result in further losses that adversely affect our financial condition. We will have ongoing responsibilities under FDA and international regulations, both before and after a product is approved and commercially released. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If the FDA were to conclude that there is non-compliance with applicable laws or regulations, or that any of our potential therapeutics are ineffective or pose an unreasonable health risk, the FDA could ban such drugs, detain or seize such drugs, order a recall, of such drugs, or require us to notify health professionals and others that the drugs present unreasonable risks of substantial harm to the public health. Additionally, the FDA may impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to therapeutics and assess civil or criminal penalties against us, our officers, our employees, or our collaborative partners. The FDA has increased its scrutiny of the therapeutic industry and U.S. and foreign governments are expected to continue to scrutinize the industry closely with inspections and possibly enforcement actions by the FDA or other agencies. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively commercializing our potential products. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our financial condition and results of operations.

We may seek orphan drug designation for one or more of our product candidates, but even if such designation is granted, we may be unable to maintain any benefits associated with orphan drug designation, including market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for a disease or condition will be recovered from sales in the United States for that drug or biologic. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity.

We may seek orphan drug designation for one or more of our products candidates, but the FDA may not approve any such request. Even if the FDA grants orphan drug designation to one or more of our product candidates, exclusive marketing rights in the United States may be limited if we seek FDA marketing approval for an indication broader than the orphan designated indication. Additionally, any product candidate that initially receives orphan drug designation, may lose such designation if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, others may obtain orphan drug exclusivity for products addressing the same diseases or conditions as products we are developing, thus limiting our ability to compete in the markets addressing such diseases or conditions for a significant period of time.

We may seek fast-track designation or breakthrough therapy and priority review programs for our product candidates. Even if received, fast-track designation or breakthrough therapy designation may not actually lead to a faster review process.

We aim to benefit from the FDA's fast track, breakthrough therapy and priority review programs. However, our drug product candidates may not receive an FDA fast-track designation, breakthrough therapy designation, or priority review. Without fast-track designation, submitting a BLA, and getting through the regulatory process to gain marketing approval is a lengthy process. Under fast-track designation, the FDA may initiate review of sections of a fast-track drug's BLA before the application is complete. However, the FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted. Additionally, the fast-track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

The FDA has also established breakthrough therapy designation, which is for a product that is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner. We may seek breakthrough therapy designation for one or more of our product candidates, but there can be no assurance that we will receive such designation.

Under the FDA policies, a product candidate is eligible for priority review, or review within a six-month time frame from the time a complete BLA is accepted for filing, if the product candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast-track or breakthrough therapy designated drug candidate would ordinarily meet the FDA's criteria for priority review.

The fast-track or breakthrough therapy designation for our drug product candidates, if either obtained, may not actually lead to a faster review process and a delay in the review process or in the approval of our potential products will delay revenue from their potential sales and will increase the capital necessary to fund these product development programs.

To obtain the necessary approval of our potential products, as a precondition, there will have to be conducted various preclinical and clinical tests, all of which will be costly and time consuming, and may not provide results that will allow us to seek regulatory approval.

The number of preclinical and clinical tests that will be required for regulatory approval varies depending on the disease or condition to be treated, the method of treatment, the nature of the drug, the jurisdiction in which approval is sought and the applicable regulations. Regulatory agencies can delay, limit or deny approval of a product for many reasons. For example, regulatory agencies may:

- not deem a therapeutic to be safe or effective;
- interpret data from preclinical and clinical testing differently than we do;
- not approve the manufacturing processes;
- conclude that our product candidate does not meet quality standards for durability, long-term reliability, biocompatibility, compatibility, or safety; and
- change their approval policies or adopt new regulations.

The FDA may make requests or suggestions regarding conduct of any clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval in the United States. Foreign regulatory agencies may similarly have the ability to influence any clinical trials occurring outside the United States. Any of these occurrences could prove materially harmful to our operations and business.

Even if a potential therapeutic is ultimately approved by the various regulatory authorities, it may be approved only for narrow indications which may render it commercially less viable.

Even if a potential therapeutic of ours is approved, it may not be approved for the indications that are necessary or desirable for successful commercialization. Our preference will be to obtain as broad an indication as possible for use in connection with the particular disease and treatment for which it is designed. However, the final indication may be more limited than originally sought. The limitation on use may make the product commercially less viable and more difficult, if not impractical, to market.

Therefore, we may not obtain the revenues that we seek in respect of the proposed product, and we may not be able to become profitable and provide an investment return to our investors.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA or foreign regulatory agencies may also require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing processes ("cGMPs") and good clinical practices ("GCPs") for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any approval that we may have obtained and we may not achieve or sustain profitability.

If commercial third-party payors or government payors fail to provide coverage or adequate reimbursement, our revenue and prospects for profitability would be harmed.

There is increasing pressure on biotechnology companies to reduce healthcare costs. In the United States, these pressures come from a variety of sources, such as managed care groups and institutional and government purchasers. Increased purchasing power of entities that negotiate on behalf of federal healthcare programs and private sector beneficiaries could increase pricing pressures in the future. Such pressures may also increase the risk of litigation or investigation by the government regarding pricing calculations. The biotechnology industry will likely face greater regulation and political and legal actions in the future.

There is increased uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement. Adverse pricing limitations may hinder our ability to recoup our investment in one or more future product candidates, even if our future product candidates obtain regulatory approval. Adverse pricing limitations prior to approval will also adversely affect us by reducing our commercial potential. Our ability to commercialize any potential products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers, pharmacy benefit managers, and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize in the future and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval in the future. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for future products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize potential products and our overall financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our business operations will subject us to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We expect to generally contract with third parties for the disposal of these materials and wastes. However, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations.

These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions and we may not have sufficient (or any) insurance to cover any such costs.

Compliance with the HIPAA security, privacy and breach notification regulations may increase our costs.

The HIPAA privacy, security and breach notification regulations, including the expanded requirements under HITECH, establish comprehensive federal standards with respect to the uses and disclosures of protected health information (“PHI”) by health plans, healthcare providers and healthcare clearinghouses, in addition to setting standards to protect the confidentiality, integrity and security of PHI. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payments for our services, and our healthcare operations activities;
- a patient’s rights to access, amend and receive an accounting of certain disclosures of PHI;
- requirements to notify individuals if there is a breach of their PHI;
- the contents of notices of privacy practices for PHI;

- administrative, technical and physical safeguards required of entities that use or receive PHI; and
- the protection of computing systems maintaining electronic PHI.

We have implemented practices intended to meet the requirements of the HIPAA privacy, security and breach notification regulations, as required by law. We are required to comply with federal privacy, security and breach notification regulations as well as varying state privacy, security and breach notification laws and regulations, which may be more stringent than federal HIPAA requirements. In addition, for healthcare data transfers from other countries relating to citizens of those countries, we must comply with the laws of those countries. The federal privacy regulations restrict our ability to use or disclose patient identifiable data, without patient authorization, for purposes other than payment, treatment, healthcare operations and certain other specified disclosures such as public health and governmental oversight of the healthcare industry.

HIPAA provides for significant fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties. Computer networks are always vulnerable to breach and unauthorized persons may in the future be able to exploit weaknesses in the security systems of our computer networks and gain access to PHI. Additionally, we share PHI with third-parties who are legally obligated to safeguard and maintain the confidentiality of PHI. Unauthorized persons may be able to gain access to PHI stored in such third-parties computer networks. Any wrongful use or disclosure of PHI by us or such third-parties, including disclosure due to data theft or unauthorized access to our or our third-parties computer networks, could subject us to fines or penalties that could adversely affect our business and results of operations. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could also incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

Risks Related to Owning Our Common Stock, Our Financial Results and Our Need for Financing

We anticipate future losses and negative cash flow, and it is uncertain if or when we will become profitable.

We do not expect to generate any commercial revenues until we successfully complete development of our first potential products and we are able to successfully commercialize them through sales and licensing. We have not yet demonstrated our ability to generate commercial revenue, and we may never be able to produce commercial revenues or operate on a profitable basis. As a result, we have incurred losses since our inception and expect to experience operating losses and negative cash flow for the foreseeable future. Our planned product candidates may never be approved or become commercially viable. Even if we and our collaborators are able to commercialize our technology, which may include licensing, we may never recover our research and development expenses.

We expect to require additional financing to support our growth and ongoing operations. Additional capital may be difficult to obtain, restrict our operations, require us to relinquish rights to our technologies or product candidates, encumber our assets and result in ongoing debt service cost, or result in additional dilution to our stockholders.

Our business will require additional capital for implementation of our long-term business plan and product development and commercialization. As we require additional funds, we may seek to fund our operations through the sale of additional equity securities, debt financing and/or strategic collaboration agreements. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on favorable terms.

Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals by the FDA and comparable regulatory authorities, including the potential that the FDA or comparable regulatory authorities may require that we perform more studies than those that we currently expect;
- the number and characteristics of product candidates that we may in-license and develop;
- our ability to successfully commercialize our product candidates;

- the amount of sales and other revenues from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party reimbursement;
- selling and marketing costs associated with our potential products, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other product candidates;
- the costs of operating as a public company;
- the cost and timing of completion of commercial-scale, outsourced manufacturing activities;
- the time and cost necessary to respond to technological and market developments;
- any disputes which may occur between us and Einstein, employees, collaborators or other prospective business partners; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

If we raise additional funds by selling shares of our common stock or other equity-linked securities, the ownership interest of our current stockholders will be diluted. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be acceptable to us. If we raise additional funds through debt financing, we may have to grant a security interest on our assets to the future lenders, our debt service costs may be substantial, and the lenders may have a preferential position in connection with any future bankruptcy or liquidation involving the company.

If we are unable to raise additional capital when needed, we may be required to curtail the development of our technology or materially curtail or reduce our operations. We could be forced to sell or dispose of our rights or assets. Any inability to raise adequate funds on commercially reasonable terms could have a material adverse effect on our business, results of operation and financial condition, including the possibility that a lack of funds could cause our business to fail and the Company to dissolve and liquidate with little or no return to investors.

We are an "emerging growth company" under the JOBS Act and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an "emerging growth company" for up to five years following the initial public offering of our common stock, although we will lose that status sooner if our revenues exceed $1.07 billion, if we issue more than $1 billion in non-convertible debt in a three year period, or if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30.

Our status as an "emerging growth company" under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements provided to us as an "emerging growth company," we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

Our stock price can be volatile and investors may have difficulty selling their shares.

Our common stock is currently listed on the Nasdaq under the symbol "CUE." The price of our common stock may fluctuate significantly in response to market and other factors, some of which are beyond our control, including those listed in this "Item 1A. Risk Factors" section and other, unknown factors. Our stock price may also be affected by:

- setbacks with respect to our research and development programs;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials;
- any adverse changes to our relationship with collaborators;
- results of internal and external studies and clinical trials;
- result of our business development efforts;
- variations in the level of expenses related to our existing product candidates or preclinical and clinical development programs;
- any intellectual property infringement actions in which we may become involved;
- variations in our results of operations;
- press reports, whether or not true, about our business;
- additions to or departures of our management;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or our common stock;
- sales or perceived potential sales of additional ordinary shares or our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future; and
- general economic and market conditions and overall fluctuations in the U.S. equity markets.

Any of these factors may result in large and sudden changes in the volume and trading price of our common stock. In addition, the stock market, in general, and small pharmaceutical and biotechnology companies have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors beyond our control may negatively affect the market price of our common stock, regardless of our actual operating performance, and cause the price of our common stock to decline rapidly and unexpectedly.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the price of our securities and trading volume could decline.

The trading market for our securities is influenced by the research and reports that industry or securities analysts publish about us or our business. We currently have one securities and industry analyst providing research coverage. If few

analysts commence research coverage of us, or one or more of the analysts who cover us issues an adverse opinion about our company, the price of our securities would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our securities or trading volume to decline.

We have not paid dividends in the past and have no immediate plans to pay dividends.

We plan to reinvest all of our earnings, to the extent we have earnings, in order to further develop our technology and potential products and to cover operating costs. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend.

We incur significant costs as a result of being a public company that reports to the Securities and Exchange Commission and our management will be required to devote substantial time to meet compliance obligations.

As a public company reporting to the Securities and Exchange Commission ("SEC"), we incur significant legal, accounting and other expenses. We are subject to reporting requirements of the Exchange Act and the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. In addition, there are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Wall Street Reform and Protection Act that increase public companies' legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on personnel, systems and resources. Our management and other personnel are expected to devote a substantial amount of time to these compliance initiatives. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

Provisions of our amended and restated certificate of incorporation (the "Certificate of Incorporation") and our amended and restated bylaws (the "Bylaws") and applicable provisions of Delaware law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our Certificate of Incorporation and Bylaws:

- authorize our board of directors to issue preferred stock without stockholder approval and to designate the rights, preferences and privileges of each class; if issued, such preferred stock would increase the number of outstanding shares of our common stock and could include terms that may deter an acquisition of us;
- limit who may call stockholder meetings;
- do not provide for cumulative voting rights;
- provide that all vacancies may be filled only by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders must comply with advance notice procedures with respect to stockholder proposals and the nomination of candidates for director;
- provide that stockholders may only amend our Certificate of Incorporation and Bylaws upon a supermajority vote of stockholders; and
- provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain legal claims.

In addition, Section 203 of the Delaware General Corporation Law may limit our ability to engage in any business combination with a person who beneficially owns 15% or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following the share acquisition. These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Our Certificate of Incorporation provides, subject to certain exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our Certificate of Incorporation provides, subject to limited exceptions, that the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (3) any action asserting a claim against us, any director or our officers and employees arising pursuant to any provision of the Delaware General Corporation Law, our Certificate of Incorporation or our Bylaws, or as to which the Delaware General Corporation Law confers exclusive jurisdiction on the Court of Chancery; or (4) any action asserting a claim against us, any director or our officers or employees that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our common stock shall be deemed to have notice of and to have consented to the provisions of our Certificate of Incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision that will be contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and results of operations.

If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our securities may decrease.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over financial reporting. Until such time as we are no longer an "emerging growth company", our auditors will not be required to attest as to our internal control over financial reporting.

If we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective or, once required, provide an attestation report from our independent registered public accounting firm, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decrease. We could also become subject to stockholder or other third-party litigation as well as investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our principal office is located in Cambridge, Massachusetts. We currently lease approximately 19,800 square feet of office and laboratory space. We expect to use this space as our new principal executive offices and for general office, research and development, and laboratory uses. The monthly rent payments due under this lease agreement will be approximately $297,500 for the first 18 months of the term and increase to approximately $330,500 for the remaining 18 months of the term. We also lease additional laboratory space consisting of three procedure and holding rooms. The monthly payments due under this lease agreement will be approximately $72,600 for the first 12 months of the term and decrease to approximately $59,000 for the remainder of the lease term which expires on April 30, 2021.

Item 3. Legal Proceedings

We are not currently a party to any pending legal proceedings that we believe will have a material adverse effect on our business or financial conditions. We may, however, be subject to various claims and legal actions arising in the ordinary course of business from time to time.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Common Stock

Our shares of common stock have been listed on the Nasdaq Capital Market under the symbol "CUE" since January 2, 2018. Prior to that date, there was no public trading market for our common stock.

As of March 6, 2020, there were approximately 42 holders of our common stock.

