Registration No. 333-220550

#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

### **AMENDMENT NO. 4**

#### TO FORM S-1

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933** 

## CUE BIOPHARMA, INC. (Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

2834 (Primary Standard Industrial Classification Code Number

675 W. Kendall St.

47-3324577 (I.R.S. Employer Identification No.)

Cambridge, MA 02142 (617) 949-2680 (Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Daniel R. Passeri Chief Executive Officer Cue Biopharma, Inc. 675 W. Kendall St.

Cambridge, MA 02142 (617) 949-2680

(Name, address, including zip code, and telephone number, including area code, of agent for service)

#### Copies to:

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As soon as practicable after the effective date of this Registration Statement. (Approximate date of commencement of proposed sale to the public)

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ⊠

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

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

Large accelerated filer $\Box$	Accelerated filer $\Box$
Non-accelerated filer ⊠	Smaller reporting company $\Box$
(Do not check if a 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 7(a)(2)(B) of the Securities Act. 🗆

#### CALCULATION OF REGISTRATION FEE

	Proposed Maximum Aggregate Offering	Amount of
Title of Each Class of Securities to be Registered	Price <sup>(1)</sup>	<b>Registration Fee</b>
Common Stock <sup>(2)</sup>	\$ 60,000,000	\$7,470.00
Underwriter Warrant <sup>(3)</sup>	\$ 1,000	_
Shares of Common Stock Underlying Underwriter Warrant	\$ 7,500,000	\$ 933.75
Total	\$ 67,501,000	\$8,403.75 <sup>(4)</sup>

Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Pursuant to Rule 416 under the Securities Act of 1933, as amended, there is also being registered hereby such indeterminate number of additional shares of common stock of the registrant as may be issued or issuable because of stock splits, stock dividends, stock distributions, and similar transactions. (2)

No registration fee required pursuant to Rule 457(g) under the Securities Act of 1933, as amended.

Previously paid.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment, which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. THESE SECURITIES MAY NOT BE SOLD UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PRELIMINARY PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND WE ARE NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED DECEMBER 11, 2017



PRELIMINARY PROSPECTUS

Up to 8,000,000 Shares of Common Stock

### **CUE BIOPHARMA, INC.**

We are offering up to 8,000,000 shares of our common stock, \$0.001 par value, on a best efforts basis as described in this prospectus, with a minimum offering amount of 5,333,334 shares of our common stock, or a minimum of approximately \$40,000,000 of common stock and a maximum of \$60,000,000 of common stock.

This is an initial public offering of our common stock. The public offering price will be \$7.50 per share. There is presently no public market for our common stock. We have applied to list our common stock on the Nasdaq Capital Market under the symbol "CUE," which listing we expect to occur upon consummation of this offering. No assurance can be given that our application will be approved. If our application is not approved or we otherwise determine that we will not be able to secure the listing of our common stock on the Nasdaq Capital Market, we will not complete this offering.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page <u>16</u> for a discussion of information that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

MDB Capital Group, LLC, or MDB, and Feltl and Company, Inc., or Feltl, are the underwriters for our initial public offering. MDB has rendered advisory services to us in the past and has acted as our placement agent in connection with private placements of common stock completed in June 2015 and December 2016. The underwriters are selling shares of our common stock in this offering on a best efforts basis and are not required to sell any specific number or dollar amount of the shares offered by this prospectus, but will use their best efforts to sell such shares. We do not intend to close this offering unless we sell at least \$40,000,000 of common stock, at the price per share set forth in the table below. This offering will terminate on \_\_\_\_\_\_\_\_\_, 2017 (30 days after the date of this prospectus) (the "Initial Offering Termination Date"), which date may be extended to a date up to and including \_\_\_\_\_\_\_\_\_\_, 2018 (the "Offering Termination Date"), unless we sell the maximum amount of common stock set forth below before that date or we decide to terminate this offering prior to that date. The gross proceeds of this offering will be deposited at JP Morgan Chase, in an escrow account established by us, until we have sold a minimum of \$40,000,000 of common stock and we otherwise satisfy the listing conditions to trade our common stock on the Nasdaq Capital Market. Once we satisfy the minimum stock sale and listing conditions, the funds will be released to us. In the event we decide to extend the offering period beyond the Initial Offering Termination Date we will seek reconfirmations from investors who have deposited funds into the escrow account and all funds deposited by investors who do not reconfirm will be promptly returned without interest or offset. In the event we do not sell a minimum of \$40,000,000 of common stock or satisfy Nasdaq's listing conditions by the Offering Termination Date, all funds received will be promptly returned to investors without interest or offset.

	Per Share	Offering	Offering
Public offering price	\$7.50	\$ 40,000,000	\$60,000,000
Underwriting commissions <sup>(1)(2)</sup>	\$0.36	\$ 1,920,000	\$ 2,880,000
Proceeds, before expenses, to us <sup>(3)</sup>	\$7.14	\$ 38,080,000	\$57,120,000

(1) We have also agreed to issue warrants to MDB in connection with this offering and agreed to reimburse the underwriters for certain expenses incurred by them. See "Underwriting (Conflicts of Interest)" for a description of compensation payable to the underwriters.

(2) Does not include a non-accountable expense allowance equal to 0.45% of gross proceeds payable to MDB and \$275,000 payable to Felt to serve as the qualified independent underwriter. See "Underwriting" for a description of compensation payable to the underwriters.
(2) We estimate the total expenses of this offering, excluding the underwriting commissions, will be \$750,000. Because this is a best efforts

(2) We estimate the total expenses of this offering, excluding the underwriting commissions, will be \$/50,000. Because this is a best effort offering, the actual public offering amount, underwriting commissions and proceeds to us are not presently determinable and may be substantially less than the total maximum offering set forth above.

In connection with this offering, we have also agreed to issue to MDB a warrant to purchase shares of our common stock in an amount up to 10% of the shares of common stock sold in the public offering, with an exercise price equal to 125% of the per-share public offering price. Because MDB and its associated persons, certain of whom are our officers and directors, collectively, beneficially hold 2,233,000 shares of our common stock, representing 21.0% of the outstanding shares prior to this offering, MDB is deemed to be an affiliate of the Company and to have a "conflict of interest" under Rule 5121 of Financial Industry Regulatory Authority Inc. Accordingly, Felt has agreed to act as a "qualified independent underwriter," within the meaning of Rule 5121 in connection with this offering. In its role as a qualified independent underwriter, Felt has participated in the preparation of the registration statement and the prospectus and has exercised the usual standards of due diligence with respect thereto. For a more complete discussion of the role and compensation of the underwriters, please see the section of this prospectus titled "Underwriting (Conflicts of Interest)."

### **MDB** Capital Group, LLC

### Feltl and Company

The date of this prospectus is

, 2017.

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Unless otherwise stated or the context otherwise requires, the terms "Cue Biopharma," "we," "us," "our" and the "Company" refer to Cue Biopharma, Inc.

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with additional or different information. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

No dealer, salesperson or any other person is authorized in connection with this offering to give any information or make any representations about us, the securities offered hereby or any matter discussed in this prospectus, other than those contained in this prospectus and, if given or made, the information or representations must not be relied upon as having been authorized by us. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any security other than the securities offered by this prospectus, or an offer to sell or a solicitation of an offer to buy any securities by anyone in any circumstance in which the offer or solicitation is not authorized or is unlawful.

We use a number of trademarks and service marks, including, among others, "CUE Biologics," "viraTope" and "MOD," some of which are pending registration under applicable intellectual property laws. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks, service marks and trade names referred to in this prospectus may appear without the TM symbols, but such references are not intended to indicate, in any way, that we will not assert, in appropriate circumstances, our rights, or the rights of an applicable licensor (if any), in and to these trademarks, service marks or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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### **PROSPECTUS SUMMARY**

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you need to consider in making your investment decision. You should carefully read this entire prospectus, as well as the information to which we refer you, before deciding whether to invest in our common stock. You should pay special attention to the "Risk Factors" section of this prospectus to determine whether an investment in our common stock is appropriate for you.

The registration statement of which this prospectus forms a part, including the exhibits and any schedules thereto, contains additional relevant information about us and our securities. With respect to the statements contained in this prospectus regarding the contents of any agreement or any other document, in each instance, the statement is qualified in all respects by the complete text of the agreement or document, a copy of which has been filed or incorporated by reference as an exhibit to the registration statement.

### About Cue Biopharma, Inc.

We are 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. While currently in preclinical development, we believe our CUE Biologics™ platform provides a potentially transformative solution to the challenges facing prevailing immunotherapeutics. By directly engaging and modulating disease relevant T cells in the patient's body, we believe our biologic drug candidates will be able to realize the true potential of immune modulation. Through our proprietary CUE Biologics™ platform, we believe we are uniquely positioned to become a prominent and leading player in immuno-oncology, immunotherapy and autoimmune disease. Our proprietary platform is intended to allow us to efficiently design and develop drug candidates that specifically and selectively engage and modulate disease relevant T cells, providing therapeutic advantages while minimizing or eliminating the unwanted side effects. We have been aggressively seeking patent protection for our pioneering innovations and, combined with a license agreement with the Albert Einstein College of Medicine ("Einstein"), continue to build a robust intellectual property portfolio. This portfolio includes our core technology platform for the engineering of biologics to selectively control T cell activity, which we call CUE Biologics<sup>TM</sup>, a growing portfolio of precision immuno-modulatory drug candidates, and two supporting technologies we call MOD<sup>™</sup> and viraTope<sup>™</sup> that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides, respectively.

### The Immune System, Cancer and Autoimmune Disease

The human immune system comprises a number of specialized cell types which collectively function to identify and defend the body against foreign threats. A 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 through interaction with antigen presenting cells ("APCs"). APCs break down proteins contained in foreign organisms (e.g., bacteria and viruses) or abnormal proteins (e.g., from genetic mutation in cancer cells) into small peptide fragments ("peptides"), also known as T cell epitopes, which are then paired with a class of host molecules called the major histocompatibility complex ("MHC") and displayed on the cell surface. These cell surface proteins are called peptide-MHC ("pMHC") complexes. T cells recognize pMHC complexes through a specialized cell surface receptor, the T cell receptor ("TCR"). The TCR is unique to each T cell and, as a consequence, each T cell is highly specific for a particular pMHC target. Although normally dormant and in limited numbers, T cells bearing specific TCRs can be readily activated and amplified by APCs to generate highly potent T cell responses that involve many millions of T cells. Such activated T cell responses are capable of attacking and clearing viral infections, bacterial infections, and other cellular threats, including tumors. However, cancer cells employ a variety of approaches to escape immune surveillance or to suppress the effects of an immune response. Conversely, the broad, non-specific activation of overly active T cell responses against self or shared antigens can give rise to T cells inappropriately attacking and destroying healthy tissues or cells.

TCR engagement by a particular pMHC delivers an activation signal to the T cell and defines the specificity of the response. However, robust and effective T cell activation requires that the TCR signal be accompanied by additional signals from the APC, collectively referred to as "costimulation." The sum of

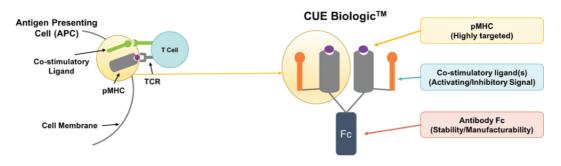
these interactions directs the quality and magnitude of the T cell response. Specific costimulatory signals (activating receptors), as well as coinhibitory signals (inhibitory receptors), may be delivered by the APC to the T cell through specific signaling molecules (ligands) at the interface of these two cells. Communication between APCs and T cells must be capable of precisely identifying threats and generating a response of appropriate quality and magnitude. An insufficient T cell response may result in a persistent pathogenic infection or, in the case of cancer, tumor persistence. Conversely, an excessive or inappropriate T cell response may damage the host acutely (*e.g.*, acute viral hepatitis) or chronically through autoimmune disease (*e.g.*, Type 1 diabetes, celiac disease, rheumatoid arthritis, Graves' disease, etc.).

Immunotherapy aims to therapeutically modify the function of immune cells, such as T cells, either to enhance tumor killing in the context of oncology, or to protect tissue in the context of autoimmune disease. Despite the tremendous promise of these therapies, there are a number of continuing challenges. For example, most currently used cancer immunotherapies rely on non-specific and general activation of T cells or the inhibition of costimulatory pathways (*e.g.*, checkpoint pathway inhibitors), both of which result in the global, non-specific stimulation of T cells. This results in significant toxicity and serious side effects and, in severe cases (*e.g.*, Proleukin<sup>TM</sup> and Yervoy<sup>TM</sup>), fatalities.

### **Our Approach for Next Generation Immunotherapies**

We have developed a proprietary platform for the design and development of biologic drugs for *in vivo* (*e.g.*, directly in the patient's body) T cell based immunotherapy. In the context of cancer, CUE Biologics are being designed to selectively activate T cells which recognize cancer antigens (*e.g.*, peptides) expressed or amplified in cancer cells (tumor antigens or neoantigens). For the treatment of autoimmune diseases such as Type 1 diabetes, celiac disease, arthritis and others, CUE Biologics are designed to selectively dampen disease-causing T cell responses directed against self-antigens.

CUE Biologics are designed to mimic the signals, or "cues", of the immune system to generate highly focused T cell responses associated with disease. We accomplish this by the fusion of unique costimulatory signaling molecules (ligands) with a TCR targeting pMHC complex. This co-engagement of signals through the TCR and costimulatory receptor mimics and recapitulates the very signals delivered by APCs to T cells during an immune response. In this way CUE Biologics allow for the precise targeting of distinct signaling ligands exclusive to the T cell population of interest, resulting in targeted T cell modulation. We call this platform CUE Biologics<sup>™</sup> for the Conditional and Unique Engagement<sup>™</sup> (CUE) of T cells.



### CUE Biologics<sup>TM</sup> are designed to mimic Antigen Presenting Cells ("APCs")

Our therapeutic approach is designed to be administered directly in patients (*in vivo*), which differs markedly from other T cell therapeutic approaches such as adoptive cell therapy ("ACT"), requiring the patients' T cells to be first harvested, then stimulated and expanded outside the body before being reinfused in an activated state. Thus, we believe CUE Biologics represent a breakthrough approach as a disease-specific biologic T cell modulator administered *in vivo* (in body) rather than the *ex vivo* (outside the body) approach deployed by current cellular immune therapies. Furthermore, we believe the desired pharmacological effect in the patients will be more precisely controlled by directly administering CUE Biologics into the patient for selective modulation of disease relevant T cells.

The therapeutic properties and selective nature of Cue Biopharma's drug candidates result from the design and optimization of key functional parameters for a given therapeutic framework. Each framework harbors an MHC and one or more costimulatory element(s) optimized to drive a particular type of T cell response, such as stimulation and expansion of a cytolytic T cell response to kill cancer cells, or specific down-regulation and inhibition in the context of autoimmune disease. The targeting of the framework to specific T cell populations is dependent on the specific peptide linked to the MHC. Notably, more than 75 peptides that are expressed by different solid tumors are currently described in the clinical literature. Thus, after finalizing a therapeutic framework (pMHC-ligand-Fc), we believe different tumors can be addressed by changing the targeting peptide, presenting the promise of greatly reducing the time and cost associated with the generation of new CUE molecules to take forward through IND-enabling studies and, potentially, into the clinic.

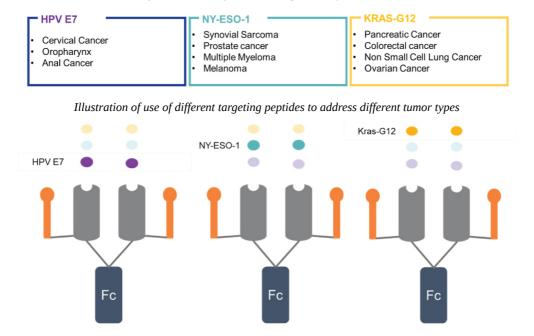


Illustration of use of different targeting peptides to address different indications

Using our CUE Biologics<sup>™</sup> platform, we believe we will be able to design biologics that will have certain advantages over existing immunotherapies. These advantages include increased specificity and reduced toxicity as described below under "Business — Immunotherapy" and greater manufacturability as described below under "Business — Manufacturing CUE Biologics." As such, we believe our approach to designing and developing immuno-modulatory biologics represents a breakthrough, next-generation solution to realizing the promise of T cell based immunotherapies.