Dividend Policy

We have never paid cash dividends on our securities and we do not anticipate paying any cash dividends on our shares of common stock in the foreseeable future. We intend to retain any future earnings for reinvestment in our business. Any future determination to pay cash dividends will be at the discretion of our board of directors, and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as our board of directors deems relevant.

Item 6. Selected Financial Data

The data set forth below should be read in conjunction with Item 7 – "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Company's Financial Statements and notes thereto.

Consolidated Statement of Operations and Comprehensive Loss Data:

	Year Ended December 31,	
	2019	**2018**
Collaboration revenue	$ 3,458,331	$ 1,142,604
Operating expenses:		
General and administrative	12,740,093	11,295,211
Research and development	27,487,485	28,544,051
Total operating expenses	40,227,578	39,839,262
Loss from operations	(36,769,247)	(38,696,658)
Other income:		
Interest income	418,712	376,008
Other income, net	64,078	165,337
Total other income	482,790	541,345
Loss before provision for income taxes	(36,286,457)	(38,155,313)
Provision for income taxes	(412,500)	(825,000)
Net loss	(36,698,957)	(38,980,313)
Unrealized gain (losses) from available-for-sale securities, net of tax of $0	637	(10,958)
Comprehensive loss	$ (36,698,320)	$ (38,991,271)
Net loss per common share – basic and diluted	$ (1.66)	$ (1.94)
Weighted average common shares outstanding – basic and diluted	22,041,792	20,134,065

Balance Sheet Data:

	2019	2018
Cash	$ 44,290,030	$ 20,800,284
Marketable securities	15,119,925	18,412,500
Restricted cash, short term	—	50,068
Working capital	49,369,712	34,393,261
Total assets	71,605,009	45,363,100
Total stockholders’ equity	54,583,896	33,971,469

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K.

Overview

The Company is an innovative biopharmaceutical company developing a novel and proprietary class of biologic drugs for the selective modulation of the human immune system to treat a broad range of cancers and autoimmune disorders. The Company's corporate offices and research facilities are located in Cambridge, Massachusetts.

The Company's product candidates are currently in various stages of clinical and preclinical development, and the Company's activities are subject to significant risks and uncertainties. The Company has not yet commenced any commercial revenue-generating operations, has minimal cash flows from operations, and will need to raise additional capital to its growth and ongoing business operations.

Plan of Operation

Our technology is in the development phase. The Company believes that its licensed platforms have the potential for creating a robust pipeline of product candidates addressing multiple medical indications. The Company intends to maximize the value and probability of commercialization of its Immuno-STAT™ product candidates by focusing on research, testing, optimizing, conducting pilot studies, performing early stage clinical development and partnering for more extensive, later stages of clinical development, as well as seeking extensive patent protection and intellectual property development.

Since the Company is a development stage company, the majority of its business activities to date and its planned future activities will be devoted to further research and development.

A fundamental part of the Company's corporate development strategy is to establish one or more strategic partnerships with leading pharmaceutical or biotechnology organizations that will allow the Company to more fully exploit the potential of its technology platform, such as those described below under the headings "Collaboration Agreement with Merck" and "Collaboration with LG Chem".

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which The Company has prepared in accordance with generally accepted accounting principles in the United States, or U.S.GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, and the reported revenue and expenses during the reported periods. Management evaluate these estimates and judgments, including those described below, on an ongoing basis. Management bases their estimates on historical experience, known trends and events, contractual milestones and various other factors that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While the Company's significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this Form 10-K, management believes that the estimates and assumptions involved in the following accounting policies may have the greatest potential impact on the financial statements and, therefore, consider these to be critical for fully understanding and evaluating our financial condition and results of operations. There were no material changes to the Company's critical accounting policies and estimates as of December 31, 2019.

Revenue Recognition

The Company adopted Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), during 2018. The Company generates revenue solely through collaboration arrangements with strategic partners for the development and commercialization of product candidates. The core principle of ASC 606 is that an entity should recognize revenue to depict the transfer of promised goods and/or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and/or services. To determine the appropriate amount of revenue to be recognized for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following steps: (i) identify the contract(s) with the customer, (ii) identify the performance

obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract and (v) recognize revenue when (or as) each performance obligation is satisfied.

The Company recognizes collaboration revenue under certain of the Company's license or collaboration agreements that are within the scope of ASC 606. The Company's contracts with customers typically include promises related to licenses to intellectual property and research and development services. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and variable consideration in the form of milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the "most likely amount" method to estimate the amount of variable consideration, to predict the amount of consideration to which it will be entitled for its one open contract. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes development and regulatory milestone payments, the Company evaluates whether the associated event is considered probable of achievement and estimates the amount to be included in the transaction price using the most likely amount method. Currently, the Company has one contract with an option to acquire additional goods and/or services in the form of additional research and development services for additional product candidates.

Research and Development Costs

Research and development expenses consist primarily of compensation costs, fees paid to consultants, outside service providers and organizations (including research institutes at universities), facility costs, and development and clinical trial costs with respect to the Company's product candidates.

Research and development expenses incurred under contracts are expensed ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different pattern of expense recognition is more appropriate. Other research and development expenses are charged to operations as incurred. Payments made pursuant to research and development contracts are initially recorded as research and development contract advances in the Company's balance sheet and then charged to research and development expenses in the Company's statement of operations as those contract services are performed. Expenses incurred under research and development contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company's balance sheet, with a corresponding charge to research and development expenses in the Company's statement of operations.

Nonrefundable advance payments for future research and development activities pursuant to an executory contractual arrangement are recorded as advances as described above. Nonrefundable advance payments are recognized as an expense as the related services are performed. The Company evaluates whether it expects the services to be rendered at each quarter end and year end reporting date. If the Company does not expect the services to be rendered, the advance payment is charged to expense. To the extent that a nonrefundable advance payment is for contracted services to be performed within 12 months from the reporting date, such advance is included in current assets; otherwise, such advance is included in non-current assets.

The Company evaluates the status of its research and development agreements and contracts, and the carrying amount of the related assets and liabilities, at each quarter end and year end reporting date, and adjusts the carrying amounts and their classification on the balance sheet as appropriate.

Stock-Based Compensation

The Company periodically issues stock based awards to officers, directors, employees, Scientific and Clinical Advisory Board members, non-employees and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date.

Stock-based payments to officers, directors and employees, including grants of employee stock options and restricted stock units, are recognized in the financial statements based on their grant date fair values. Stock option grants and restricted stock units, which are generally time-vested, are measured at the grant date fair value and charged to operations on a straight-line basis over the vesting period.

The fair value of stock options and restricted stock units is determined utilizing the Black-Scholes option-pricing model, which is affected by several variables, including the risk-free interest rate, the expected dividend yield, the life of the equity award, the exercise price of the stock option as compared to the fair value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award.

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. Until the Company has established a trading market for its common stock, estimated volatility is based on the average historical volatilities of comparable public companies in a similar industry. The expected dividend yield is based on the current yield at the grant date; the Company has never declared or paid dividends and has no plans to do so for the foreseeable future. As permitted by Staff Accounting Bulletin No. 107, due to the Company's lack of history and option activity, management utilizes the simplified method to estimate the expected term of options at the date of grant. The fair value of common stock is determined by reference to either recent or anticipated cash transactions involving the sale of the Company's common stock.

The Company recognizes the fair value of stock-based compensation in general and administrative expenses and in research and development expenses in the Company's statement of operations, depending on the type of services provided by the recipient of the equity award. The Company issues new shares of common stock to satisfy stock option exercises.

Income Taxes

The Company accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

The Company is subject to U.S. Federal and Massachusetts state income taxes. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal and state taxing authorities in which the Company currently operates.

The Company recognizes interest accrued relative to unrecognized tax benefits in interest expense and penalties in operating expense.

Recent Accounting Pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to the consolidated financial statements in this Annual Report on Form 10-K.

Significant Contracts and Agreements Related to Research and Development Activities

Einstein License Agreement

On January 14, 2015, the Company entered into a license agreement, as amended and restated on July 31, 2017 (the "Einstein License"), with Einstein for certain patent rights (the "Patents") relating to the Company's core technology platform for the engineering of biologics to control T cell activity, precision, immune-modulatory product candidates, and two supporting technologies that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides.

The Company holds an exclusive worldwide license, with the right to sublicense, import, make, have made, use, provide, offer to sell, and sell all products, processes and services that use the patents covered by the Einstein License, including certain technology received from Einstein related thereto (the "Licensed Products"). Under the Einstein License, the Company is required to:

- Pay royalties based on certain percentage of proceeds, as defined in the Einstein License, from sales of Licensed Products, including sublicense agreements.
- Pay escalating annual maintenance fees, which are non-refundable, but are creditable against the amount due to Einstein for royalties.
- Make significant payments based upon the achievement of certain milestones, as defined in the Einstein License. At December 31, 2019, none of these milestones had been achieved by the Company.
- Incur minimum product development costs per year until the first commercial sale of the first Licensed Product.

The Company was in compliance with its obligations under the Einstein License at December 31, 2019 and 2018.

The Einstein License expires upon the expiration of the last obligation to make royalty payments to Einstein which may be due with respect to certain Licensed Products, unless terminated earlier under the provisions thereof. The Einstein License includes certain termination provisions if the Company fails to meet its obligations thereunder.

The Company accounts for the costs incurred in connection with the Einstein License in accordance with ASC 730, Research and Development. For the years ended December 31, 2019 and 2018, costs incurred with respect to the Einstein License aggregated $565,659 and $487,929, respectively. Such costs are included in research and development costs in the statements of operations.

Pursuant to the Einstein License, the Company issued to Einstein 671,572 shares of common stock of the Company in connection with the consummation of the initial public offering of its common stock on December 27, 2017.

The Company accounted for the issuance of these shares in accordance with ASC 730, Research and Development, as a charge to research and development expenses in the statements of operations at their aggregate fair value of $5,036,789, as the Patents acquired from Einstein are for use in the Company's research and development activities exclusively with respect to its core technology platform, have no alternative future use by the Company, and therefore no separate economic value.

Collaboration Agreement with Merck

On November 14, 2017, the Company entered into an Exclusive Patent License and Research Collaboration Agreement (the "Collaboration Agreement") with Merck for a partnership to research and develop certain of the Company's proprietary biologics that target certain autoimmune disease indications (the "Initial Indications"). The Company views this Collaboration Agreement as a component of our development strategy since it will allow us to advance our autoimmune programs in partnership with a world class pharmaceutical company, while also continuing our focus on our more advanced cancer programs. The research program outlined in the Collaboration Agreement entails (1) our research, discovery and development of certain Immuno-STAT™ drug candidates up to the point of demonstration of certain biologically relevant effects ("Proof of Mechanism") and (2) the further development by Merck of the Immuno-STAT™ drug candidates that have demonstrated Proof of Mechanism (the "Proposed Product Candidates") up to the point of demonstration of all or substantially all of the properties outlined in such Proposed Product Candidates' profiles as described in the Collaboration Agreement.

For the purposes of this collaboration, the Company granted to Merck under the Collaboration Agreement an exclusive license under certain of its patent rights, including a sublicense of patent rights licensed from Einstein, to the extent applicable to the specific Immuno-STAT™ that are elected to be developed by Merck. So long as Merck continues product development on a Proposed Product Candidate, the Company is restricted from conducting any development activities within the Initial Indication covered by such Proposed Product Candidate other than pursuant to the Collaboration Agreement.

In exchange for the licenses and other rights granted to Merck under the Collaboration Agreement, Merck paid to the Company a $2.5 million nonrefundable up-front payment. Additionally, the Company may be eligible to receive funding in developmental milestone payments, as well as tiered royalties, if all research, development, regulatory and commercial milestones agreed upon by both parties are successfully achieved. Excluding the up-front payment described above, the Company is eligible to earn up to $101 million for the achievement of certain research and development milestones, $120 million for the achievement of certain regulatory milestones and $150 million for the achievement of certain commercial

milestones, in addition to tiered royalties on sales, if all pre-specified milestones associated with multiple products across the primary disease indication areas are achieved. The Collaboration Agreement requires the Company to use the first $2.5 million of milestone payments the Company receives under the agreement to fund contract research. The amount of the royalty payments is a percentage of product sales ranging in the single digits based on the amount of such sales. The Company recorded approximately $874,000 in revenue for the year ended December 31, 2019 related to this collaboration agreement, compared to $1,142,605 for the year ended December 31, 2018.

The term of the Merck Agreement extends until the expiration of all royalty obligations following a product candidate's receipt of marketing authorization, at which point Merck's licenses and sublicenses granted under the agreement shall become fully paid-up, perpetual licenses and sublicenses, as applicable. Royalties on each product subject to the Merck Agreement shall continue on a country-by-country basis until the expiration of the later of: (1) the last-to-expire patent claiming the compound on which such product is based and (2) a period of ten years after the first commercial sale of such product in such country.

Notwithstanding the foregoing, Merck may terminate the Merck Agreement at any time upon 30 days' notice to the Company. The Merck Agreement may also be terminated by either party if the other party is in breach of its obligations thereunder and fails to cure such breach within 90 days after notice or by either party if the other party files for bankruptcy or other similar insolvency proceedings.

Collaboration Agreement with LG Chem

Effective November 6, 2018, the Company entered into the LG Chem Agreement with LG Chem, related to the development of Immuno-STATs focused in the field of oncology.

Pursuant to the LG Chem Agreement, the Company granted LG Chem an exclusive license to develop, manufacture and commercialize our lead product, CUE-101, as well as Immuno-STATs that target T-cells against two additional Product Candidates, in the LG Chem Territory. On December 20, 2018, the Company reported the selection of Wilms Tumor 1 ("WT1") as the first target antigen for a Product Candidate under the LG Chem Agreement. The Company retains rights to develop and commercialize all assets included in the LG Chem Agreement in the United States and in global markets outside of the LG Chem Territory. Under the LG Chem Agreement, the Company will engineer the selected Immuno-STATs for up to three alleles, which are expected to include the predominant alleles in the LG Chem Territory, thereby enhancing Cue's market reach by providing for greater patient coverage of populations in global markets, while LG Chem will establish a CMC process for the development and commercialization of selected Product Candidates. In addition, LG Chem has the option to select one additional Immuno-STAT for an oncology target (an "Additional Immuno-STAT") within two years of the effective date of the LG Chem Agreement for an exclusive worldwide development and commercialization license. If LG Chem exercises this option, then the parties will execute a license and collaboration agreement ("Global License and Collaboration Agreement") setting forth the terms and conditions relating to such arrangement. The Company will retain an option to co-develop and co-commercialize the additional program worldwide.

Under the terms of the LG Chem Agreement, LG Chem paid us a $5.0 million non-refundable, non-creditable upfront payment and purchased approximately $5.0 million of shares of our common stock at a price per share equal to a twenty percent (20%) premium to the volume weighted-average closing price per share over the thirty (30) trading day period immediately prior to the effective date of the LG Chem Agreement. The Company is also eligible to receive additional aggregate payments of approximately $400 million if certain research, development, regulatory and commercial milestones are successfully achieved. On May 16, 2019, the Company earned a $2.5 million milestone payment for the FDA acceptance of the IND for the Company's lead drug candidate, CUE-101, pursuant to the LG Chem Agreement. In addition, the LG Chem Agreement also provides that LG Chem will pay us tiered single-digit royalties on net sales of commercialized Product Candidates ("Collaboration Products") in the LG Chem Territory on a product-by-product and country-by-country basis, until the later of expiration of patent rights in a country, the expiration of regulatory exclusivity in such country, or ten years after the first commercial sale of a Collaboration Product in such country, subject to certain royalty step-down provisions set forth in the LG Chem Agreement.

Pursuant to the LG Chem Agreement, the parties will share research costs related to Collaboration Products, and LG Chem will provide CMC process development for selected Product Candidates and potentially additional downstream manufacturing capabilities, including clinical and commercial supply for Collaboration Products. In return for performing CMC process development, LG Chem is eligible to receive low-single digit royalty payments on the sales of Collaboration Products sold in all countries outside the LG Chem Territory. Furthermore, should the parties enter into a Global License and Collaboration Agreement for an Additional Immuno-STAT, LG Chem will pay us a one-time, non-refundable, non-creditable upfront payment and will be eligible to receive up to approximately $470 to $675 million in fees and milestone payments as well as tiered royalty payments on future global sales that range from high-single digits to mid-double digit teens in the United

States and mid-single to low-double digits outside of the United States. The amount of fees and milestone payments, as well as whether the Company receives royalty payments, will depend on when LG Chem nominates the Additional Immuno-STAT Biologic, the number of alleles selected by LG Chem and whether the Company exercises our option to co-develop and co-commercialize the additional program worldwide, in which case the Company would share costs and profits instead of receiving royalties and post-option-exercise milestones. For the years ended December 31, 2019 and 2018, the Company recognized approximately $2,584,000 and $0, respectively, in collaboration revenue related to this agreement.

The LG Chem Agreement includes various representations, warranties, covenants, indemnities and other customary provisions. LG Chem may terminate the LG Chem Agreement for convenience or change of control of the Company on a program-by-program, product-by-product or country-by-country basis, or in its entirety, at any time following the notice period set forth in the LG Chem Agreement. Either party may terminate the LG Chem Agreement, in its entirety or on a program-by-program, product-by-product or country-by-country basis, in the event of an uncured material breach. The LG Chem Agreement is also terminable by either party (i) upon the bankruptcy, insolvency or liquidation of the other party or (ii) for certain activities involving the challenge of certain patents controlled by the other party. Unless earlier terminated, the LG Chem Agreement will expire on a product-by-product and country-by-country basis upon the expiration of the applicable royalty term.

Results of Operations

Collaboration Revenue

The Company has not generated commercial revenue from product sales. To date, the Company has generated collaboration revenue from the Merck and LG Chem Agreement.

Operating Expenses

The Company generally recognizes operating expenses as they are incurred in two general categories, general and administrative expenses and research and development expenses. The Company's operating expenses also include non-cash components related to depreciation and amortization of property and equipment, trademark, and stock-based compensation, which are allocated, as appropriate, to general and administrative expenses and research and development expenses.

General and administrative expenses consist of salaries and related expenses for executive, legal, finance, human resources, information technology and administrative personnel, as well as professional fees, insurance costs, and other general corporate expenses. Management expects general and administrative expenses to increase in future periods as the Company adds personnel and incurs additional expenses related to an expansion of its research and development activities and its operation as a public company, including higher legal, accounting, insurance, compliance, compensation and other expenses.

Research and development expenses consist primarily of compensation expenses, fees paid to consultants, outside service providers and organizations (including research institutes at universities), facility expenses, and development and clinical trial expenses with respect to the Company's product candidates. The Company charges research and development expenses to operations as they are incurred. Management expects research and development expenses to increase in the future as the Company increases its efforts to develop technology for potential future products based on its technology and research.

Years Ended December 31, 2019 and 2018

The Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2019 and 2018, as discussed herein are presented below.

	Years Ended December 31,	
	2019	**2018**
Collaboration revenue	$ 3,458,331	$ 1,142,604
Operating expenses:		
General and administrative	12,740,093	11,295,211
Research and development	27,487,485	28,544,051
Total operating expenses	40,227,578	39,839,262
Loss from operations	(36,769,247)	(38,696,658)
Other income:		
Interest income	418,712	376,008
Other income	64,078	165,337
Total other income	482,790	541,345
Loss before provision for income taxes	(36,286,457)	(38,155,313)
Provision for income taxes	(412,500)	(825,000)
Net loss	(36,698,957)	(38,980,313)
Unrealized gains (losses) from available-for-sale securities, net of tax of $0	637	(10,958)
Comprehensive loss	(36,698,320)	(38,991,271)

Collaboration Revenue

Collaboration revenue totaled $3,458,331 and $1,142,605 for the years ended December 31, 2019 and 2018, respectively. This increase was due primarily to the revenue earned from the LG Chem Agreement during the year ended December 31, 2019.

General and Administrative

General and administrative expenses totaled approximately $12,740,000 and $11,295,000 for the years ended December 31, 2019 and 2018, respectively. This increase of approximately $1,445,000 was due primarily to the growth of the Company which required increased headcount and infrastructure to properly support expanded operations. We expect our general and administrative expenses to continue to increase as we further expand our operations. General and administrative expenses for the year ended December 31, 2019 included expenses related to employee and board compensation of $3,547,000, professional and consulting fees of $4,663,000, rent of $965,000, insurance of $448,000, stock-based compensation of $2,109,000, investor relations of $200,000, travel of $179,000, depreciation and amortization of $115,000, and other expenses of $514,000. General and administrative expenses for the year ended December 31, 2018 consisted of expenses related to employee and board compensation of $2,504,000, professional and consulting fees of $3,232,000, rent of $538,000, insurance of $555,000, stock-based compensation of $3,222,000, investor relations of $202,000, travel of $311,000, and other expenses of $731,000.

Research and Development

Research and development expenses totaled approximately $27,487,000 and $28,544,000 for the years ended December 31, 2019 and 2018, respectively. This decrease of approximately $1,057,000 was due primarily to a reduction in headcount, as well as, a reduction in laboratory and drug substance manufacturing costs. We expect our research and development expenses to increase as we expand our clinical development activities. Research and development expenses for the year ended December 31, 2019 included expenses related to employee and Scientific and Clinical Advisory Board compensation of $6,997,000, depreciation and amortization of $885,000, stock-based compensation of $4,412,000, research and laboratory expenses of $6,500,000, rent of $3,509,000, licensing fees of $658,000, other professional fees of $1,271,000, clinical expenses of $2,053,000, travel of $128,000, insurance expense of $234,000, and other expenses of $840,000. Research and development expenses for the year ended December 31, 2018 included expenses related to employee and Scientific and Clinical Advisory Board compensation of $5,443,000, depreciation and amortization of $725,000, stock-based compensation of $3,952,000, research and laboratory expenses of $14,061,000, rent of $2,846,000, licensing fees of $117,000, other professional fees of $834,000, and other expenses of $566,000.

Interest Income

Interest income was $418,712 for the year ended December 31, 2019, as compared to $376,008 for the year ended December 31, 2018. The increase in interest income was due to the investment of a portion of the Company's cash in cash equivalents and marketable securities during 2018 versus a full year of investment income activity during 2019.

Other Income and Expense

Other income and expense for the year ended December 31, 2019, was comprised of $64,078 of other income during the year, compared to $165,337 of other income for the year ended December 31, 2018.

Foreign Withholding Taxes

Provision for income tax for the year ended December 31, 2019, was comprised of $412,500 in foreign income tax expense on the LG Chem upfront payment, compared to the year ended December 31, 2018 comprised of $825,000.

Net Loss

As a result of the foregoing, the Company's net loss was $36,698,957 for the year ended December 31, 2019, as compared to $38,980,313 for the year ended December 31, 2018.

Liquidity and Capital Resources—December 31, 2019 and December 31, 2018

The Company has financed its working capital requirements primarily through private and public offerings of equity securities, cash received in December 2017 from Merck in connection with the Merck Agreement and cash received from LG Chem in connection with the LG Chem Agreement. At December 31, 2019 and December 31, 2018, the Company had unrestricted cash, cash equivalents and marketable securities totaling $59,409,955 and $39,212,784, respectively, available to fund the Company's ongoing business activities. Additional information concerning the Company's financial condition and results of operations is provided in the financial statements included in this report.

The amounts that the Company actually spends for any specific purpose may vary significantly and will depend on a number of factors, including, but not limited to, the Company's research and development activities and programs, clinical testing, regulatory approval, market conditions, and changes in or revisions to the Company's business strategy and technology development plans. Investors will be relying on the judgment of the Company's management regarding the application of the proceeds from the sale of the Company's common stock.

The Company believes that its existing cash resources will be sufficient to fund the Company's projected operating requirements for at least the next 12 months based on current operating plans. Until the Company is able to generate sustainable revenues that generate operating profitability and positive operating cash flows, the Company expects to finance its future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. However, there can be no assurances that the Company will be able to obtain additional financing on acceptable terms and in the amounts necessary to fully fund its future operating requirements, if at all. If the Company is unable to obtain sufficient cash resources to fund its operations, the Company may be forced to reduce or discontinue its operations entirely.

In June 2019, the Company entered into an at-the-market equity offering sales agreement with Stifel Nicolaus & Company, Inc. ("Stifel") to sell shares of the Company's common stock for aggregate gross proceeds of up to $30 million, from time to time, through an "at-the-market" equity offering program under which Stifel acted as sales agent. For the year ended December 31, 2019, the Company sold 3,584,945 common shares under the sales agreement for proceeds of approximately $29.4 million, net of commissions paid, but excluding transaction expenses and terminated this equity offering upon completion.

In November 2019, the Company entered into a second at-the-market equity offering sales agreement with Stifel to sell shares of the Company's common stock for aggregate gross proceeds of up to $20 million, from time to time, through an "at-the-market" equity offering program under which Stifel acted as sales agent. For the quarter and year ended December 31, 2019, the Company sold 1,729,110 common shares under the sales agreement for proceeds of approximately $19.6 million, net of commissions paid, but excluding transaction expenses and terminated this equity offering upon completion.

If the Company issues additional equity securities to raise funds, the ownership percentage of the Company's existing stockholders would be reduced. New investors may demand rights, preferences or privileges senior to those of existing holders of the Company's common stock. If the Company issues debt securities, the Company may be required to grant security interests in its assets, could have substantial debt service obligations, and lenders may have a senior position (compared to

stockholders) in any potential future bankruptcy or liquidation of the Company. Additionally, corporate collaboration and licensing arrangements may require us to incur non-recurring and other charges, give up certain rights relating to our intellectual property and research and development activities, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, issue debt which may require liens on our assets and which will increase our monthly expense obligations, or disrupt our management and business.

Operating Activities

During the year ended December 31, 2019, the Company used cash of approximately $30,797,000 in operating activities, as compared to $26,411,000 in operating activities during the year ended December 31, 2018. This increase of approximately $4,386,000 consisted primarily of our net loss of approximately $36,699,000, and increases of approximately $755,000 in accounts receivable, $929,000 in research and development contract liabilities and other current assets, offset by decreases of approximately $4,278,000 in operating lease liability, $1,153,000 in accounts payable, $439,000 in accrued expenses, and $487,000 in prepaid expenses, as well as non-cash charges in operating lease right of use amortization of approximately $4,355,000, depreciation of $811,000, and stock based compensation of $6,521,000. Use of cash during the year ended December 31, 2018, of approximately $26,411,000 consisted primarily of depreciation and amortization of approximately $760,000, stock-based compensation of approximately $7,174,000, and changes in operating assets and liabilities, including an increase in contract liabilities related to the recording of the upfront nonrefundable payment pursuant to the LG Chem Agreement.

Investing Activities

During the year ended December 31, 2019, the Company generated cash of approximately $3,447,000 from investing activities, compared to approximately $20,354,000 used in investing activities during the year ended December 31, 2018. The change of approximately $23,801,000 consisted primarily of approximately $18,500,000 for the redemption of short-term investments, and $127,500 cash received for the sale of lab equipment, offset by the purchase of property and equipment of approximately $46,000 and the purchase of short-term investments of $15,134,000. Compared to the use of cash during the year ended December 31, 2018, of approximately $20,354,000 which consisted primarily of approximately $1,854,000 for the purchase of office and laboratory equipment and $18,500,000, net, for the purchase and redemption of short term investments in 2018.

Financing Activities

During the year ended December 31, 2019, the Company generated cash from financing activities of approximately $50,790,000, compared to approximately $4,182,000 generated in financing activities during the year ended December 31, 2018. The increase of approximately $46,608,000 consisted primarily of cash proceeds from the common stock sold through our at-the-market sales agreements with Stifel of approximately $48,999,000, net of underwriting commissions and fees, and the exercise of common stock options of approximately $1,882,000, and restricted stock awards net of taxes withheld of $91,000. Compared to cash generated during the year ended December 31, 2018, of approximately $4,182,000, consisted of $4,169,000 in net proceeds from the November 2018 common stock private placement with LG Chem and $12,500 from the exercise of stock options in 2018.

Principal Commitments

Leased Facilities

On January 19, 2018, the Company entered into an operating lease agreement for its corporate headquarters in Cambridge, Massachusetts, with a termination date of April 2021. This lease was amended on June 18, 2019 to provide the Company with a reduction in rental fees in exchange for prepayment of a portion of the fees. The lease contains escalating payments during the lease period. The Company records monthly rent expense on a straight-line basis, equal to the total of the lease payments over the lease term divided by the number of months of the lease term.

On September 20, 2018, the Company entered into an operating lease for additional laboratory space in Cambridge, Massachusetts for the period from October 15, 2018 through April 14, 2021. The lease contains escalating payments during the lease period. The monthly rental rate under the lease agreement is $72,600 for the first 12 months and $78,600 for the remainder of the term. Upon execution of this lease agreement the Company prepaid twelve months rent pursuant to the lease agreement.

On September 16, 2019, the Company entered into an amended lease agreement that removed one holding room from the additional laboratory space lease entered into on September 20, 2018. The amendment was effective beginning on October

1, 2019 and expires on April 14, 2021. The monthly rental rate under the amended lease agreement decreased from $78,600 to $58,995, for the remainder of the lease term.

Einstein License Agreement

The Company's commitments with respect to the Einstein License are summarized above at "Significant Contracts and Agreements Related to Research and Development Activities".

Contractual Commitments and Other Commitments

The following table sets forth certain information concerning the Company's estimated fixed obligations and commitments to make future payments under existing contracts at December 31, 2019. This table excludes potential milestone and royalty payments due under our Einstein License agreements.

		Payments Due by Period			
Description	**Total**	**Less Than One Year**	**1 - 3 Years**	**3 - 5 Years**	**More Than 5 Years**
Operating lease obligations	6,037,948	4,674,540	1,363,408	—	—
Total	$ 6,037,948	$ 4,674,540	$ 1,363,408	$ —	$ —

Off-Balance Sheet Transactions

At December 31, 2019, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act, we are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

The Company's financial statements and the related notes, together with the Report of Independent Registered Public Accounting Firm thereon, are set forth beginning on page F-1 of this Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, management performed, with the participation of our principal executive and principal financial officers, an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosures. Based on the evaluation, our principal executive and principal financial officers concluded that, as of December 31, 2019, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of Treadway Commission in Internal Control- Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2019, our internal control over

financial reporting was effective based on those criteria. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include an attestation report of our registered public accounting firm due to the transition period established by the JOBS Act for emerging growth companies.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is incorporated by reference to our Definitive Proxy Statement on Schedule 14A relating to our 2020 annual meeting of stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated by reference to our Proxy Statement on Schedule 14A relating to our 2020 annual meeting of stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters.