### **CUE Biologics™ Drug Candidates**

The relative effectiveness of immunotherapies depends on whether a relevant or optimal therapeutic mechanism to engage the immune system has been addressed by the therapy, and it is likely that different immune stimulatory mechanisms will be required to optimally address certain cancers over others. The versatility of the CUE Biologics<sup>™</sup> platform allows access to multiple distinct mechanisms with a series of biologic frameworks addressing a variety of conditions and requirements. We have currently designed two promising therapeutic frameworks to support distinct and potent mechanisms of T cell activation: our pMHC/IL-2 based CUE-100 series (to enhance overall numbers of tumor specific T cells) and our pMHC/CD80:4-1BBL based CUE-200 series (to reinvigorate exhausted T cells). We expect to be able to

target antigen-specific T cell populations in a variety of indications by a simple peptide exchange into validated CUE Biologics<sup>™</sup> frameworks. We continue to evaluate additional constructs from which we will launch further framework series in both oncology and autoimmunity.

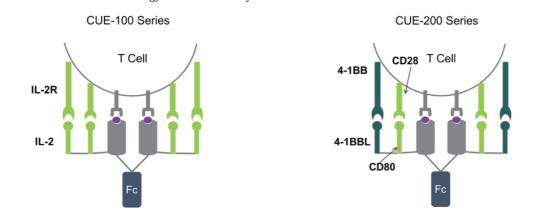
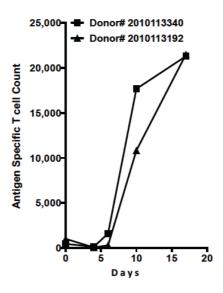
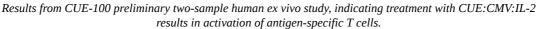
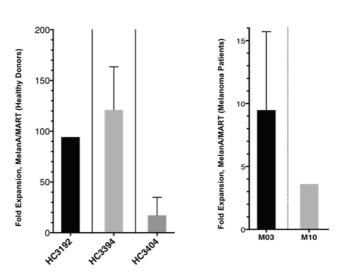


Illustration of CUE-100 and CUE-200 frameworks

In furtherance of our efforts to design and test various frameworks addressing a variety of conditions, we are developing and implementing a complementary *ex vivo* (outside the body) human cancer model assay system for testing and evaluating CUE Biologics<sup>TM</sup> molecules directly in cancer patient-derived T cells. The *ex vivo* assays have the potential to provide a powerful tool for demonstrating human translatability by evaluating preclinical proof of mechanism and proof of concept directly in human samples, as well as for defining relevant metrics and critical parameters informing clinical application(s). Through this assay system, we have recently tested various epitopes (CMV and MelanA/MART, shown below) on the CUE-100 framework to support the versatility and robustness of our CUE Biologics<sup>TM</sup> platform.







Results from CUE-100 human ex vivo study, indicating treatment with CUE-100 (MelanA/MART) results in activation of antigen-specific T cells in healthy donors and melanoma patients as measured by T cell expansion.

As exemplary of our CUE Biologics<sup>™</sup> platform, we continue to develop supporting data surrounding our current lead clinical candidate, CUE-101 (described below) and are utilizing our *ex vivo* assay capabilities to generate data for proof of concept demonstration with potent, tumor antigen-selective T cell activation. The *ex vivo* assays, utilizing clinical samples of peripheral blood mononuclear cells ("PBMCs") for testing and evaluating CUE-101, are expected to provide an informative and representative data set for guiding our assessment with respect to IND filing and clinical development strategy. By titrating drug levels and varying the duration of drug exposure, as well as altering the time of endpoint measurements (PD effect), drug concentration and duration of treatment can be correlated with the magnitude and duration of effects, such as antigen-specific T cell activation, expansion and tumor lysis. In addition to providing potentially insightful data relating to the prospects of antitumor efficacy in patients, the assays also inform the drug exposure range for antitumor activity as well as provide evidence for clinical biomarker selection and the biopsy schedule for clinical proof of mechanism.

### CUE-101

Our current lead drug candidate, CUE-101, uses the pMHC/IL-2 CUE-100 framework, and is a fusion of a variant form of the cytokine Interleukin-2 (IL-2) and a T cell antigen (pMHC) derived from the human papilloma virus E7 protein (HPV-E7). CUE-101 is a single, covalently-assembled biologic designed to target and activate T cells specific to HPV-related cancers. HPV-related cancers are an important unmet clinical need, which account for approximately 24,600 cases of cervical, head and neck, and genitoanal cancers in the United States every year, leading to approximately 9,000 deaths annually. Notably, HPV-driven cancers lead to approximately 225,000 deaths worldwide each year. We believe our drug candidate CUE-101 has the potential to provide patients with a more effective and safer alternative in treating their HPV-driven cancers. While it is our current intention to file an IND for CUE-101 by the end of 2018, we plan to evaluate the completed *ex vivo* data prior to committing to proceed with clinical studies for CUE-101.

While CUE-101 targets the HPV-E7 TCR in cervical/head and neck cancers, we believe our CUE Biologics<sup>™</sup> platform may be used to target a large variety of alternative peptides, which may allow us to address many tumors with high therapeutic need in the oncology patient population. In support of this, we have recently demonstrated highly potent efficacy in preclinical murine models targeting non-viral epitopes. These data, together with the recent human *ex vivo* experiments using a melanoma specific epitope (MelanA/MART, shown above) in both healthy donor and melanoma patient samples, support CUE-100 framework's ability to activate distinct T cell populations via a simple 9 amino acid peptide antigen exchange on an otherwise validated scaffold, which should reduce the time to clinic (and associated costs) of next-generation biologics. We are currently exploring multiple unique epitopes in the context of the CUE-100 series framework in human *ex vivo* assays to help guide prioritization of programs.

### **Extension to Autoimmune Indications**

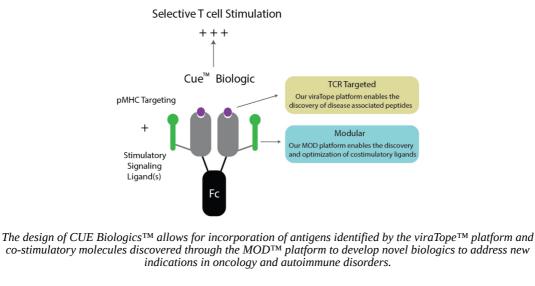
In addition to oncology, we are expanding our technology's reach to generate highly promising and novel immunotherapeutics for the treatment of debilitating autoimmune disorders. Autoimmune indications may be addressed with our technology through two general strategies: (1) depleting disease causing autoreactive T cells by selectively delivering inhibitory signals or (2) by delivering signals to induce and expand regulatory T cells, which subsequently act to inhibit disease-causing T cells (bystander protection).

CUE Biologics<sup>™</sup> 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 CUE Biologics<sup>™</sup> 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. Both pathogenic (*i.e.*, disease causing) and regulatory (disease limiting) CD4 T cell subsets are known to exist in autoimmune disease. Our CUE Biologics<sup>™</sup> frameworks in autoimmunity will therefore be intended to treat autoimmune disease by either depleting pathogenic CD4 T cells or amplifying regulatory CD4 T cell responses to specific disease relevant antigens. Potential autoimmune indications of interest include Type 1 diabetes, arthritis, autoimmune thyroiditis (*e.g.*, Graves' disease), celiac disease and CNS/neurological autoimmune disorders (*e.g.*, multiple sclerosis, Parkinson's disease, etc.).

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 certain of our 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. For further information, see below "Business — Our Collaboration Agreement with Merck".

### **MOD<sup>™</sup>** and viraTope<sup>™</sup> Technology Platforms

Supporting our CUE Biologics<sup>™</sup> platform are two companion discovery platforms: MOD<sup>™</sup>, a costimulatory optimization and discovery platform, and viraTope<sup>™</sup>, a T cell epitope discovery platform, both illustrated below.



We believe that the MOD<sup>™</sup> technology platform has a unique ability to optimize existing costimulatory ligands for use in our biologics as well as discover as yet unknown costimulatory signaling molecules. The MOD<sup>™</sup> platform represents a high throughput method for determining specific cell surface protein-protein interactions (*e.g.*, signaling receptor:ligand pair(s)). In brief, MOD<sup>™</sup> allows for the detection of associations between distinct cell surface query proteins (*i.e.*, ligands) and cell surface expression libraries (*i.e.*, receptors) to first identify molecular engagements and further allows for the mechanistic dissection of complex biochemical function by screening large numbers of mutant molecules. Taken together, we believe that MOD<sup>™</sup> can provide powerful tools to first define novel protein-protein interactions associated with T cell activation. Secondly, MOD<sup>™</sup> is designed to allow us to modulate these signaling ligands through the rapid screening of mutants in order to dissect biochemical function and alter binding properties (*i.e.*, altered affinities and specificities). A key component of our therapeutic design involves decreasing the binding of the costimulatory element while retaining its biological activity (*i.e.*, affinity attenuation). Affinity attenuation allows the pMHC to drive the engagement with the target T cells and limits off-target engagement and associated collateral toxicity.