The information required by this Item is incorporated by reference to our Proxy Statement on Schedule 14A relating to our 2020 annual meeting of stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated by reference to our Proxy Statement on Schedule 14A relating to our 2020 annual meeting of stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated by reference to our Proxy Statement on Schedule 14A relating to our 2020 annual meeting of stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Cue Biopharma, Inc. and Subsidiary

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Cue Biopharma, Inc. and Subsidiary (the Company) as of December 31, 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the year then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ RSM US LLP

We have served as the Company's auditor since 2018.

Boston, Massachusetts
March 11, 2020

CUE BIOPHARMA, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2019	**2018**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,290,030	$ 20,800,284
Marketable securities	15,119,925	18,412,500
Accounts receivable	754,898	—
Restricted cash, short term	—	50,068
Prepaid expenses and other current assets	860,107	1,347,288
Total current assets	61,024,960	40,610,140
Property and equipment, net	1,846,922	2,781,459
Operating lease right-of-use	5,337,026	—
Deposits	2,572,476	1,012,772
Restricted cash, long term	150,000	150,000
Other long term assets	673,625	808,729
Total assets	$ 71,605,009	$ 45,363,100
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 882,666	$ 2,035,354
Accrued expenses	2,227,352	1,788,062
Research and development contract liability, current portion	4,097,443	2,011,998
Deferred rent	—	381,465
Operating lease liability, current portion	4,447,787	—
Total current liabilities	11,655,248	6,216,879
Research and development contract liability, net of current portion	4,017,894	5,174,752
Operating lease liability, net of current portion	1,347,971	—
Total liabilities	17,021,113	11,391,631
Stockholders' equity:		
Preferred stock, $0.001 par value, authorized – 10,000,000 shares; issued and outstanding – none	—	—
Common stock, $0.001 par value; authorized – 50,000,000 shares; issued and outstanding – 26,562,178 shares and 20,697,453 shares at December 31, 2019 and 2018, respectively	26,562	20,697
Additional paid in capital	163,067,773	105,762,891
Accumulated other comprehensive loss	(10,321)	(10,958)
Accumulated deficit	(108,500,118)	(71,801,161)
Total stockholders' equity	54,583,896	33,971,469
Total liabilities and stockholders' equity	$ 71,605,009	$ 45,363,100

See accompanying notes to consolidated financial statements.

CUE BIOPHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years Ended December 31,	
	2019	**2018**
Collaboration revenue	$ 3,458,331	$ 1,142,604
Operating expenses:		
General and administrative	12,740,093	11,295,211
Research and development	27,487,485	28,544,051
Total operating expenses	40,227,578	39,839,262
Loss from operations	(36,769,247)	(38,696,658)
Other income:		
Interest income	418,712	376,008
Other income, net	64,078	165,337
Total other income	482,790	541,345
Loss before provision for income taxes	$ (36,286,457)	$ (38,155,313)
Provision for income taxes	(412,500)	(825,000)
Net loss	(36,698,957)	(38,980,313)
Unrealized gain (losses) from available-for-sale securities, net of tax of $0	637	(10,958)
Comprehensive loss	$ (36,698,320)	$ (38,991,271)
Net loss per common share – basic and diluted	$ (1.66)	$ (1.94)
Weighted average common shares outstanding – basic and diluted	22,041,792	20,134,065

See accompanying notes to consolidated financial statements.

CUE BIOPHARMA, INC.

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
Years Ended December 31, 2019 and 2018

	Common Stock		Common Stock to be Issued		Additional	Accumulated Other		Total
	Shares	Par Value	Shares	Par Value	Paid-in Capital	Comprehensive Income (Loss)	Accumulated Deficit	Stockholders' Equity
Balance, December 31, 2017	19,459,194	19,460	671,572	671	94,407,895	—	(32,820,848)	61,607,178
Common stock issued'	1,235,759	1,235	(671,572)	(671)	4,168,785	—	—	4,169,349
Stock-based compensation	—	—	—	—	7,173,713	—	—	7,173,713
Exercise of stock options	2,500	2	—	—	12,498	—	—	12,500
Other comprehensive income (loss)	—	—	—	—	—	(10,958)	—	(10,958)
Net loss	—	—	—	—	—	—	(38,980,313)	(38,980,313)
Balance, December 31, 2018	20,697,453	20,697	—	—	105,762,891	(10,958)	(71,801,161)	33,971,469
Issuance of common stock from public offerings, net of underwriter commissions and fees	5,314,055	5,314	—	—	48,993,593	—	—	48,998,907
Stock-based compensation	—	—	—	—	6,520,982	—	—	6,520,982
Exercise of stock options	485,105	485	—	—	1,881,388	—	—	1,881,873
Issuance of common stock upon cashless exercise of warrants, net of shares withheld	44,319	45	—	—	(45)	—	—	—
Restricted stock awards	33,333	33	—	—	(21)	—	—	12
Repurchase of restricted stock awards	(12,087)	(12)	—	—	(91,015)	—	—	(91,027)
Other comprehensive income (loss)	—	—	—	—	—	637	—	637
Net loss	—	—	—	—	—	—	(36,698,957)	(36,698,957)
Balance, December 31, 2019	26,562,178	$ 26,562	—	$ —	$ 163,067,773	$ (10,321)	$ (108,500,118)	$ 54,583,896

See accompanying notes to consolidated financial statements.

CUE BIOPHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (36,698,957)	$ (38,980,313)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	810,782	760,011
Deferred rent	—	345,101
Stock-based compensation	6,520,982	7,173,713
Operating lease right of use amortization	4,354,810	—
Loss on disposal of fixed asset	54,274	3,315
Non-cash investment income	(72,464)	76,544
Changes in operating assets and liabilities:		
Account receivable	(754,898)	—
Prepaid expenses and other current assets	487,182	(701,939)
Other assets	123,437	—
Operating lease liability	(4,277,544)	—
Deposits	(1,559,704)	(787,272)
Accounts payable	(1,152,688)	376,147
Accrued expenses	439,290	636,975
Research and development contract liability	928,588	4,686,750
Net cash used in operating activities	(30,796,910)	(26,410,968)
Cash flows from investing activities:		
Purchases of property and equipment	(46,353)	(1,854,246)
Redemption of short term investments	18,500,000	21,000,000
Purchase of short term investments	(15,134,324)	(39,500,000)
Cash received from sale of fixed asset	127,500	—
Net cash provided by/(used in) investing activities	3,446,823	(20,354,246)
Cash flows from financing activities:		
Proceeds from private placements of common stock	48,998,907	4,169,349
Issuance of restricted stock awards	12	—
Restricted stock repurchase at vesting to cover taxes	(91,027)	
Proceeds from the exercise of stock options	1,881,873	12,500
Net cash provided by financing activities	50,789,765	4,181,849
Net increase/(decrease) in cash, cash equivalents, and restricted cash	23,439,678	(42,583,365)
Cash, cash equivalents, and restricted cash at beginning of period	21,000,352	63,583,717
Cash, cash equivalents, and restricted cash at end of period	$ 44,440,030	$ 21,000,352
Supplemental disclosures of cash flow information:		
Cash paid for –		
Interest	$ —	$ —
Income taxes	$ (412,500)	$ (825,000)

See accompanying notes to consolidated financial statements.

1. Organization and Basis of Presentation

Cue Biopharma, Inc. (the "Company") was incorporated in the State of Delaware on December 31, 2014 under the name Imagen Biopharma, Inc., and completed its organization, formation and initial capitalization activities effective as of January 1, 2015. In October 2016, the Company changed its name to Cue Biopharma, Inc. The Company's corporate office and research facilities are located in Cambridge, Massachusetts.

The Company is a clinical biopharmaceutical company that is developing a novel and proprietary class of biologic drugs for the selective modulation of the human immune system to treat a broad range of cancers, chronic infectious diseases, and autoimmune disorders.

The Company is in the development stage and has incurred recurring losses and negative cash flows from operations. As of December 31, 2019, the Company had unrestricted cash, cash equivalents and marketable securities of approximately $59,409,955. Management believes that current cash, cash equivalents and marketable securities on hand at December 31, 2019 are sufficient to fund operations for at least the next twelve months from the date of issuance of these financial statements; however, the future viability of the Company is dependent on its ability to raise additional capital to finance its operations and to fund increased research and development costs in order to seek approval for commercialization of its product candidates. The Company's failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies as this capital is necessary for the Company to perform the research and development activities required to develop the Company's product candidates in order to generate future revenue streams.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements for the years ended December 31, 2019 and 2018, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC") and Generally Accepted Accounting Principles in the United States ("U.S. GAAP") for financial information, which prescribes elimination of all significant intercompany accounts and transactions in the accounts of the Company and its wholly owned subsidiary Cue Biopharma Securities Corporation, Inc. which was formed in December 2018 and incorporated in the Commonwealth of Massachusetts. In the opinion of management, these financial statements reflect all adjustments which are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented.

Public Offerings

In June 2019, the Company entered into an at-the-market equity offering sales agreement with Stifel Nicolaus & Company, Inc. ("Stifel") to sell shares of the Company's common stock for aggregate gross proceeds of up to $30 million, from time to time, through an "at-the-market" equity offering program under which Stifel acted as sales agent. For the year ended December 31, 2019, the Company sold 3,584,945 common shares under the sales agreement for proceeds of approximately $29.4 million, net of commissions paid, but excluding transaction expenses, and terminated this equity offering upon completion.

In November 2019, the Company entered into a second at-the-market equity offering sales agreement with Stifel to sell shares of the Company's common stock for aggregate gross proceeds of up to $20 million, from time to time, through an "at-the-market" equity offering program under which Stifel acted as sales agent. For the quarter and year ended December 31, 2019, the Company had sold 1,729,110 common shares under the sales agreement for proceeds of approximately $19.6 million, net of commissions paid, but excluding estimated transaction expenses, and terminated this equity offering upon completion.

Consolidation

The accompanying consolidated financial statements include the Company and its wholly-owned subsidiary, Cue Biopharma Securities Corporation, Inc. The Company has eliminated all intercompany transactions for the years presented.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates include estimates related to revenue, the accounting for potential liabilities and accrued expenses, the assumptions utilized in valuing stock-based compensation issued for services, the realization of deferred tax assets, and the useful life with respect to long-lived assets and intangibles. Actual results could differ from those estimates.

Cash Concentrations

The Company maintains its cash balances with a financial institution in Federally-insured accounts and may periodically have cash balances in excess of insurance limits. The Company maintains its accounts with a financial institution with a high credit rating. The Company has not experienced any losses to date and believes that it is not exposed to any significant credit risk on cash.

Cash and Cash Equivalents

The Company considers all liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents. The Company currently invests available cash in money market funds.

Marketable Securities

Marketable securities consist of investments with original maturities greater than ninety days and less than one year from the balance sheet date. The Company classifies all of its investments as available-for-sale securities. Accordingly, these investments are recorded at fair value, which is based on quoted market prices. Unrealized gains are recognized and are included in other comprehensive income (loss). Realized gains are recognized and determined on a specific identification basis and are included in other income (loss) on the income statement. Amortization and accretion of discounts and premiums is recorded in interest income. The Company currently invests in United States Treasury obligations.

Restricted Cash

The Company purchased a $50,000 certificate of deposit to collateralize a credit card account with a commercial bank that was classified as short-term certificate of deposit as of December 31, 2018. As of December 31, 2019, the account was closed, resulting in a $0 balance in short-term restricted cash. As of December 31, 2019 and 2018, the Company also had $150,000 in restricted cash with a commercial bank to collateralize a credit card.

Property and Equipment

Property and equipment is recorded at cost. Major improvements are capitalized, while maintenance and repairs are charged to expense as incurred. Gains and losses from disposition of property and equipment are included in income and expense when realized. Amortization of leasehold improvements is provided using the straight-line method over the shorter of the lease term or the useful life of the underlying assets. Depreciation of property and equipment is provided using the straight-line method over the following estimated useful lives:

Laboratory equipment	5 years
Computer equipment	3 years
Furniture and fixtures	3-8 years

The Company recognizes depreciation and amortization expense in general and administrative expenses and in research and development expenses in the Company’s statements of operations, depending on how each category of property and equipment is utilized in the Company’s business activities.

Trademark

Trademark consists of the Company’s right, title and interest in and to the CUE BIOLOGICS Mark, and any derivative mark incorporating CUE, throughout the world, together with all associated goodwill and common law rights appurtenant thereto, including, but not limited to, any right, title and interest in any corporate name, company name, business name, trade name, dba, domain name, or other source identifier incorporating CUE.

As the Company can renew the underlying rights to the CUE BIOLOGICS Mark indefinitely at nominal cost, this acquired intangible asset has been classified as a component of other long term assets, having a useful life of 14 years at December 31, 2019. The Company recorded $11,668 in amortization related to the trademark at December 31, 2019.

Revenue Recognition

The Company adopted Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), during 2018. The Company generates revenue solely through collaboration arrangements with strategic partners for the development and commercialization of product candidates. The core principle of ASC 606 is that an entity should recognize revenue to depict the transfer of promised goods and/or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and/or services. To determine the appropriate amount of revenue to be recognized for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following steps: (i) Identify the contract(s) with the customer, (ii) Identify the performance obligations in the contract, (iii) Determine the transaction price, (iv) Allocate the transaction price to the performance obligations in the contract and (v) Recognize revenue when (or as) each performance obligation is satisfied.

The Company recognizes collaboration revenue under certain of the Company's license or collaboration agreements that are within the scope of ASC 606. The Company's contracts with customers typically include promises related to licenses to intellectual property and research and development services. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and variable consideration in the form of milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the "most likely amount" method to estimate the amount of variable consideration, to predict the amount of consideration to which it will be entitled for its one open contract. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes development and regulatory milestone payments, the Company evaluates whether the associated event is considered probable of achievement and estimates the amount to be included in the transaction price using the most likely amount method. Currently, the Company has one contract with an option to acquire additional goods and/or services in the form of additional research and development services for additional product candidates which it evaluated and determined that it was not a material right related to the LG Chem agreement.

Research and Development Expenses

Research and development expenses consist primarily of compensation costs, fees paid to consultants, outside service providers and organizations (including research institutes at universities), facility costs, and development and clinical trial costs with respect to the Company's product candidates.

Research and development expenses incurred under contracts are expensed ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different pattern of performance is more appropriate. Other research and development expenses are charged to operations as incurred.

Nonrefundable advance payments are recognized as an expense as the related services are performed. The Company evaluates whether it expects the services to be rendered at each quarter end and year end reporting date. If the Company does not expect the services to be rendered, the advance payment is charged to expense. Nonrefundable advance payments for research and development services are included in prepaid and other current assets on the balance sheet. To the extent that a nonrefundable advance payment is for contracted services to be performed within 12 months from the reporting date, such advance is included in current assets; otherwise, such advance is included in non-current assets.

The Company evaluates the status of its research and development agreements and contracts, and the carrying amount of the related assets and liabilities, at each quarter end and year end reporting date, and adjusts the carrying amounts and their classification on the balance sheet as appropriate.