The viraTope™ platform addresses the historic difficulty of identifying disease associated T cell signatures through the monitoring of complex T cell repertoires. As discussed previously, at the core of the molecular events comprising a T cell-mediated immune response is the engagement of the T cell receptor ("TCR") with a small peptide antigen presented by an MHC molecule, referred to as a T cell epitope. This represents the immune system's targeting mechanism and is a requisite molecular interaction for T cell activation and function, and forms the basis of our targeted immunotherapeutics (i.e., TCR targeting). The viraTope platform is designed to achieve rapid, comprehensive, and quantitative immunomonitoring by interrogating primary T cells with a combinatorial library of pMHC in conjunction with deep sequencing. viraTope's™ libraries would query T cells with all possible mimotopes, leaving cognate pMHC bound to their respective T cells. Deep sequencing of the bound pMHC would comprehensively enumerate all T cell epitopes recognized by a given T cell sample. In this way, viraTope™ could allow the identification of novel epitopes differentially represented in diseased versus control patients and would further make the frequencies of all known and unknown T cell specificities accessible for prospective, in-study, and retrospective analyses of clinical trials. Thus, the ability to systematically identify the entire ensemble of epitopes for a given disease state represents a unique opportunity for the development of diagnostics and highly targeted therapeutics against infectious diseases, autoimmunity and cancers. We believe that viraTope<sup>™</sup> has the ability to comprehensively and quantitatively monitor T cell responses, which could lead to the discovery of novel drug candidates and biomarkers for internal use or to potentially license to strategic partners.

### **Our Business Strategy**

Our primary objective is to become a leading, immunotherapeutics/biopharmaceutical company developing the next generation of highly specific and precisely regulated biotherapeutics. We plan to do this through coordinated and integrated strategic initiatives. Key elements of our strategy include:

- Modular and versatile platform allowing for efficient and rapid drug design, prototyping and optimization. We plan to leverage our CUE Biologics<sup>™</sup> platform's modular capabilities to rapidly and efficiently develop our drug candidates. We believe our platform will provide a highly productive portfolio of promising clinical drug candidates aimed at specifically targeting disease relevant T cells for effective immune modulation. The modular design of our CUE Biologics<sup>™</sup> platform provides the flexibility and versatility to construct drug frameworks comprised of various MOD combinations to elicit novel mechanisms of action. As described above under "Our Approach to Next Generation Immunotherapies," after we establish a successful framework that uses a specific peptide to target a particular disease indication, we expect to be able to use that framework to target additional disease indications by changing the targeting peptide. Therefore, by leveraging the previous work done to establish a framework, we believe we will be able to significantly compress the timeline (by as much as six to twelve months) and capital requirements associated with the development of additional drug candidates.
- Using preclinical data and efficient Phase I clinical study design to accelerate the development *process.* We recently demonstrated through ex vivo assays using human clinical samples that

CUE:IL-2 activates T cells in an antigen specific manner. We plan to continue testing our biologic drug constructs in ex vivo studies with human clinical samples using various cancer relevant epitopes to demonstrate selective activation of T cells specific for various antigens spanning a range of oncology indications. We believe this approach provides meaningful validating data enhancing the quality of our preclinical data package for IND filing. This data also has the potential of increasing the probability for identifying relevant pharmacodynamic ("PD") biomarkers for patient monitoring and as a potential surrogate marker of anti-tumor activity in the clinical setting. Furthermore, we believe these ex vivo studies will supplement and potentially reduce our reliance on preclinical animal models, providing a more cost and time efficient means of testing our drug candidates' activities. Given the urgent medical needs we intend to address with our drug candidates, we are planning to design and conduct our Phase I clinical studies to generate safety data and a clinically meaningful data package around efficacy with the aim of approaching the U.S. Food and Drug Administration (the "FDA") for an accelerated registration study.

Using our process development and protein biochemistry capabilities as a competitive advantage. We anticipate devoting significant resources to optimizing drug design and process development, including protein engineering and optimization, which are key components to maximizing the value of our current and future drug candidates. Through our core competencies and proprietary CUE Biologics<sup>™</sup>, MOD<sup>™</sup> and viraTope<sup>™</sup> technology platforms, we are designing and developing a growing intellectual property portfolio of novel and proprietary immune modulatory biologics. We believe our modular approach to designing biologics, coupled with the protein engineering and optimization capabilities offered by our platform technologies, should enable us to more rapidly and cost-effectively design and optimize potential drug candidates, as compared to more traditional preclinical development processes. Although we have yet to advance any of our drug candidates into the clinic, we believe this efficient preclinical development process positions us well to potentially establish a leading position in the discovery and development of promising next generation immunotherapies.

• Establishing key strategic partnerships with leading pharmaceutical companies. We believe that our CUE Biologics<sup>™</sup> platform offers the promise of enabling us to develop multiple drug candidates that address a variety of potential indications. Accordingly, as we continue to evolve and progress our drug candidates through preclinical and early clinical development, we plan to establish strategic partnerships with leading pharmaceutical or biotechnology organizations, such as our partnership with Merck Sharp & Dohme Corp. ("Merck") pursuant to the Collaboration Agreement described below under "Business — Our Collaboration Agreement with Merck". We believe that this will allow us to further enhance our capabilities and capacities to discover and develop multiple, promising drug candidates for unmet medical needs in oncology and autoimmunity in a highly productive and cost-effective manner.

 Leveraging our relationships with Einstein, our scientific founders and other scientific advisors. Our renowned scientific founders and Einstein, as well as our scientific and clinical advisors ("SAB/CABs"), have a history of seminal, pioneering discoveries and possess significant experience in oncology, immunotherapy, immunology, and biophysics, as well as clinical development. We plan to leverage our scientific founders' and SAB/CABs' scientific and clinical expertise and guidance as we develop our product pipeline and technologies.

### **Risks Related to Our Business**

Our business is subject to a number of risks. You should understand these risks before making an investment decision with respect to the common stock offered hereby. If any of these risks actually occurs, our business, financial condition or results of operations would likely be materially adversely affected. In such case, the value of our common stock would likely decline, and you may lose all or part of your investment. Below is a summary of some of the principal risks we face. The risks are discussed more fully in the section of this prospectus below titled "Risk Factors."

- We are a preclinical stage biopharmaceutical company, have no history of generating revenue, have a history of operating losses, and we may never achieve or maintain profitability. Furthermore, our independent registered public accounting firm, in its report on our financial statements for the year ended December 31, 2016, has raised substantial doubt about our ability to continue as a going concern.
- We currently do not have, and may never develop, any FDA-approved or commercialized products.
- We have no history of conducting clinical trials or commercializing biotechnology products, which
  may make it difficult to evaluate the prospects for the future viability of our business or any of our
  potential products.
- Results and data from our preclinical studies may not be predictive or indicative of results in current ongoing preclinical studies or potential future clinical trials. A failure of a preclinical study or clinical trial can occur at any stage of testing.
- We expect to pursue strategic partnerships and collaborations with third parties that we cannot control, including leading pharmaceutical or biotechnology organizations, to develop, manufacture, commercialize and distribute our potential products. If we are unable to form these relationships, or if these relationships are unsuccessful, our business will be materially harmed.
- Our potential products, development activities, manufacturing and distribution will be subject to extensive and rigorous regulation by numerous agencies, including the FDA and other governmental agencies, both in the United States and overseas. Our potential products will not be viable if we are unable to receive approvals from these agencies or comply with their regulations.
- We face significant competition from other biotechnology and pharmaceutical companies, most of which are larger and have greater access to resources than we do, and our operating results will suffer if we fail to compete effectively.
- If we or our licensor are unable to preserve and protect our/its intellectual property rights, then our financial condition, results of operations and the value of our technology and potential products (and the value of our common stock) could be adversely affected. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not currently own issued patents covering all of the recent developments in our technology and we are unsure of the extent to which we will obtain adequate patent protection, if any.
- We will 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 of or commercialize our planned product candidates.
- We will need capital beyond the net proceeds we expect to receive from this offering to support our growth and ongoing business operations. Additional capital may be difficult to obtain, restrict our operations, require us to relinquish rights to our technologies or product candidates, or result in substantial dilution to our stockholders. As described below in "Use of Proceeds," we believe the proceeds from this offering will be sufficient for us to be able to initiate the Phase I trial for our lead drug candidate. However, we will require additional funds to implement the balance of our business plan thereafter.
- Concentration of ownership among our existing executive officers, directors and significant stockholders may prevent other investors from influencing significant corporate decisions.
- As an investor, you may lose a portion or all of your investment in the Company.