Patent Expenses

The Company is the exclusive worldwide licensee of, and has patent applications pending for, numerous domestic and foreign patents. Due to the significant uncertainty associated with the successful development of one or more commercially viable product candidates based on the Company's research efforts and any related patent applications, all patent costs, including patent-related legal fees, filing fees and other costs are charged to operations as incurred. For the years ended December 31, 2019 and 2018, patent expenses were $1,934,000 and $1,222,000, respectively. Patent expenses are included in general and administrative expenses in the Company's statement of operations.

Licensing Fees and Costs

Licensing fees and costs consist primarily of costs relating to the acquisition of the Company's license agreement with Einstein, including related royalties, maintenance fees, milestone payments and product development costs. Licensing fees and costs are charged to operations as incurred.

Long-Lived Assets

The Company reviews long-lived assets, consisting of property and equipment and a trademark, for impairment at each fiscal year end or when events or changes in circumstances indicate the carrying value of these assets may exceed their current fair values. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the assets. Assets to be disposed of are separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The Company has not historically recorded any impairment to its long-lived assets. In the future, if events or market conditions affect the estimated fair value to the extent that a long-lived asset is impaired, the Company will adjust the carrying value of these long-lived assets in the period in which the impairment occurs. During the year ended December 31, 2019, the Company sold lab equipment with a net book value of approximately $181,000 that was being decommissioned and recognized a loss of approximately $54,000. During the year ended December 31, 2018, the Company disposed of equipment totaling approximately $58,000, resulting in a loss of $3,315.

Leases

In February 2016, the FASB issued ASU 2016-02, Leases (ASC 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, for most lease arrangements on the balance sheet. Under the standard, disclosure of key information about leasing arrangements to assist users of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases are required. The new standard is effective for fiscal years beginning after December 15, 2018.

The standard permits two transition methods, (1) to apply the new lease requirements at the beginning of the earliest period presented, or (2) to apply the new lease requirements at the effective date. The Company adopted ASC 842 as of January 1, 2019 using the effective date method, in which we did not restate prior periods. Upon adoption, the Company elected the package of practical expedients permitted under the transition guidance within ASC 842, which among other things, allowed it to carry forward the historical lease classification.

The adoption of ASC 842 on January 1, 2019 resulted in the recognition of approximately $ 9,692,000 of right-of-use asset and $9,347,000 of lease liabilities on the Company's balance sheet. The adoption did not have a material net impact on the Company's consolidated statements of operations or accumulated deficit. Please refer to Note 14 for more detail.

Stock-Based Compensation

The Company periodically issues stock based awards to officers, directors, employees, Scientific and Clinical Advisory Board members, non-employees and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date.

Stock-based payments to officers, directors, members of the Company's Scientific and Clinical Advisory Board, non-employees and outside consultants and employees, including grants of employee stock options, are recognized in the financial statements based on their grant date fair values. Stock option grants, which are generally time-vested, are measured at the grant date fair value and charged to operations on a straight-line basis over the service period, which generally approximates the vesting term. The Company also grants performance-based awards to periodically to officers of the Company. The Company recognizes compensation costs related to performance awards over the requisite service period if and when the Company concludes that it is probable that the performance condition will be achieved.

The fair value of stock options and restricted stock units is determined utilizing the Black-Scholes option-pricing model, which is affected by several variables, including the risk-free interest rate, the expected dividend yield, the life of the equity award, the exercise price of the stock option as compared to the fair value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award.

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. Until the Company has established a trading history for its common stock that approximates the expected term of the options, estimated volatility is based on the average historical volatilities of comparable public companies in a similar industry. The expected dividend yield is based on the current yield at the grant date; the Company has never declared or paid dividends and has no plans to do so for the foreseeable future. As permitted by Staff Accounting Bulletin No. 107, due to the Company's limited trading history and option activity, management utilizes the simplified method to estimate the expected term of options at the date of grant. The exercise price is determined based on the fair value of the Company's common stock at the date of grant. The Company accounts for forfeitures as they occur.

The Company recognizes the fair value of stock-based compensation in general and administrative expenses and in research and development expenses in the Company's statements of operations, depending on the type of services provided by the recipient of the equity award.

Income Taxes

The Company accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by U.S. GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

The Company is subject to U.S. Federal and Massachusetts state income taxes. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal and state taxing authorities in which the Company currently operates.

The Company recognized approximately, $412,500 and $825,000, of income tax expense related to the foreign taxes withheld from the LG Chem upfront payment received during the year ended December 31, 2019 and 2018, respectively.

The Company recognizes interest accrued relative to unrecognized tax benefits in interest expense and penalties in operating expense. During the years ended December 31, 2019 and 2018, the Company did not recognize any income tax related interest and penalties. The Company did not have any accruals for income tax related interest and penalties at December 31, 2019 and 2018.

Comprehensive Income (Loss)

Components of comprehensive income or loss, including net income or loss, are reported in the financial statements in the period in which they are recognized. Other comprehensive income or loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss) are reported net of any related tax effect to arrive at comprehensive income (loss). Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. The Company's only element of other comprehensive loss in all periods presented, other than its net loss, was unrealized loss on available-for-sale securities.

Earnings (Loss) Per Share

The Company's computation of earnings (loss) per share ("EPS") for the respective periods includes basic and diluted EPS. Basic EPS is measured as the income (loss) attributable to common stockholders divided by the weighted average number of common shares outstanding for the period. Diluted EPS is similar to basic EPS but presents the dilutive effect on a per share basis of potential common shares that would result from the exercise of outstanding stock options and warrants as if they had been exercised at the beginning of the periods presented, or issuance date, if later. Potential common shares that have an anti-dilutive effect (i.e., those that increase income per share or decrease loss per share) are excluded from the calculation of diluted EPS. Basic and diluted loss per common share is the same for all periods presented because all outstanding stock options and warrants are anti-dilutive.

At December 31, 2019 and 2018, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	December 31,	
	2019	**2018**
Common stock warrants	1,189,827	1,252,441
Common stock options	4,859,920	4,540,321
Total	6,049,747	5,792,762

Fair Value of Financial Instruments

The authoritative guidance with respect to fair value established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active-exchange traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently-traded non-exchange-based derivatives and commingled investment funds and are measured using present value pricing models.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

The Company had $39,303,609 in cash equivalents and $15,119,925 in short-term marketable securities that were measured and recorded at fair value on the Company's balance sheet at December 31, 2019. The Company had $10,547,628 in cash equivalents and $18,412,500 in short-term marketable securities that were measured and recorded at fair value on the Company's balance sheet at December 31, 2018.

The carrying value of financial instruments (consisting of cash, a certificate of deposit, accounts payable, accrued compensation and accrued expenses) is considered to be representative of their respective fair values due to the short-term nature of those instruments.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments, on the balance sheet for all leases with terms longer than 12 months, as well as the disclosure of key information about leasing arrangements. ASU 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures

are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. We elected to adopt the package of practical expedients, which among other things, allows us to carry forward the historical lease classification and combine lease and non-lease components as a single component. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company adopted the provisions of ASU 2016-02 on January 1, 2019 which resulted in a recognition of a right of use asset of approximately $9,692,000 and lease liability of approximately $9,347,000. There was no cumulative adjustment to retained earnings as a result of this adoption. This adoption resulted in a balance sheet presentation that is not be comparable to the prior period in the first year of adoption. For the year ended December 31, 2019, the Company recorded a right of use asset of approximately $5,337,000 and lease liability of approximately $5,796,000. The change in the right of use asset and lease liability is due to rental expense of approximately $4,473,800, recorded for the year ended December 31, 2019.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments- Credit Losses: Measurement of Credit Losses on Financial Instruments (Topic 326) (CECL). The new standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. The new standard is effective for annual reporting periods beginning after December 15, 2022, including interim reporting periods within each annual reporting period for smaller reporting companies. The Company is still evaluating the impact of ASU 2016-13 on the Company's consolidated financial statements; however, it does not expect the impact to be material.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income. This ASU relates to the impacts of the tax legislation commonly referred to as the Tax Reform Act. The guidance permits the reclassification of certain income tax effects of the Tax Reform Act from other comprehensive income to retained earnings (stranded tax effects). The guidance also requires certain new disclosures. The guidance was effective for annual periods beginning after December 15, 2018, and interim periods within those reporting periods. Early adoption was permitted. Entities may adopt the guidance using 1 of 2 transition methods: retrospective to each period (or periods) in which the income tax effects of the Tax Reform Act related to the items remaining in other comprehensive income are recognized or at the beginning of the period of adoption. We adopted ASU No. 2018-02 on January 1, 2019 and it did not have a material effect on our financial position, results of operations or disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, or ASU 2018-03. The guidance in this ASU modify the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. Under the new guidance, transfers between asset classes and the valuation related to level 3 assets is modified. The new standard is effective for annual reporting periods beginning after December 15, 2019, including interim reporting periods within each annual reporting period. The Company is currently evaluating the impact of the adoption of this ASU on the financial statements.

In July 2019, the FASB issued ASU No. 2019-07, Codification Updates to SEC Sections. This ASU amends various SEC paragraphs pursuant to the issuance of SEC Final Rule Releases No. 33-10532, Disclosure Update and Simplification, and Nos. 33-10231 and 33-10442, Investment Company Reporting Modernization. One of the changes in the ASU requires a presentation of changes in stockholders' equity in the form of a reconciliation, either as a separate financial statement or in the notes to the financial statements, for the current and comparative year-to-date interim periods. We presented changes in stockholders' equity as separate financial statements for the current and comparative year-to-date periods. The additional elements of the ASU did not have a material impact on our consolidated financial statements. This guidance was effective immediately upon issuance.

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes," which is intended to simplify various aspects related to accounting for income taxes. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. ASU No. 2019-12 is effective for us beginning in fiscal 2021. We are currently in the process of evaluating the effects of this pronouncement on our financial statements.

Management does not believe that any other recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statement presentation or disclosures.

3. Fair Value

The Company accounts for its financial assets and liabilities using fair value measurements. The authoritative accounting guidance defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The following table presents information about the Company's assets that are measured at fair value on a recurring basis as of December 31, 2019 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of December 31, 2019			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 39,303,609	$ —	$ —	$ 39,303,609
Marketable securities	—	15,119,925	—	15,119,925
Total	$ 39,303,609	$ 15,119,925	$ —	$ 54,423,534

	Fair Value Measurements as of December 31, 2018			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 10,547,628	$ —	$ —	$ 10,547,628
Marketable securities	—	18,412,500	—	18,412,500
Total	$ 10,547,628	$ 18,412,500	$ —	$ 28,960,128

As of December 31, 2019, the Company's cash equivalents that are invested in money market funds valued using Level 1 inputs for identical securities. The Company measures the fair value of marketable securities that are invested in United States Treasury securities using Level 2 inputs and primarily relies on quoted prices in active markets for similar marketable securities. During the year ended December 31, 2019 and 2018, there were no transfers between Level 2 and Level 3.

4. Marketable Securities

As of December 31, 2019, and 2018, the fair value of available-for-sale marketable securities by type of security was as follows:

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury Securities	$ 15,130,246	$ —	$ (10,321)	$ 15,119,925
	$ 15,130,246	$ —	$ (10,321)	$ 15,119,925

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury Securities	$ 18,423,458	$ —	$ (10,958)	$ 18,412,500
	$ 18,423,458	$ —	$ (10,958)	$ 18,412,500

At December 31, 2019, marketable securities consisted of $15,119,925 of investments that mature within twelve months. The Company recorded an unrealized gain on investments of $637 for the year ended December 31, 2019. At

December 31, 2018, the Company marketable securities consisted of $18,412,500 of investments that mature within twelve months. The Company recognized a loss on investments of $612 for the year ended December 31, 2018.

5. Property and Equipment

Property and equipment as of December 31, 2019 and 2018 is summarized as follows:

	December 31,	
	2019	2018
Laboratory equipment	$ 3,587,559	$ 3,872,233
Furniture and fixtures	93,321	93,321
Computer equipment	192,092	181,844
Leasehold improvements	—	—
	3,872,972	4,147,398
Less accumulated depreciation and amortization	(2,026,050)	(1,365,939)
Net property and equipment	$ 1,846,922	$ 2,781,459

Depreciation expense for the years ended December 31, 2019 and 2018 was included in the statement of operations as follows, excluding trademark amortization:

	Years Ended December 31,	
	2019	2018
General and administrative	$ 60,974	$ 35,287
Research and development	738,140	724,724
Total	$ 799,114	$ 760,011

During the year ended December 31, 2019, the Company sold lab equipment with an acquisition cost of $320,778 and accumulated depreciation of $139,003, and realized a loss of $54,274.

6. Accrued Expenses

Accrued expenses as of December 31, 2019 and 2018 is summarized as follows:

	December 31,	
	2019	2018
Accrued compensation	$ 1,575,821	$ 1,195,749
Contract manufacturing services	150,250	160,650
Professional Services	383,910	207,440
Contract research services	117,371	145,035
Other expenses	—	79,188
	$ 2,227,352	$ 1,788,062

7. Einstein License and Service Agreement

License Agreement

On January 14, 2015, the Company entered into a license agreement, as amended on June 2, 2015 (the “Einstein License”), with Einstein for certain patent rights (the “Patents”) relating to the Company’s core technology platform for the engineering of biologics to control T-cell activity, precision, immune-modulatory drug candidates, and two supporting technologies that enable the discovery of costimulatory signaling molecules (ligands) and T-cell targeting peptides. On July 31, 2017, the Company entered into an amended and restated license agreement which modified certain obligations of the parties under the Einstein License.

Under the Einstein License, the Company holds an exclusive worldwide license, with the right to sublicense, import, make, have made, use, provide, offer to sell, and sell all products, processes and services that use the Patents, including certain technology received from Einstein relating thereto (the "Licensed Products"). Under the Einstein License, the Company is required to:

- Pay royalties based on certain percentage of proceeds, as defined in the Einstein License, from sales of Licensed Products, including sublicense agreements.

- Pay escalating annual maintenance fees as follows: $25,000 on January 14, 2017; $50,000 on each of January 14, 2018 and 2019; $75,000 on each of January 14, 2020 and 2021; and $100,000 on January 14, 2022 and each year thereafter. Annual maintenance fees are nonrefundable but are creditable against the amount due to Einstein for royalties during the 12 month period following each of the due dates for annual maintenance fees.

- Make significant payments up to $5,000,000 based upon the achievement of certain milestones, as defined in the Einstein License. Payments made upon achievement of milestones are nonrefundable and are not creditable against any other payment due to Einstein. At December 31, 2019, none of these milestones had been achieved by the Company.

- Incur a minimum of $250,000 per year of product development costs until the first commercial sale of the first licensed product.

The Company was in compliance with its obligations under the Einstein License at December 31, 2019 and 2018.

The Einstein License expires upon the expiration of the Company's last obligation to make royalty payments to Einstein which may be due with respect to certain Licensed Products, unless terminated earlier under the provisions thereof. The Einstein License includes certain termination provisions if the Company fails to meet its obligations thereunder.