### 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.

### THE OFFERING

The following summary contains basic information about our initial public offering and our common stock and is not intended to be complete. It does not contain all of the information that may be important to you. For a more complete understanding of our common stock, please refer to the section of this prospectus titled "Description of Capital Stock."

Issuer	Cue Biopharma, Inc., a Delaware corporation.
Securities Offered	5,333,334 shares of common stock (minimum) up to 8,000,000 shares of common stock (maximum), or a minimum of approximately \$40,000,000 of common stock and a maximum of \$60,000,000 of common stock.
Best Efforts Offering	The underwriters are selling the shares of our common stock offered in this prospectus on a "best efforts" basis and are not required to sell any specific number or dollar amount of the shares offered by this prospectus, but will use their best efforts to sell such shares. We do not intend to close this offering unless we sell a minimum of \$40,000,000 of common stock.
Common Stock Outstanding Prior To This Offering	10,635,684 shares of common stock. <sup>(1)</sup>
Initial Public Offering Price	\$7.50 per share.
Common Stock Outstanding After	• · · · · F · · · · · ·
This Offering	16,640,590 shares of common stock (if the minimum amount of common stock is sold) or 19,307,256 shares of common stock (if the maximum amount of common stock is sold). <sup><math>(1)(2)</math></sup>
Use of Proceeds	We intend to use the net proceeds from this offering primarily for ongoing research and development activities for our drug product candidates and platform technologies, IND-enabling studies, Chemistry, Manufacturing and Controls ("CMC") drug manufacturing, IND filing, initiating clinical studies, purchasing necessary equipment and other research-related purchases, salaries for current and new personnel, as well as for general corporate and working capital purposes including patent portfolio development and maintenance costs. See the section of this prospectus titled "Use of Proceeds" for additional information. However, this is a best efforts offering and, in the event that the minimum amount of common stock is not sold and all funds are returned to purchasers, we will not sell any shares or receive any proceeds.
Escrow	The gross proceeds of this offering will be deposited at JP Morgan Chase, in an escrow account established by us. The funds will be held in escrow until \$40,000,000 of gross proceeds from the offering has been received and we otherwise satisfy the listing conditions to trade our common stock on the Nasdaq Capital Market, at which time the funds will be released to us. Any funds received in excess of \$40,000,000 and up to \$60,000,000 will immediately be available to us, after deducting the applicable underwriting commissions. If the minimum amount of \$40,000,000 has not been received by , 2017 (30 days after the date of this prospectus) (the "Initial Offering Termination Date"), which date may be extended to a date up to and including , 2018 (the "Offering Termination Date"), all funds will be returned to purchasers in this offering on the next business day after the offering's

	termination, without charge, deduction or interest. Prior to , 2017, in no event will funds be returned to you, unless we elect, at our option, to terminate the offering. In the event we decide to extend the offering period beyond the Initial Offering Termination Date, we will seek reconfirmations from investors who have deposited funds into the escrow account and all funds deposited by investors who do not reconfirm will be promptly returned without interest or offset. Except as described in the preceding sentence, you will only be entitled to receive a refund of your subscription if we do not raise a minimum of \$40,000,000 and satisfy the Nasdaq listing conditions by the Offering Termination Date, or if we terminate the offering before such date.
Market And Trading Symbol For The Common Stock	There is currently no market for our common stock. We have applied to list our common stock on the Nasdaq Capital Market under the symbol "CUE". No assurance can be given that our application will be approved. If our application is not approved or we otherwise determine that we will not be able to secure the listing of our common stock on the Nasdaq Capital Market, we will not complete this offering.
Underwriter's Warrant to Purchase Common Stock	In connection with this offering, we have also agreed to sell to MDB Capital Group, LLC, or MDB, a warrant to purchase common stock in an amount up to 10% of the shares sold in this offering. If this warrant is exercised, each share may be purchased by MDB at a per share exercise price equal to 125% of the price of the shares sold in this offering. This warrant will have a five-year term and be subject to a six-month lock-up. See "Underwriting (Conflicts of Interest)" for additional information.
Issuance of Shares To Einstein	Pursuant to the terms of our license agreement with Albert Einstein College of Medicine ("Einstein"), immediately prior to the consummation of this offering we are required to issue to Einstein 671,572 shares of our common stock.
Risk Factors	An investment in our common stock offered hereby is speculative and involves a high degree of risk. The Company and its business are subject to numerous risks, including, among others, those associated with development of the Company's planned product candidates, technology development, the ability of the Company to obtain additional funds, and those associated with new business enterprises. See the section titled "Risk Factors" elsewhere in this prospectus.
Conflicts of Interest	Because MDB and its associated persons collectively, beneficially hold 2,233,000 shares of our common stock, representing 21.0% of the outstanding shares prior to this offering, MDB is deemed to be an affiliate of the Company and to have a "conflict of interest" under Rule 5121 of Financial Industry Regulatory Authority Inc. Accordingly, this offering will be made in compliance with the applicable provisions of Rule 5121. The rule requires that a "qualified independent underwriter" meeting certain standards participate in the preparation of the registration statement and prospectus and exercise the usual

standards of due diligence with respect thereto. Feltl and Company, Inc. ("Feltl") has agreed to act as a "qualified independent underwriter" within the meaning of Rule 5121 in connection with this offering. For more information, please see the section titled "Underwriting (Conflicts of Interest)" in the prospectus.

(1) The number of shares of our common stock outstanding both before and after this offering is based on the number of shares outstanding as of September 30, 2017 and excludes:

 2,366,221 shares of our common stock reserved for issuance under stock option agreements issued pursuant to our 2016 Omnibus Incentive Plan and 2016 Non-Employee Equity Incentive Plan at a weighted average exercise price of \$3.50 per share;

- 370,370 shares of common stock reserved for issuance under outstanding warrants at a weighted average exercise price of \$2.70 per share;
- 803,779 shares of our common stock reserved for future issuance under our 2016 Omnibus Incentive Plan (for further information, see "Description of Capital Stock — Stock Options and Warrants" below);
- 130,000 shares of our common stock reserved for future issuance under our 2016 Non-Employee Equity Incentive Plan; and
- shares of our common stock issuable upon exercise of the warrant to be issued to the underwriter.
- (2) The number of shares of our common stock to be outstanding after this offering includes shares of common stock that will be issued in this offering and 671,572 shares of our common stock issuable to Einstein immediately prior to the consummation of this offering pursuant to our license agreement with Einstein.

### SUMMARY SELECTED FINANCIAL INFORMATION

The following selected financial and other data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the Company's audited and unaudited financial statements and related notes, which are included elsewhere in this prospectus. The Company has derived the selected statement of operations data for the years ended December 31, 2016 and 2015 and the selected balance sheet data as of December 31, 2016 and 2015 from its audited financial statements included elsewhere in this prospectus. The Company has derived the selected unaudited statement of operations data for the nine months ended September 30, 2017 and 2016 and the selected unaudited balance sheet data as of September 30, 2017 from its unaudited interim financial statements included elsewhere in this prospectus. The Company has included all adjustments, including normal recurring accruals, which it considers necessary for a fair presentation of the financial information set forth in the unaudited interim financial statements. The Company's historical results are not necessarily indicative of the results to be expected in future periods, and the Company's interim results are not necessarily indicative of the results to be expected for the full fiscal year.