The Einstein License required the Company to issue to Einstein a specified number of shares of common stock of the Company on a fully diluted, as converted basis, depending on the achievement of (1) a funding threshold and (2) a liquidity event, each as defined in the Einstein License. The funding threshold was achieved through the completion of the June 15, 2015 private placement as described in Note 11. The Company's initial public offering in December 27, 2017 met the definition of a liquidity event as defined by the agreement and therefore the Company issued 671,572 shares of the Company's common stock.

The Company accounted for the issuance of these shares as a charge to research and development expenses in the statement of operations at their aggregate fair value of $5,036,789 on the date of issuance, in accordance with ASC 730, Research and Development, as the Patents acquired from Einstein are for use in the Company's research and development activities exclusively with respect to its core technology platform and have no alternative future use by the Company, and therefore no separate economic value. The shares issuable in connection with Einstein License were recorded as common stock to be issued at December 31, 2017 and were issued on January 9, 2018.

The Company accounts for the costs incurred in connection with the Einstein License in accordance with ASC 730, Research and Development. For the years ended December 31, 2019 and 2018, costs incurred with respect to the Einstein License aggregated $565,659 and $487,929, respectively. For the years ended December 31, 2019 and 2018, $50,000 and $50,000 were included in research and development expenses in the statements of operations. For the year ended December 31, 2019, the Company capitalized $525,554 in costs incurred with respect to the Einstein License pursuant to ASC 606 and ASC 340. The Company recorded $265,262 and $260,292 in prepaid expenses and other current assets and other long term assets, respectively. For the year ended December 31, 2018, the Company capitalized costs of $437,929.

8. Stock-Based Compensation

Effective March 23, 2016, the Company adopted the 2016 Omnibus Incentive Plan (the "Omnibus Plan") and the 2016 Non-Employee Equity Incentive Plan (the "Non-Employee Plan"), which are intended to allow the Company to compensate and retain the services of key employees, non-employees, Scientific and Clinical Advisory Board members, and outside advisors and consultants. The plans are under the administration of the Company's Board of Directors. Under the plans, the Company, at its discretion, may grant stock option awards to certain employees and non-employees through March 23, 2026. The Omnibus Plan and the Non-Employee Plan provide for the grant of a total of 2,000,000 shares of common stock and 500,000 shares of common stock, respectively.

On August 13, 2017, the Company's Board of Directors approved an amendment and restatement of the Company's 2016 Omnibus Incentive Plan to increase the number of shares authorized for issuance under such plan by 800,000 shares,

from 2,000,000 shares to 2,800,000 shares, subject to stockholder approval of such amendment within 12 months following board approval thereof. The Company's stockholders approved the plan in December 2017. Additionally, on May 17, 2019, the Company's Board of Directors approved Amendment No. 1 to the 2016 Omnibus Incentive Plan to increase the number of shares that may be issued as incentive stock options under the plan, which the Company's stockholders approved on August 6, 2019. The 2016 Omnibus Incentive Plan, as amended and restated, provides that on the first day of each fiscal year of the Company during the period beginning in fiscal year 2018 and ending on the second day of fiscal year 2027, the number of shares of common stock authorized to be issued under such plan shall be increased by an amount equal to the lesser of (i) the number of shares necessary such that the aggregate number of shares available to be issued under the plan equals 20% of the number of fully diluted outstanding shares on such date (assuming the conversion of all outstanding shares of preferred stock and other outstanding convertible securities and exercise of all outstanding options and warrants to purchase shares) and (ii) an amount to be determined by the Company's Board of Directors.

Pursuant to the plans, during the year ended December 31, 2019, the Company granted stock options to purchase 1,288,100 shares of the Company's common stock and 100,000 restricted stock units. At December 31, 2019, stock options for 4,378,320 shares of common stock and 100,000 restricted stock units had been granted and 459,705 shares of common stock were reserved for future grants under the Omnibus Plan, and stock options for 481,600 shares of common stock had been granted and 5,400 shares of common stock were reserved for future grants under the Non-Employee Plan. In the aggregate, at December 31, 2019, stock options for a total of 4,859,920 shares of common stock and 100,000 restricted stock units had been granted and 465,105 shares of common stock were reserved for future grants. Such grants are accounted for as share-based compensation in accordance with ASC 718, Compensation - Stock Compensation, and ASC 505-50, Equity-Based Payments to Non-Employees.

Stock Option Valuation

For stock options requiring an assessment of value during the years ended December 31, 2019 and 2018, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model utilizing the following assumptions:

	December 31,	
	2019	**2018**
Risk-free interest rate	1.75 to 2.58%	2.43 to 2.95%
Expected dividend yield	0%	0%
Expected volatility	88.0-94.0%	82.0-83.6%
Expected life	4.0 to 6.25 years	4.0 to 7.0 years

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected term of the stock option award; as permitted by Staff Accounting Bulletin 107, due to insufficient history of stock option activity, management has utilized the simplified approach to estimate the expected term of the stock options, which represents the period of time that stock options granted are expected to be outstanding; the expected volatility is based upon historical volatilities of comparable companies in a similar industry; and the expected dividend yield based upon the Company's current dividend rate and future expectations.

A summary of stock option activity for the years ended December 31, 2019 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2017	2,732,221	$ 4.07	5.76
Granted	1,835,600	11.33	
Exercised	(2,500)	5.00	
Cancelled	(25,000)	7.79	
Stock options outstanding at December 31, 2018	4,540,321	$ 7.08	5.16
Granted	1,288,100		
Exercised	(485,105)		
Cancelled	(550,063)		
Stock options outstanding at December 31, 2019	4,793,253	$ 7.10	5.64
Stock options exercisable at December 31, 2019	2,025,858	$ 6.26	4.47

The Company recognized, $6,208,949 and $7,173,713, in stock-based compensation during the years ended December 31, 2019 and 2018, respectively related to stock option activity. As of December 31, 2019, total unrecognized stock-based compensation was approximately $12,211,819, which is expected to be recognized as an operating expense in the Company's statement of operations through June 2022.

The aggregate intrinsic value of exercisable but unexercised in-the-money stock options at December 31, 2019 was approximately $19,471,155 based on a fair value average exercise price of $6.26 per share. The aggregate intrinsic value of options is calculated as the difference of the market close price of $15.88 on December 31, 2019, and the weighted average exercise price of $6.26, with a weighted average remaining contractual term of 4.47 years.

The aggregate intrinsic value of exercisable but unexercised in-the-money stock options at December 31, 2018 was approximately $1,682,014, based on a fair value exercise price of $4.70 per share at December 31, 2018.

Restricted Stock Units

On October 3, 2019, the Company granted 100,000 restricted stock units ("RSUs") with time-based vesting conditions to certain executives. During the year ended December 31, 2019, the Company awarded 100,000 RSUs at an average grant date fair value of $7.53 per share. The RSUs vest in three substantially equal installments beginning on grant date, and annually thereafter. Compensation expense is recognized on a straight-line basis.

The following table summarizes the RSU activity for the under the 2016 Omnibus Incentive Plan for the years ending December 31, 2019 and 2018:

Restricted Securities	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested balance as of December 31, 2018	—	$ —
Granted	100,000	7.53
Vested/Released	(33,333)	7.53
Forfeited	—	—
Nonvested balance at December 31, 2019	66,667	$ 7.53

The Company recognized, $312,032 and $0, in stock-based compensation during the years ended December 31, 2019 and 2018, respectively related to stock option activity. As of December 31, 2019, total unrecognized stock-based compensation was approximately $440,967, which is expected to be recognized as an operating expense in the Company's statement of operations through June 2022.

Stock-based Compensation

Stock-based compensation for the years ended December 31, 2019 and 2018 was included in the statement of operations as follows:

	December 31,	
	2019	2018
General and administrative	$ 2,109,335	$ 3,221,512
Research and development	4,411,647	3,952,201
Total	$ 6,520,982	$ 7,173,713

9. Warrants

The Company has two tranches of common stock warrants outstanding at December 31, 2019. The first tranche is exercisable for 370,370 shares of common stock issued on June 15, 2015 with an exercise price of $2.70 per share. These warrants were issued with a 7 year life and expire on June 15, 2022. For the year ended December 31, 2019, 48,111 of common stock warrants were exercised via a cashless exercise for which 37,601 shares of common stock were issued, 10,510 shares were withheld and returned for reuse, leaving 322,259 shares remaining to be issued upon exercise of such warrants. The second tranche is exercisable for 882,071 shares of common stock issued on December 27, 2017 with an exercise price of $9.38 per share. These warrants were issued with a 5 year life and expire on December 26, 2022. For the year ended December 31, 2019, 14,503 common stock warrants were exercised via cashless exercise for which 6,718 shares of common stock were issued, 7,785 shares were withheld and returned for reuse, leaving 867,568 shares remaining to be issued upon exercise of the warrants. The intrinsic value of exercisable but unexercised in-the-money common stock warrants at December 31, 2019 was approximately $9,890,900 based on a fair value of $15.88 per share on December 31, 2019.

Each tranche of warrants was evaluated under ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*, and the Company determined that equity classification was appropriate.

10. Revenue Recognition

The Company recognizes collaboration revenue under certain of the Company's license or collaboration agreements that are within the scope of ASC 606. The Company's contracts with customers typically include promises related to licenses to intellectual property and research and development services. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company's contracts may include options to acquire additional goods and/or services.

The terms of the Company's arrangements with customers typically include the payment of one or more of the following: (i) Non-refundable, up-front payment, (ii) Development, regulatory and commercial milestone payments, (iii) Future options and (iv) Royalties on net sales of licensed products. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and variable consideration in the form of milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the "most likely amount" method to estimate the amount of variable consideration, to predict the amount of consideration to which it will be entitled for its one open contract. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Milestone payments that are not within the control of the Company or the licensee, such as those dependent upon receipt of regulatory approval, are not considered to be probable of achievement until the triggering event occurs. At the end of each reporting period, the Company reevaluates the probability of achievement of each milestone and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based upon the achievement of a certain level of product sales, the Company recognizes revenue upon the later of: (i) When the related sales occur or (ii) When the performance obligation to which some or all of the payment has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any development, regulatory or commercial milestones or royalty revenue resulting from any of its collaboration arrangements. Consideration that would be received for optional goods and/or services is excluded from the transaction price at contract inception.

The Company allocates the transaction price to each performance obligation identified in the contract on a relative standalone selling price basis, when applicable. However, certain components of variable consideration are allocated specifically to one or more particular performance obligations in a contact to the extent both of the following criteria are met: (i) The terms of the payment relate specifically to the efforts to satisfy the performance obligation or transfer the distinct good or service and (ii) Allocating the variable amount of consideration entirely to the performance obligation or the distinct good or service is consistent with the allocation objective of the standard whereby the amount allocated depicts the amount of consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services. The Company develops assumptions that require judgement to determine the standalone selling price for each performance obligation identified in each contract. The key assumptions utilized in determining the standalone selling price for each performance obligation may include forecasted revenues, development timelines, estimated research and development costs, discount rates, likelihood of exercise and probabilities of technical and regulatory success.

Revenue is recognized based on the amount of the transaction price that is allocated to each respective performance obligation when or as the performance obligation is satisfied by transferring a promised good and/or service to the customer. For performance obligations that are satisfied over time, the Company recognizes revenue by measuring the progress toward complete satisfaction of the performance obligation using a single method of measuring progress which depicts the performance in transferring control of the associated goods and/or services to the customer. The Company uses input methods to measure the progress toward the complete satisfaction of performance obligations satisfied over time. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment. The Company measures progress toward satisfaction of the performance obligation overtime as effort is expended.

As it relates to the Merck Agreement , the Company recognized the upfront payment associated with its one open contract as a contract liability upon receipt of payment as it requires deferral of revenue recognition to a future period until the Company performs its obligations under the arrangement. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date are classified in current liabilities. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as contract liabilities, net of current portion. The Company determined that there was one performance obligation: consisting of the license and research development services. Thus, the transaction price of $2.5 million was allocated to the single performance obligation.

The Company does not believe that any variable consideration should be included in the transaction price at December 31, 2019. Such assessment considered the application of the constraint to ensure that estimates of variable consideration would be included in the transaction price only to the extent the Company had a high degree of confidence that revenue would not be reversed in a subsequent reporting period. The Company will re-evaluate the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as other changes in circumstances occur by assessing the effort and expense expended during the period. For the year ended December 31, 2019, the Company recognized approximately $874,000 in collaboration revenue related to this agreement and recorded short and long-term research and development liabilities on its balance sheet dated December 31, 2019 of $483,515 and $0, respectively. For the year ended December 31, 2018, the Company recognized approximately $1,142,605 in collaboration revenue related to this agreement and recorded short and long-term research and development liabilities on its balance sheet dated December 31, 2018 of $1,198,122 and $159,272, respectively.

On November 6, 2018, the Company entered into the LG Chem Agreement with LG Chem related to the development of the Company's Immuno-STATs focused in the field of oncology. Pursuant to the Collaboration Agreement the Company granted LG Chem an exclusive license to develop, manufacture and commercialize the Company's lead product, CUE-101, as well as Immuno-STATs that target T-cells against two additional cancer antigens, in the LG Chem Territory. LG Chem has the option to elect one additional Immuno-STAT for an oncology target within two years of the agreement for a worldwide development and commercialization license, and Cue Biopharma will retain an option to co-develop and co-commercialize the additional program worldwide. Cue Biopharma retains rights to develop and commercialize all assets included in the agreement in the United States and in global markets outside of Asia. In exchange for the licenses and other rights granted to LG Chem under the Collaboration Agreement, LG Chem will make a $5.0 million equity investment in common stock of Cue Biopharma, Inc. and a $5.0 million nonrefundable upfront cash payment. Cue Biopharma is also be eligible to receive up to an additional $400 million in research, development, regulatory and sales milestones. In addition, the Collaboration Agreement

also provides that LG Chem will pay the Company tiered single-digit royalties on net sales of commercialized product candidates in the LG Chem Territory.

As it relates to the LG Chem Agreement, the Company recognized the $5.0 million upfront payment associated with its one open contract as a contract liability upon receipt of payment as it requires deferral of revenue recognition to a future period until the Company performs its obligations under the arrangement. Of the $5.0 million upfront payment, $825,000 was recognized as tax withholding, shown as income tax expense on the statement of operations and comprehensive loss. The Company also recorded approximately $829,000 in premium paid for the stock purchased by LG Chem pursuant to the Stock Purchase Agreement dated November 6, 2018, as a contract liability upon receipt of payment. These amounts require deferral of revenue recognition to a future period until the Company performs its obligations under the arrangement. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date are classified in current liabilities. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as contract liabilities, net of current portion. Thus, the transaction price of $5.8 million was recorded in short and long-term research and development liabilities on its balance sheet dated December 31, 2018.

On May 16, 2019, LG Chem paid the Company a $2.5 million milestone payment for the United States Food and Drug Administration ("FDA") acceptance of the Investigational New Drug ("IND") for the Company's lead drug candidate, CUE-101, pursuant to the LG Chem Agreement. The $2.5 million milestone payment was recorded as a contract liability upon receipt of payment as it requires deferral of revenue recognition to a future period until the Company performs its obligations related to the development of CUE-101 under the arrangement. Of the $2.5 million milestone payment, approximately $412,500 was recognized as tax withholding, shown as income tax expense on the statement of operations and comprehensive loss. The Company recorded short and long-term research and development liabilities on its balance sheet dated of approximately $3,614,000 and $4,018,000, respectively, for the year ended December 31, 2019.

Aside from the $2.5 million milestone payment, the Company does not believe that any variable consideration should be included in the transaction price as of December 31, 2019. Such assessment considered the application of the constraint to ensure that estimates of variable consideration would be included in the transaction price only to the extent the Company had a high degree of confidence that revenue would not be reversed in a subsequent reporting period. The Company will re-evaluate the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as other changes in circumstances occur. For the year ended December 31, 2019, the Company recognized revenue of approximately $2,584,000, related to the LG Chem Agreement.

The Company does not believe that any variable consideration should be included in the transaction price as of December 31, 2019. Such assessment considered the application of the constraint to ensure that estimates of variable consideration would be included in the transaction price only to the extent the Company had a high degree of confidence that revenue would not be reversed in a subsequent reporting period. The Company will re-evaluate the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as other changes in circumstances occur. For the year ended December 31, 2019, the Company did not recognized revenue related to this agreement.

The Company considered the capitalization of contract costs under the guidance in ASC 340-40, *Other Assets and Deferred Costs: Contracts with Customers*. There were no contract costs identified in the Collaboration Agreement with Merck. As it related to the LG Chem agreement, the Company capitalized license expenses of approximately $751,000 as of December 31, 2019, pursuant to the Einstein license agreement which requires the Company to pay a percentage of sublicenses related to the Company's patent rights for components of its core technology that is licensed from Einstein. This amount is comprised of approximately $438,000 of capitalized license expenses related to the upfront payment received from LG Chem in December 2018 and approximately $313,000 in capitalized license expenses related to the milestone payment received in June 2019, net of accumulated amortization of approximately $225,000. For the year ended December 31, 2019, $264,503 was included in prepaid expenses and other short-term assets and $260,497 is included in other long-term assets. Related to the LG Chem agreement, the Company capitalized license expenses of approximately $438,000 as of December 31, 2018, pursuant to the Einstein license agreement. Of the total approximately, $54,000 is included in prepaid expenses and other short-term assets and approximately $384,000 is included in other long-term assets as of December 31, 2018.
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11. Stockholders' Equity

Preferred Stock

The Company has authorized a total of 10,000,000 shares of preferred stock, par value $0.001 per share, none of which were outstanding at December 31, 2019 and 2018. The Company's Board of Directors has the authority to issue preferred stock and to determine the rights, preferences, privileges, and restrictions, including voting rights.

Common Stock

The Company has authorized a total of 50,000,000 shares of common stock, par value $0.001 per share, of which 26,562,178 shares and 20,697,453 shares were issued and outstanding at December 31, 2019 and 2018, respectively.

12. Related Party Transactions

As of December 31, 2019, MDB beneficially owned approximately 5% of the Company's common stock, has served as the underwriter of the Company's initial public offering as well as the placement agent in previous private placements of the Company's common stock, and one MDB employee is a director of the Company.

Beginning in June 2015, the former interim Chief Financial Officer of the Company, who is also the Chief Financial Officer of MDB, was compensated at a rate of $6,000 per month, reflecting an aggregate annual charge to operations for the year ended December 31, 2018 of $24,000, until his resignation on April 30, 2018.

Information with respect to payments under the Einstein License is described in Note 7.

13. Income Taxes

The Company accounts for income taxes under the provision of ASC 740, *Income Taxes*. The Company reported a $412,500 tax provision for the year ended December 31, 2019 related to foreign withholding taxes paid.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31, 2019 and 2018 are as follows:

	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 23,348,000	$ 15,738,000
Research and other credits	2,069,000	1,450,000
Reserves and accruals	5,281,000	1,953,000
Other	3,000	3,000
Intangibles	—	—
Total gross deferred tax assets	30,701,000	19,144,000
Less valuation allowance	(29,095,000)	(19,004,000)
Total deferred tax assets	1,606,000	140,000
Deferred tax liability:		
Depreciation	1,606,000	(140,000)
Net deferred tax assets	$ —	$ —

In assessing the potential realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during the periods in which those temporary differences become deductible. As of December 31, 2019, and 2018, management was unable to determine if it is more likely than not that the Company's deferred tax assets will be realized and has therefore recorded a 100% valuation allowance against deferred tax assets at such dates.

No Federal tax provision has been provided for the years ended December 31, 2019, 2018, and 2017, due to the losses incurred during such periods. A reconciliation of the difference between the income tax rate computed by applying the U.S. Federal statutory rate and the effective tax rate for the years ended December 31, 2019, 2018, and 2017 is as follows:

	Years Ended December 31,	
	2019	2018
U. S. Federal statutory tax rate	(21)%	(21)%
State Taxes	(6)%	(4)%
Change in valuation allowance	27%	24%
Tax credits	(2)%	(2)%
Stock based compensation	1%	3%
Tax reform	0%	0%
Foreign withholding taxes	1%	2%
Other	1%	0%
Effective tax rate	1%	2%

The Company has applied the provisions of ASC 740, Income Taxes, which clarifies the accounting for uncertainty in tax positions and requires the recognition of the impact of a tax position in the financial statements if that position is more likely than not of being sustained on a tax return, based on the technical merits of the position, upon examination by the relevant taxing authority. At December 31, 2019 and 2018, the Company had unrecognized tax benefits related to Federal and state research tax credits of approximately $1,334,000 and $972,000, respectively. The Company is subject to Federal and state income tax examinations by tax authorities for all years since its incorporation in 2014. The Company is currently not under examination by any tax authority.

At December 31, 2019, the Company has available net operating loss carryforwards for Federal and state income tax purposes of approximately $85,710,000 and $84,560,000, respectively, which, if not utilized earlier, will begin to expire in 2035. Approximately, $57,198,000 of the federal net operating losses have an indefinite carryforward. The Company has Federal research credits of approximately $1,202,000, which, if not utilized earlier, will begin to expire in 2035, and state research credits of approximately $1,002,000, which, if not utilized earlier, will begin to expire in 2031. At December 31, 2019 the Company recorded $250,000 in research credits as prepaid to be offset against payroll tax liabilities associated with research and development personnel in 2019 in addition to the approximately $140,000 in research and development credits remaining in prepaid from 2018.

The following is a reconciliation of the Company's gross uncertain tax position at December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
Balance at the beginning of year	$ 972,000	$ 510,000
Additions for current year tax provisions	294,000	430,000
Additions for prior year tax provisions	81,000	32,000
Reductions of prior year tax provisions	(13,000)	—
Balance as of end of year	$ 1,334,000	$ 972,000

14. Commitments and Contingencies

Einstein License and Service Agreement

The Company's remaining commitments with respect to the Einstein License are based on the attainment of future milestones. The aggregate amount of milestone payments made under the Einstein License may equal up to $1.85 million for each product, process or service that use the patents covered by the Einstein License, including certain technology received from Einstein relating thereto ("Licensed Products"), and up to $1.85 million for each new indication of a Licensed Product. Additionally, the aggregate amount of one-time milestone payments based on cumulative sales of all Licensed Products may

equal up to $5.75 million. The Company is also party to a service agreement with Einstein to support the Company's ongoing research and development activities.

Collaboration Agreement with Merck

The research program outlined in the Collaboration Agreement entails (1) our research, discovery and development of certain Immuno-STAT™ product candidates up to the point of Proof of Mechanism, and (2) the further development by Merck of the Immuno-STAT™ product candidates that have demonstrated Proof of Mechanism (the "Proposed Product Candidates") up to the point of demonstration of all or substantially all of the properties outlined in such Proposed Product Candidates' profiles as described in the Collaboration Agreement.

In exchange for the licenses and other rights granted to Merck under the Collaboration Agreement, Merck paid to the Company a $2.5 million nonrefundable up-front payment. Additionally, the Company may be eligible to receive funding in developmental milestone payments, as well as tiered royalties, if all research, development, regulatory and commercial milestones agreed upon by both parties are successfully achieved. Excluding the up-front payment described above, the Company is eligible to earn up to $101 million for the achievement of certain research and development milestones, $120 million for the achievement of certain regulatory milestones and $150 million for the achievement of certain commercial milestones, in addition to tiered royalties on sales, if all pre-specified milestones associated with multiple products across the primary disease indication areas are achieved. The Collaboration Agreement requires the Company to use the first $2.5 million of milestone payments we receive under the agreement to fund contract research. The amount of the royalty payments is a percentage of product sales ranging in the single digits based on the amount of such sales. For the years ended December 31, 2019 and 2018, the Company recorded approximately $0.9 million and $1.1 million in collaboration revenue related to this agreement, respectively (Note 10).

Collaboration Agreement with LG Chem Life Sciences

On November 6, 2018, the Company entered into the LG Chem Agreement with LG Chem Life Sciences. related to the development of the Company's Immuno-STATs focused in the field of oncology. Pursuant to the Collaboration Agreement the Company granted LG Chem an exclusive license to develop, manufacture and commercialize the Company's lead product, CUE-101, as well as Immuno-STATs that target T-cells against two additional cancer antigens, in certain Asian countries (collectively, the "LG Chem Territory"). LG Chem has the option to elect one additional Immuno-STAT for an oncology target within two years of the agreement for a worldwide development and commercialization license, and Cue Biopharma will retain an option to co-develop and co-commercialize the additional program worldwide. Cue Biopharma retains rights to develop and commercialize all assets included in the agreement in the United States and in global markets outside of Asia. In exchange for the licenses and other rights granted to LG Chem under the Collaboration Agreement, LG Chem will make a $5.0 million equity investment in common stock of Cue Biopharma, Inc. and a $5.0 million nonrefundable upfront cash payment. Cue Biopharma is also be eligible to receive up to an additional $400 million in research, development, regulatory and sales milestones. In addition, the Collaboration Agreement also provides that LG Chem will pay the Company tiered single-digit royalties on net sales of commercialized product candidates in the LG Chem Territory.

On May 16, 2019, LG Chem paid the Company a $2.5 million milestone payment for the FDA acceptance of the IND for the Company's lead drug candidate, CUE-101, pursuant to the LG Chem Agreement. The $2.5 million milestone payment was recorded as a contract liability upon receipt of payment as it requires deferral of revenue recognition to a future period until the Company performs its obligations under the arrangement pursuant to the Company's revenue recognition policy. The Company recognized collaboration revenue for the year ended December 31, 2019 and 2018, respectively, approximately $2.6 million, and $0, respectively, related to this agreement.

Leased Facilities

The Company leases approximately 19,900 square feet of office space in Cambridge, Massachusetts under a lease that began in May 2018 and is scheduled to expire on April 14, 2021 (the "Lease"). Upon adoption of ASU 2016-02, the Company recorded a right-of-use asset and corresponding lease liability for the Lease on January 1, 2019, by calculating the present value of lease payments, discounted at 6%, the Company's estimated incremental borrowing rate annually, over the 2.3-year remaining term.

On July 29, 2015, the Company entered into an operating lease agreement for its previous laboratory space for the period from August 1, 2015 through April 30, 2018. The lease contained escalating payments during the lease period. The Company records monthly rent expense on the straight-line basis.

On November 14, 2016 and January 16, 2018 the Company entered into an amendments to the operating lease agreement that each provided the Company with additional laboratory space. These amendments were effective beginning December 1, 2016 and January 16, 2018, respectively, and continued through the expiration of the lease on April 30, 2018.

On January 18, 2018, the Company entered into an operating lease agreement for its laboratory and office space in Cambridge, Massachusetts for the period from May 1, 2018 through April 30, 2021. The lease contains escalating payments during the lease period. Upon execution of this lease agreement the Company prepaid three months of rent, two of which will be held in escrow and credited against future rent payments and one month that was applied to the first months rent. The Company also prepaid seven and one half months rent pursuant to an amendment to the lease agreement executed on June 18, 2018. These amounts were recorded to deposits and prepaid expenses, respectively at December 31, 2018. The monthly rent payments due under this lease agreement will be approximately $297,500 for the first 18 months of the term and increase to approximately $330,500 for the remaining 18 months of the term.

On June 18, 2018, the Company entered into an amended lease agreement that provided the Company with a reduction in rental fees for its office and laboratory space in exchange for prepayment of a portion of the fees. This amendment was effective beginning on May 15, 2018 and expires on April 14, 2021.

On September 20, 2018, the Company entered into an operating lease for additional laboratory space in Cambridge, Massachusetts for the period from October 15, 2018 through April 14, 2021. The lease contains escalating payments during the lease period. Upon execution of this lease agreement the Company prepaid three months of rent which will be held in escrow and credited against future rent payments. The monthly rental rate under the lease agreement is $72,600 for the first 12 months and $78,600 for the remainder of the term. Upon execution of this lease agreement the Company prepaid twelve months rent pursuant to the lease agreement executed on September 20, 2018.

On September 16, 2019, the Company entered into an amended lease agreement that removed one holding room from the additional laboratory space lease entered into on September 20, 2018. The amendment was effective beginning on October 1, 2019 and expires on April 14, 2021. The monthly rental rate under the amended lease agreement decreased from $78,600 to $58,995, for the remainder of the lease term. The partial termination of the lease did not change the classification of the lease and remained accounted for as an operating lease. The weighted-average discount rate remained the same at 6%. The Company accounted for the lease modification under ASC 842 that removed one holding room by electing Approach 1, which remeasured the right of use asset on the basis of the amount of the liability change. The modification of the partial termination resulted in a reduction to right-of-use asset and lease liability of $335,465 and $327,079, respectively. The difference of $8,386 was recorded as a loss to the right-of-use asset as of December 31, 2019. At December 31, 2019, the Company recorded approximately $5,337,000 to operating right-of-use asset, and approximately $4,448,000 and $1,348,000 to short and long-term operating lease liability, respectively. At December 31, 2019 the remaining lease term was 1.29 years.

Future minimum lease payments under these leases at December 31, 2019 are as follows:

Year	
2020	4,674,540
2021	1,363,408
Total lease payments	6,037,948
Less: present value discount	(242,190)
Present value of lease payments	$ 5,795,758

Total rent expense of approximately $4,474,000 and $3,311,000 was included in the statement of operations for the years ended December 31, 2019 and 2018, respectively.

Contingencies

The Company accrues for contingent liabilities to the extent that the liability is probable and estimable. There are no accruals for contingent liabilities in these consolidated financial statements.

The Company may be subject to various legal proceedings from time to time as part of its business. As of December 31, 2019, the Company was not a party to any legal proceedings or threatened legal proceedings, the adverse outcome of which, individually or in the aggregate, would have a material adverse effect on its business, financial condition or results of operations.

15. Cue Biopharma 401(k) Plan

Effective as of January 1, 2017, the Company adopted the Cue Biopharma 401(k) Plan (the “Plan”) for all employees of the Company. Employees may participate in the Plan upon complying with the Plan’s eligibility requirements, subject to limitations imposed by the Internal Revenue Service. Under the Plan, the Company may match employee contributions at its discretion. The Company did not make any contributions to the Plan during the year ended December 31, 2019 or 2018.

16. Subsequent Events

The Company has evaluated subsequent events through the date on which the consolidated financial statements were issued, to ensure that this submission includes appropriate disclosure of events both recognized in the consolidated financial statements and events which occurred subsequently but were not recognized in the consolidated financial statements.

PART IV

Item 15. Exhibits, Financial Statements and Schedules

(a) List of documents filed as part of this report:

1 Financial Statements (see "Financial Statements and Supplementary Data" at Item 8 and incorporated herein by reference).