### **Statement of Operations Data:**

	Year Ended December 31,			Nine Months Ended September 30,								
	2016 2015		2017		2016							
				(Una		(Unau		(Unaudited)		(Unaudited)		audited)
Revenue	\$		\$		\$		\$					
Operating expenses:												
General and administrative	1,	970,488		425,081	2	,914,452	1,	193,527				
Research and development	5,	687,847	1,	,503,649	9	,880,529	3,	622,409				
Total operating expenses	7,	658,335	1,	,928,730	12	,794,981	4,	815,936				
Loss from operations	(7,	658,335)	(1,	,928,730)	(12	,794,981)	(4,	815,936)				
Interest income		52						52				
Net loss	\$(7,	658,283)	<b>\$(1</b> ,	,928,730)	\$(12	,794,981)	\$(4,	815,884)				
Net loss per common share – basic and diluted	\$	(1.03)	\$	(0.34)	\$	(1.20)	\$	(0.65)				
Weighted average common shares outstanding – basic and diluted	7,	433,433	5,	,658,282	10	,635,684	7,	352,704				

### **Balance Sheet Data:**

	Deceml	September 30, 2017	
	2016 2015		
			(Unaudited)
Cash	\$14,925,820	\$6,405,207	\$3,400,481
Certificate of deposit	50,033	50,000	50,033
Working capital	14,070,638	6,164,449	2,215,871
Total assets	16,278,617	7,314,626	6,295.430
Total stockholders' equity	15,174,640	6,938,331	4,380,690

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND OTHER INFORMATION CONTAINED IN THIS PROSPECTUS

This prospectus contains forward-looking statements. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. You can find many (but not all) of these statements by looking for words such as "approximates," "believes," "hopes," "expects," "anticipates," "estimates," "projects," "intends," "plans," "would," "should," "could," "may" or other similar expressions in this prospectus. These statements may be found under the sections of this prospectus captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" included in this prospectus, as well as in this prospectus generally. In particular, these include statements relating to future actions, prospective products, applications, customers, technologies, future performance or results of anticipated products, expenses, and financial results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our historical experience and our present expectations or projections. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to:

- our limited operating history, limited cash and a history of losses;
- our ability to achieve profitability;
- our ability to secure required FDA or other governmental approvals for our product candidates and the breadth of the indication sought;
- the impact of competitive or alternative products, technologies and pricing;
- whether we are successful in developing and commercializing our technology, including through licensing;
- the adequacy of protections afforded to us and/or our licensor by the anticipated patents that we own or license and the cost to us of maintaining, enforcing and defending those patents;
- our and our licensor's ability to protect non-patented intellectual property rights;
- our exposure to and ability to defend third-party claims and challenges to our and our licensor's anticipated patents and other intellectual property rights;
- our ability to obtain adequate financing to fund our business operations in the future;
- our ability to continue as a going concern; and
- other factors discussed in the "Risk Factors" section of this prospectus.

The forward-looking statements are based upon management's beliefs and assumptions and are made as of the date of this prospectus. We undertake no obligation to publicly update or revise any forward-looking statements included in this prospectus or to update the reasons why actual results could differ from those contained in such statements, whether as a result of new information, future events or otherwise, except to the extent required by federal securities laws. Actual future results may vary materially as a result of various factors, including, without limitation, the risks outlined under the section of this prospectus captioned "Risk Factors" and matters described in this prospectus generally. In light of these risks and uncertainties, we cannot assure you that the forward-looking statements contained in this prospectus will in fact occur. You should not place undue reliance on these forward-looking statements.

### **RISK FACTORS**

We are subject to various risks that may materially harm our business, prospects, financial condition and results of operations. An investment in our common stock is speculative and involves a high degree of risk. In evaluating an investment in of our shares of our common stock, you should carefully consider the risks described below, together with the other information included in this prospectus.

If any of the events described in the following risk factors actually occurs, or if additional risks and uncertainties that are not presently known to us or that we currently deem immaterial later materialize, then our business, prospects, results of operations and financial condition could be materially adversely affected. In that event, the trading price of our common stock could decline, and you may lose part or all of your investment in our shares. The risks discussed below include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements. See "Special Note Regarding Forward-Looking Statements and Other Information Contained in this Prospectus."

### **Risks Related to Our Business**

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

We are a preclinical stage biopharmaceutical company. We have a limited operating history and only a preliminary business plan upon which investors may evaluate our prospects. We have never generated revenues and have a history of losses from operations. As of September 30, 2017, we had an accumulated deficit of approximately \$22.4 million. Even assuming the sale of the common stock in this offering, without additional capital our existing cash and cash equivalents will be insufficient to fully fund our business plan and the development of our planned product candidates. Our ability to achieve 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 revenues or achieve profitability.

Our independent registered public accounting firm, in its report on our financial statements for the year ended December 31, 2016, has raised substantial doubt about our ability to continue as a going concern.

#### 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 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 Albert Einstein College of Medicine ("Einstein") (described in more detail elsewhere in this prospectus) 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 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 or preclinical trials 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;
- our future products 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; and
- rapid technological change may make our technology and future products obsolete.

## 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.

We have product candidates in our oncology preclinical development pipeline, but 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 no history of conducting clinical trials or commercializing biotechnology 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. Although we have recruited a team that has experience with clinical trials in the United States, as a company, we have no experience conducting clinical trials in any jurisdiction and have not had previous experience commercializing product candidates or submitting an investigational new drug application ("IND") or a Biologics License Application to the FDA or similar submissions to initiate clinical trials or obtain marketing authorization to foreign regulatory authorities. We cannot be certain that planned clinical trials will begin or be completed on time, if at all, 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, 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;
- 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.

# We have never dosed any of our product candidates in humans. Our 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 product candidates, we must demonstrate the safety 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 not yet initiated any clinical trials or dosed any of our product candidates in humans. 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 early stage 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.

### 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 a collaboration agreement with Merck under which Merck will partner with us in the development of our CUE Biologics<sup>™</sup> targeting certain autoimmune diseases. Pursuant to the collaboration agreement, Merck will acquire rights to develop, commercialize and sell CUE Biologics<sup>™</sup> 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. This agreement does not commit Merck to a long-term relationship and it may disengage with us at any time upon 30 days' notice.

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 and efficacy. If we are unable to establish additional strategic partnerships or other alternative arrangements to develop our drug candidates, the costs for us to independently develop our drug 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 agreement with Merck contains exclusivity and forbearance provisions that restrict our research and development activities.

On November 14, 2017, we entered into an Exclusive Patent License and Research Collaboration Agreement (the "Collaboration Agreement") with Merck for a partnership to research and develop certain of our proprietary biologics that target certain autoimmune disease indications (the "Initial Indications"). For the purposes of this collaboration, we have granted to Merck under the Collaboration 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 CUE Biologics<sup>™</sup> that are elected to be developed by Merck. From the effective date of the Collaboration Agreement until the earlier of (i) the first achievement of demonstration of certain biologically relevant effects for a Cue Biologic<sup>™</sup> drug candidate ("Proof of Mechanism") or (ii) 18 months after we notify the joint steering committee that the first product candidate has been synthesized under the research program, we are required to forebear from researching, developing or licensing to a third party rights related to any CUE Biologics<sup>™</sup> drug candidate for the treatment of autoimmune diseases other than pursuant to the Collaboration Agreement. In addition, so long as Merck

continues product development on a CUE Biologics<sup>™</sup> drug candidate that has demonstrated Proof of Mechanism (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 Collaboration Agreement. These restrictions on our development activities could impact our ability to successfully develop drug candidates for the Initial Indications, which could harm our future business prospects for commercializing drugs for those Initial Indications.

## 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 technologies, CUE Biologics<sup>™</sup>, MOD<sup>™</sup>, and viraTope<sup>™</sup>, may not adequately enable us to design, discover and validate drug 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, 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.

In the field of immunotherapeutics, we will face significant competition from other companies, many of which have greater resources than we have. Immunotherapy technologies are advancing at a rapid pace and we anticipate competing with the largest pharmaceutical companies in the world, such as F. Hoffman-La Roche AG (Roche), Novartis A.G., Johnson & Johnson, Bristol-Myers Squibb and Merck & Co, as well as smaller biopharmaceutical companies like Acceleron Pharma, Inc., Five Prime Therapeutics, Inc., Juno Therapeutics, Inc., Kite Pharma, Inc., Apitope International N.V., Seattle Genetics, Inc., Immatics Biotechnologies GmbH, Sutro Biopharma, Inc., ImmunoGen, Inc., Zyngenia, Inc., Immunocore Limited, and Covagen A.G., which are all currently conducting research in immunotherapeutics and all of which have greater financial and human 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.

For additional information regarding our competition, see the section of this prospectus captioned "*Business* — *Competition*."

## 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 President and Chief Executive Officer, Ronald Seidel, Ph.D., our Executive VP of Research and Development, Rodolfo Chaparro, Ph.D., our Executive VP of Immunology, and other members of our scientific and clinical advisory team, including Steven Almo, Ph.D., the Chairman of our Scientific and Clinical Advisory Board. We intend to hire additional key scientific and management employees and expand our board of directors and Scientific and Clinical Advisory Board following this offering. 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 provided stock options 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 and unauthorized access. 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.

### **Risks Related to Intellectual Property and Other Legal Matters**

### If we or our licensor are unable to protect our/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 anticipated 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.

For additional information regarding our license agreement with Einstein, see the section of this prospectus captioned "*Business* — *Our License Agreement with Einstein*."

### If we are unable to patent 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. We own or have licensed 14 pending patent applications in the United States (including 11 pending U.S. provisional patent applications), four pending international PCT applications and 33 pending foreign patent applications intended to protect the intellectual property underlying our technology. Our patent applications describe certain features of our technologies, including our CUE Biologics<sup>TM</sup> platform and specific biologic molecules and drug candidates, viraTope<sup>TM</sup>, MOD<sup>TM</sup> screening, MOD<sup>TM</sup> variants and MOD<sup>TM</sup> combinations. 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 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 anticipated 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 anticipated 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.

## 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 therapeutic and drug 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 or clearance 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, repairs or replacements of our potential products;
- require design changes 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 noncompliance 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, repair, replacement, or refund of purchases 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 status or breakthrough therapy designation for one or more of our product candidates, but even if either is granted, we may be unable to maintain any benefits associated with orphan drug status or breakthrough therapy 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 Biologics License Application, 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. In 2012, the FDA established a Breakthrough Therapy Designation which is intended to expedite the development and review of products that treat serious or life-threatening conditions.

We may seek orphan drug status for one or more of our products candidates, but the FDA may not approve any such request. Even if the FDA grants orphan drug status 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 status 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, 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. In addition, others may obtain orphan drug status 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 for our drug product candidates. Even if received, fast-track designation may not actually lead to a faster review process.

We aim to benefit from the FDA's fast track and accelerated approval processes. However, our drug product candidates may not receive an FDA fast-track designation or priority review. Without fast-track designation, submitting a new drug application, or NDA, 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 NDA 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 NDA 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. Under the FDA policies, a drug candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast-track designated drug candidate would ordinarily meet the FDA's criteria for priority review.

The fast-track designation for our drug product candidates, if 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 drug 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 classification 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 processes, 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 current good clinical practices ("cGCPs") 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 processes, 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 filed 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.

## Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives could harm our business in the future.

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.

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 and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

A primary 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. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. 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.

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

## The best efforts structure of this offering may yield insufficient gross proceeds to fully execute our business plan.

The underwriters are offering shares of our common stock in this offering on a best efforts basis. The underwriters are not required to sell any specific number or dollar amount of common stock, but will use their best efforts to sell the shares offered by us. It is a condition of this offering that the minimum amount of gross proceeds of \$40,000,000 be received by , 2017 (30 days after the date of this prospectus). As a "best efforts" offering, there can be no assurance that the offering contemplated by this prospectus will successfully raise this minimum amount or that the offering will ultimately be completed or will result in any proceeds being made available to us.

### 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 revenues until we successfully complete development of our first potential products and we are able to successfully commercialize them through sales and licensing. As of the date of this prospectus, our technology is still in development and products are only proposed.

We have not yet demonstrated our ability to generate revenue, and we may never be able to produce 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.

Our independent registered public accounting firm, in its report on our financial statements for the year ended December 31, 2016, has raised substantial doubt about our ability to continue as a going concern.

# We will need additional capital beyond this offering 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.

Our independent registered accounting firm, in its report on our financial statements for the year ended December 31, 2016, has also raised substantial doubt about our ability to continue as a going concern.

#### As an investor, you may lose a portion or all of your investment.

Investing in our common stock involves a high degree of risk. As an investor, you may never recoup all, or even part, of your investment and you may never realize any return on your investment. You must be prepared to lose all of your investment.

## Prior to the completion of this offering, there has been no public trading market for our common stock. An active public trading market for our common stock may not develop and our common stock may trade below the public offering price.

The offering under this prospectus is an initial public offering of our securities. Prior to the closing of the offering, there has been no public market for our common stock. While we have applied to list our common stock on the Nasdaq Capital Market ("Nasdaq"), we cannot assure you that our application will be approved or, if approved, that an active public market for our common stock will develop. Additionally,



approval of our shares of common stock to be listed on Nasdaq is a closing condition of this offering under our agreement with the underwriters. If our application is not approved or we otherwise determine that we will not be able to secure the listing of our common stock on the Nasdaq Capital Market, we will not complete this offering.

If an active trading market for our common stock does not develop after this offering, the market price and liquidity of our common stock may be materially and adversely affected. The public offering price for our common stock has been determined by negotiation among us and the underwriter based upon several factors, and the price at which our common stock trades after this offering may decline below the public offering price. Investors in our common stock may experience a significant decrease in the value of their common stock regardless of our operating performance or prospects. If we are unable to develop a market for our common stock after this offering, you may not be able to sell your common stock at prices you consider to be fair or at times that are convenient for you, or at all.

## Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock.

If, after listing, we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

## 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, although we will lose that status sooner if our revenues exceed \$1 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.

## If a public market for our common stock develops, it may be volatile. This may affect the ability of our investors to sell their shares as well as the price at which they sell their shares.

If a market for our common stock develops, the market price for the shares may be significantly affected by factors such as variations in quarterly and yearly operating results, general trends in the biopharmaceutical industry, and changes in state or federal regulations affecting us and our industry. Furthermore, in recent years the stock market has experienced extreme price and volume fluctuations that are unrelated or disproportionate to the operating performance of the affected companies. Such broad market fluctuations may adversely affect the market price of our common stock, if a market for it develops.

In addition to market and industry factors, the price and trading volume for our common stock may be highly volatile for specific business reasons, including:

- announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- any adverse changes to our relationship with manufacturers or suppliers;
- results of our testing and clinical trials;
- results of our efforts to acquire or license additional product candidates;
- 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;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- variations in our results of operations;
- publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts;
- changes in financial estimates by securities research analysts;
- 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;
- general economic and market conditions and overall fluctuations in the U.S. equity markets; and
- changes in accounting principles.

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.



## Assuming a market for our common stock develops, shares eligible for future sale may adversely affect the market for our common stock.

Commencing on the 90<sup>th</sup> day following the close of this offering, certain of our current stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations and lock-up agreements. In general, pursuant to Rule 144, non-affiliate stockholders may sell freely after six months subject only to the current public information requirement (which disappears after one year). Of the 16,640,590 shares of our common stock expected to be outstanding following completion of the offering (if the minimum amount of common stock is sold), 4,360,572 shares will be freely tradable without restriction pursuant to Rule 144 following the expiration of the 12-month lock-up agreed by those stockholders, 3,703,704 shares will be freely tradable without restriction pursuant to Rule 144 following the expiration of the 180-day lock-up previously agreed to by those stockholders and 3,242,980 shares will be freely tradable without restriction pursuant to Rule 144 following the expiration of the expiration of the 90-day lock-up previously agreed to by those stockholders.

In addition, in connection with the June 2015 and December 2016 private placements, we have granted piggyback and demand registration rights in respect of 6,986,684 shares of common stock. These rights commence on the six-month anniversary of the completion of this offering. We have also granted piggyback and demand registration rights to MDB for the 370,370 shares of common stock underlying the warrant issued as compensation for the June 2015 private placement. These rights commence six months after the consummation of this offering, subject to a six-month lock up.

Under our license agreement with Einstein, we must also use our best efforts to file a registration statement covering the resale of the 671,572 shares to be issued to Einstein immediately prior to this offering no later than 180 days after the consummation of the offering.

Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus (including sales by investors of securities acquired in connection with this offering) may have a material adverse effect on the market price of our common stock.

#### 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. Therefore, you should not expect to receive cash dividends on the common stock we are offering.

### Concentration of ownership among our existing executive officers, directors and significant stockholders may prevent new investors from influencing significant corporate decisions.

All decisions with respect to the management of the company will be made by our board of directors and our officers, who, before this offering, beneficially own approximately 28.9% of our common stock (including shares directly owned by MDB that may be deemed to be beneficially owned by certain directors and any securities of which such directors and officers have the right to acquire beneficial ownership within 60 days pursuant to options, warrants, conversion privileges or similar rights). After the issuance of our common stock in this offering, management will beneficially own at least approximately 18.8% of our common stock if the minimum amount of common stock is sold, or 16.3% of our common stock if the maximum amount of common stock is sold. In addition, before this offering, MDB and its affiliates, including its employees who are also officers or directors of the Company, beneficially own approximately 23.6% of our common stock (taking into account warrants currently exercisable for our common stock) and after this offering will beneficially own at least approximately 17.9% of our common stock if the minimum amount of common stock is sold, or 16.6% of our common stock is sold (which amounts take into account the warrant in an amount equal to 10% of the shares of common stock sold in this offering to be issued to MDB in connection with this offering). Furthermore, three of the seven members of our board of directors are also employees of MDB. As a



result, these stockholders will be able to exercise a significant level of control over all matters requiring stockholder approval, including the election of directors, amendment of our certificate of incorporation and approval of significant corporate transactions. This control could have the effect of delaying or preventing a change of control of the company or changes in management, in each case, which other stockholders might find favorable, and will make the approval of certain transactions difficult or impossible without the support of these significant stockholders.