2. Financial Statement Schedules (Schedules to the Financial Statements have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Financial Statements or notes thereto)

3. Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

		Incorporated by Reference				
Exhibit Number	**Exhibit Description**	**Filed Herewith**	**Form**	**Exhibit**	**Filing Date**	**Registration /File No.**
3.1	Amended and Restated Certificate of Incorporation of the Registrant		8-K	3.1	12/27/17	005-90232
3.2	Amended and Restated Bylaws of the Registrant		S-1	3.5	12/05/17	333-220550
4.1	Specimen Certificate representing shares of common stock of the Registrant		S-1	4.1	12/05/17	333-220550
4.2	Warrant to Purchase Common Stock issued to the placement agent in the Registrant's 2015 private placement offering		S-1	4.3	09/21/17	333-220550
4.3	Form of Warrant issued to the underwriter in the Registrant's 2017 initial public offering		10-K	4.3	03/29/18	001-38327
4.4	Description of Common Stock of the Registrant Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	X				
10.1	Form of Registration Rights Agreement between the Registrant and investors for an offering completed on June 15, 2015		S-1	10.4	09/21/17	333-220550
10.2	Form of Joinder and Amendment to Registration Rights Agreement between the Registrant and investors for an offering completed on December 22, 2016		S-1	10.6	09/21/17	333-220550
10.3	Form of Indemnification Agreement between the Registrant and its directors and officers		S-1	10.10	09/21/17	333-220550
10.4	Amended and Restated License Agreement by and between the Registrant and Albert Einstein College of Medicine dated July 31, 2017†		S-1	10.11	12/13/17	333-220550
10.5	Cue Biopharma, Inc. 2016 Omnibus Incentive Plan, as amended and restated*		S-1	10.13	09/21/17	333-220550
10.6	Form of stock option award under 2016 Omnibus Incentive Plan*		S-1	10.14	09/21/17	333-220550
10.7	Cue Biopharma, Inc. 2016 Non-Employee Equity Incentive Plan*		S-1	10.15	09/21/17	333-220550
10.8	Form of stock option award under 2016 Non-Employee Equity Incentive Plan*		S-1	10.16	09/21/17	333-220550

10.9	Director Compensation Policy dated October 30, 2018*		10-K	10.10	03/14/2019	001-38327
10.10	Exclusive Patent License and Research Collaboration Agreement between the Registrant and Merck Sharp & Dohme Corp. dated November 14, 2017†		S-1	10.21	12/04/17	333-220550
10.11	Executive Employment Agreement between the Registrant and Colin G. Sandercock dated as of November 15, 2017*		S-1	10.22	12/04/17	333-220550
10.12	License Agreement between the Registrant and MIL 21 E, LLC dated January 19, 2018		10-K	10.21	03/29/18	001-38327
10.13	First Amendment to the License Agreement between Registrant and MIL 21E, LLC dated June 18, 2018		8-K	10.1	06/20/18	001-38327
10.14	Executive Employment Agreement between the Registrant and Bethany Mancilla dated June 22, 2018*		10-Q	10.3	8/13/2018	001-38327
10.15	Collaboration, License and Option Agreement between the Registrant and LG Chem, Ltd. dated November 6, 2018†		8-K	10.1	12/26/18	001-38327
10.16	Amendment No. 1 to Cue Biopharma, Inc. 2016 Omnibus Incentive Plan*	X				
10.17	Amended and Restated Executive Employment Agreement between the Registrant and Anish Suri dated October 3, 2019*		8-K	10.1	10/07/19	001-38327
10.18	Amended and Restated Executive Employment Agreement between the Registrant and Daniel Passeri dated October 3, 2019		8-K	10.2	10/07/19	001-38327
21	List of Subsidiaries	X				
23.1	Consent of RSM Inc., Independent Registered Public Accounting Firm	X				
24.1	Power of Attorney (included on signature page)	X				
31.1	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934	X				
31.2	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934	X				
32.1	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
101.INS	XBRL Instance Document	X				
101.SCH	XBRL Taxonomy Extension Schema Document	X				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X				

***** Indicates management compensatory plan, contract or arrangement.
† Confidential portions of this exhibit, indicated by asterisks, have been omitted.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Dated: March 11, 2020

By: /s/ Daniel R. Passeri
Daniel R. Passeri
Chief Executive Officer and Director
(Principal Executive Officer)

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Cue Biopharma, Inc., hereby severally constitute and appoint Daniel R. Passeri our true and lawful attorney, with full power to him to sign for us and in our names in the capacities indicated below, any amendments to this Annual Report on Form 10-K, and generally to do all things in our names and on our behalf in such capacities to enable Cue Biopharma, Inc. to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all the requirements of the Securities Exchange Commission.

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ Daniel R. Passeri Daniel R. Passeri	Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2020
/s/ Kerri-Ann Millar Kerri-Ann Millar	Vice President, Finance (Principal Financial and Accounting Officer)	March 11, 2020
/s/ Aaron Fletcher Aaron Fletcher	Director	March 11, 2020
/s/ Cameron Gray Cameron Gray	Director	March 11, 2020
/s/ Peter A. Kiener Peter A. Kiener	Director	March 11, 2020
/s/ Barry Simon Barry Simon	Director	March 11, 2020
/s/ Frederick Driscoll Frederick Driscoll	Director	March 11, 2020
/s/ Frank Morich Frank Morich	Director	March 11, 2020

EXHIBIT 4.4

DESCRIPTION OF COMMON STOCK OF CUE BIOPHARMA, INC.
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following information is a summary of information concerning the common stock, par value $0.001 per share (the "Common Stock"), of Cue Biopharma, Inc. ("we," "our," or "us") and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") and Amended and Restated Bylaws (the "Bylaws"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.4 is a part.

Authorized Common Stock

The Certificate of Incorporation authorizes the issuance of 50,000,000 shares of Common Stock. Our authorized but unissued shares of Common Stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange or automated quotation system on which our securities may be listed or traded.

Voting

Each holder of Common Stock is entitled to one vote for each such share outstanding in the holder's name. No holder of Common Stock is entitled to cumulate votes in voting for directors.

Dividends

Holders of Common Stock are entitled to such dividends as may be declared by our board of directors out of funds legally available for such purpose.

Rights and Preferences

Shares of Common Stock are neither redeemable nor convertible. Holders of Common Stock have no preemptive or subscription rights to purchase any of our securities.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of Common Stock are entitled to receive, pro rata, our assets which are legally available for distribution, after payments of all debts and other liabilities.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the designations, powers, rights, preferences, qualifications, limitations and restrictions thereof. These designations, powers, rights and preferences could include voting rights, dividend rights, dissolution rights, conversion rights, exchange rights, redemption rights, liquidation preferences, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of Common Stock. The issuance of preferred stock could adversely affect the voting power of holders of Common Stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in our control or other corporate action.

Anti-Takeover Provisions

The provisions of Delaware law, the Certificate of Incorporation and the Bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of us. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law (the "DGCL"), an anti-takeover law. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination (as defined below) with any interested stockholder (as defined below) for a period of three years following the date that the stockholder became an interested stockholder, unless:

- prior to that date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares of voting stock outstanding (but not the voting stock owned by the interested stockholder) those shares owned by persons who are directors and officers and by excluding employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to that date, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to limited exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

Section 203 generally defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation, or who beneficially owns 15% or more of the outstanding voting stock of the corporation at any time within a three-year period immediately prior to the date of determining whether such person is an interested stockholder, and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

Certificate of Incorporation and Bylaw Provisions

The Certificate of Incorporation and the Bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of us. Certain of these provisions are summarized in the following paragraphs.

Effects of authorized but unissued Common Stock. One of the effects of the existence of authorized but unissued Common Stock may be to enable our board of directors to make more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, and thereby to protect the continuity of management. If, in the due exercise of its fiduciary obligations, the board of directors were to determine that a takeover proposal was not in our best interest, such shares could be issued by the board of directors without stockholder approval in one or more transactions that might prevent or render more difficult or costly the completion of the takeover transaction by diluting the voting or other rights of the proposed acquirer or insurgent stockholder group, by putting a substantial voting block in institutional or other hands that might undertake to support the position of the incumbent board of directors, by effecting an acquisition that might complicate or preclude the takeover, or otherwise.

Cumulative Voting. The Certificate of Incorporation does not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors.

Director Vacancies. The Certificate of Incorporation provides that all vacancies may be filled only by the affirmative vote of a majority of directors then in office, even if less than a quorum.

Stockholder Action; Special Meeting of Stockholders. The Bylaws provide that stockholders may act by written consent. However, stockholders pursuing an action by written consent will be required to comply with certain notice and record date requirements that are set forth in the DGCL. A special meeting of stockholders may be called by the Chairman of the board of directors, the President, the Chief Executive Officer, or a majority of the board of directors at any time and for any purpose or purposes as shall be stated in the notice of the meeting, or by request of the holders of record of at least 20% of outstanding shares of Common Stock. This provision could prevent stockholders from calling a special meeting because, unless certain significant stockholders were to join with them, they might not obtain the percentage necessary to request the meeting. Therefore, stockholders holding less than 20% of issued and outstanding Common Stock, without the assistance of management, may be unable to propose a vote on any transaction which may delay, defer or prevent a change of control, even if the transaction were in the best interests of our stockholders.

Advance Notice Requirements for Stockholder Proposals and Director Nominations. The Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as director. In order for any matter to be "properly brought" before a meeting, a stockholder will have to comply with such advance notice procedures and provide us with certain information. The Bylaws allow the presiding officer at a meeting of stockholders to adopt rules and regulations for the conduct of meetings which may have the effect of precluding the conduct of certain business at a meeting if such rules and regulations are not followed. These provisions may also defer, delay or discourage a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to influence or obtain control of us.

Supermajority Voting for Amendments to Our Governing Documents. Any amendment to the Certificate of Incorporation requires the affirmative vote of at least 66 2/3% of the voting power of all shares of our capital stock then outstanding. The Certificate of Incorporation provides that the board of directors is expressly authorized to adopt, amend or repeal the Bylaws and that our stockholders may amend the Bylaws only with the approval of at least 66 2/3% of the voting power of all shares of our capital stock then outstanding.

Choice of Forum. The Certificate of Incorporation provides that, subject to certain exceptions, the Court of Chancery of the State of Delaware will be the exclusive forum for any claim, including any derivative claim, (i) that is based upon a violation of a duty by a current or former director or officer or stockholder in such capacity or (ii) as to which the DGCL, or any other provision of Title 8 of the Delaware Code, confers jurisdiction upon the Court of Chancery.

Listing on the Nasdaq Capital Market

Shares of Common Stock are listed on the Nasdaq Capital Market under the symbol "CUE."

Transfer Agent

The name, address and telephone number of the transfer agent of Common Stock is Corporate Stock Transfer, Inc. at 3200 Cherry Creek Drive South, Suite 430, Denver, Colorado 80209.

Amendment No. 1 to the
Cue Biopharma, Inc. 2016 Omnibus Equity Incentive Plan

This Amendment No. 1 ("Amendment"), dated May 17, 2019, of the 2016 Omnibus Equity Incentive Plan, as amended (the "Existing Plan"; as amended hereby, the "Plan"), of Cue Biopharma, Inc., a Delaware corporation (the "Company"), is made and adopted by the Company, subject to approval of the stockholders of the Company.

Statement of Purpose

The Existing Plan was originally approved by the Company's Board of Directors (the "Board") on March 23, 2016 and approved by our stockholders on May 8, 2016, initially becoming effective on such date. The 2016 Plan was amended and restated by the Board on August 12, 2017 and approved by the Company's stockholders on December 7, 2017. The Board may amend the Existing Plan at any time, pursuant to and subject to Section 5.2 of the Existing Plan, contingent on approval by the stockholders of the Company, if stockholder approval is required by applicable law or applicable securities exchange listing requirements. The Board has determined that it is advisable and in the best interest of the Company to amend the Existing Plan to increase the number of shares of the Company's common stock, par value $0.001, authorized for issuance under the Existing Plan as "incentive stock options" within the meaning of Internal Revenue Code (the "Code") Section 422 ("ISOs") by 2,498,043 shares, and to make the other changes to the Existing Plan described in this Amendment.

NOW, THEREFORE, the Existing Plan is hereby amended as follows, subject to approval by the stockholders of the Company:

1. Capitalized Terms. All capitalized terms used and not defined herein shall have the meanings given thereto in the Existing Plan.

2. Amendment of Section 4.3.1 of Existing Plan. Section 4.3.1 of the Existing Plan is hereby deleted in its entirety and replaced with the following:

"4.3.1 Incentive Stock Options

Subject to adjustment under **Section 14**, 5,300,000 Shares available for issuance under the Plan shall be available for issuance as Incentive Stock Options (the "ISO Limit"), effective as of May 17, 2019, subject to stockholder approval; *provided*, *however*, that on the first day of each fiscal year of the Company during the period beginning in fiscal year 2020 and ending on the second day of fiscal year 2027, the ISO Limit shall be increased by a number of Shares equal to any increase of the total number of Shares authorized to be issued under the Plan pursuant to **Section 4.1** hereof; *provided*, *further*, that in no event shall the ISO Limit be greater than 20,000,000 Shares."

3. Reference to and Effect on the Plan. The Plan, as amended hereby, and all other documents, instruments and agreements executed and/or delivered in connection therewith, shall remain in full force and effect, and are hereby ratified and confirmed.

4. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware.

Effective this 17th day of May 2019.

EXHIBIT 21

SUBSIDIARIES OF CUE BIOPHARMA, INC.

Registrant's consolidated subsidiaries are shown below, together with the state or jurisdiction of organization of each subsidiary and the percentage of voting securities that Registrant owns in each subsidiary.

Name of Subsidiary	Jurisdiction of Incorporation or Organization	Percent of Outstanding Voting Securities Owned
Cue Biopharma Securities Corp.	Massachusetts	100%

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (No. 333-229140) on Form S-3 and Registration Statements (Nos. 333-224018 and 333-230282) on Form S-8 of Cue Biopharma, Inc. of our report dated March 11, 2020, relating to the consolidated financial statements of Cue Biopharma, Inc. and Subsidiary, appearing in this Annual Report on Form 10-K of Cue Biopharma, Inc. for the year ended December 31, 2019.

/s/ RSM US LLP

Boston, Massachusetts
March 11, 2020

EXHIBIT 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel R. Passeri, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cue Biopharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2020

/s/ Daniel R. Passeri
Name: Daniel R. Passeri
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kerri-Ann Millar, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cue Biopharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2020

/s/ Kerri-Ann Millar
Name: Kerri-Ann Millar
Title: Vice President Finance
(Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Cue Biopharma, Inc. (the "Company") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Daniel R. Passeri, Chief Executive Officer of the Company, and Kerri-Ann Millar, Vice President, Finance and Principal Accounting Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to our knowledge that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to Cue Biopharma, Inc. and will be retained by Cue Biopharma, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Daniel R. Passeri
Name: Daniel R. Passeri
Title: Chief Executive Officer
(Principal Executive Officer)

Date: March 11, 2020

/s/ Kerri-Ann Millar
Name: Kerri-Ann Millar
Title: Vice President, Finance
(Principal Accounting Officer)

Date: March 11, 2020