## MDB and its affiliates collectively beneficially own more than 10% of our outstanding common stock and have an interest in this offering beyond customary underwriting commissions.

Because MDB and its affiliates collectively beneficially own more than 10% of our outstanding common stock, MDB is deemed to be an affiliate of the Company and to have a "conflict of interest" under Rule 5121 of Financial Industry Regulatory Authority Inc. Accordingly, this offering will be made in compliance with the applicable provisions of Rule 5121. The rule requires that a "qualified independent underwriter" meeting certain standards participate in the preparation of the registration statement and prospectus and exercise the usual standards of due diligence with respect thereto. Feltl has agreed to act as a "qualified independent underwriter" within the meaning of Rule 5121 in connection with this offering. Feltl will receive \$275,000 for serving as a qualified independent underwriter in connection with this offering. In its role as qualified independent underwriter, Feltl has participated in due diligence and the preparation of this prospectus and the registration statement of which this prospectus forms a part. Although Feltl has, in its capacity as qualified independent underwriter, participated in due diligence and the preparation of this prospectus and the registration statement of which this prospectus forms a part, we cannot assure you that this will adequately address all potential conflicts of interest. We have agreed to indemnify Feltl against liabilities incurred in connection with acting as qualified independent underwriter, including liabilities under the Securities Act. In accordance with Rule 5121, MDB will not sell shares of our common stock to a discretionary account without the prior written approval from the account holder. See the section of this prospectus captioned "Underwriting (Conflicts of Interest)" for additional information.

# We will incur significant increased costs as a result of becoming a public company that reports to the Securities and Exchange Commission ("SEC") and our management will be required to devote substantial time to meet compliance obligations.

Once we are a public company listed in the United States upon the closing of this offering, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to reporting requirements of the Exchange Act and the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and Nasdaq that impose significant requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. In addition, on July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that are expected to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. In addition, these rules and regulations may 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.

# We may allocate the net proceeds from this offering in ways that differ from the estimates discussed in the section titled "Use of Proceeds" and with which you may not agree, and if we do not use those proceeds effectively your investment could be harmed.

The allocation of net proceeds of this offering set forth in the section of this prospectus captioned "Use of Proceeds" represents our estimates based upon our current plans and assumptions regarding industry and general economic conditions, and our future revenues and expenditures. The amounts and timing of our actual expenditures will depend on numerous factors, including market conditions, cash

generated by our operations, business developments and related rate of growth. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes. Circumstances may give rise to a change in the use of proceeds. You may not have an opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use our proceeds. As a result, you and other stockholders may not agree with our decisions. If we do not use the net proceeds that we receive in this offering effectively, our business, results of operations and financial condition could be harmed. See the section of this prospectus captioned "Use of Proceeds" for additional information.

#### You will experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered is substantially higher than the book value per share of our common stock, you will experience substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the offering price of \$7.50 per share, if you purchase shares of common stock in this offering, you will experience immediate and substantial dilution of \$5.03 per share if the minimum amount of common stock is sold and \$4.39 per share if the maximum amount of common stock is sold, in the net tangible book value of the common stock at September 30, 2017. See the section of this prospectus captioned "Dilution" for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

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

Effective upon the closing of this offering, 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, once we become a publicly traded corporation, 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. See the section of this prospectus captioned "Description of Capital Stock — Anti-Takeover Effects of Certain Provisions of Delaware Law and Our Charter Documents" for additional information.

# Our Certificate of Incorporation will provide, 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 amended and restated certificate of incorporation will provide, 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 amended and restated certificate of incorporation or our amended and restated 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.

#### Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures will be designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified by the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Currently we have identified a material weakness in our internal control over financial reporting. The material weakness related to a lack of effective controls to adequately restrict access and segregation of duties, specifically due to the limited number of staff in our accounting function. Upon identifying this material weakness, we performed additional procedures and believe the material weakness did not result in any material misstatements in our financial statements. However, this material weakness could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected. We are in the process of designing and implementing our internal control over financial reporting, which process will be time consuming, costly and complicated. However, we are a small organization with limited management resources. In addition to serving as our interim Chief Financial Officer, Gary Schuman is the Chief Financial Officer and Chief Compliance Officer of MDB, an underwriter of this offering. This other commitment may prevent Mr. Schuman from dedicating sufficient time and attention to us, which could limit our ability to maintain effective internal controls over financial reporting.

Until such time as we are no longer an "emerging growth company," as defined in the JOBS Act, our auditors will not be required to attest as to our internal control over financial reporting. If we continue to identify material weaknesses in 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, if our independent registered public accounting firm is unable to attest that our internal control over financial reporting is effective, 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.

#### **USE OF PROCEEDS**

Based on an initial public offering price of \$7.50 per share, we estimate that the net proceeds from our sale of shares of common stock in this offering, after deducting estimated underwriting commissions and estimated offering expenses, will be approximately \$36,875,000 if we sell the minimum of \$40,000,000 of common stock or \$55,825,000 if we sell all \$60,000,000 of common stock in this offering. However, this is a best efforts offering and, in the event that the minimum amount of common stock is not sold and all funds are returned to purchasers, we will not sell any shares or receive any proceeds.

We intend to use the net proceeds from this offering to fund:

- \$27 million to \$29 million, if we sell the minimum of \$40,000,000 of common stock, or \$44 million to \$46 million, if we sell the maximum of \$60,000,000 of common stock, of ongoing research and development of our drug candidates and platform technologies including, but not limited to, investigational new drug application ("IND") enabling studies, CMC drug manufacturing, IND filing, initiating clinical studies, purchasing necessary equipment and other research-related purchases, salaries for current and new personnel; and
- \$5 million to \$7 million, if we sell the minimum of \$40,000,000 of common stock, or \$8 million to \$10 million, if we sell the maximum of \$60,000,000 of common stock, of general corporate purposes, including patent portfolio development and maintenance costs, working capital, business development, administrative support services, hiring of additional personnel and the costs of operating as a public company.

We believe that the net proceeds from this offering will be sufficient to allow us to:

- complete IND-enabling studies for our lead product candidate, file such IND and initiate the Phase I trial for that candidate;
- identify, optimize and nominate one additional drug candidate for immuno-oncology;
- optimize drug scaffold for the treatment of autoimmune indications through the generation of T regulatory cells *in vivo*; and
- continue to advance our drug discovery platform technologies, including funding to proof of concept of viraTope<sup>™</sup>, our T cell epitope discovery platform.

The amounts that we actually spend for any specific purpose may vary significantly and will depend on a number of factors including, but not limited to, the pace of progress of our research and development efforts, unexpected difficulties arising in the process of protecting our intellectual property, market conditions, changes in or revisions to our marketing strategies and the number of shares of common stock sold in this offering. In addition, we may use a portion of any net proceeds to acquire complementary products, technologies or businesses; however, we do not have plans for any acquisitions at this time. We will have significant discretion in the use of any net proceeds. Investors will be relying on the judgment of our management regarding the application of the proceeds of any sale of our common stock.

Pending our use of the net proceeds from this offering, we plan to invest our net proceeds from this offering in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States government.

We believe that the net proceeds from this offering (assuming that at least the minimum amount of common stock offered is sold), combined with our existing cash resources, will be sufficient to fund our projected operating requirements into and possibly through the second half of 2018. However, the expected net proceeds from this offering are not expected to be sufficient for us to complete the development and commercialization of any of our drug candidates or platform technologies. Until we are able to generate sustainable revenues that generate a profit, we expect to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. However, there can be no assurances that we will be able to obtain additional financing on acceptable terms and in the amounts necessary to fully fund our future operating requirements.

#### CAPITALIZATION

The following table sets forth our actual cash and cash equivalents and capitalization, each as of September 30, 2017:

- on an actual basis;
- on a pro forma basis to give effect to the sale of the minimum of \$40,000,000 of our common stock in this offering and 671,572 shares of our common stock issuable to Einstein immediately prior to the consummation of this offering and charged to research and development expenses in the statement of operations; and
- on a pro forma basis to give effect to the sale of the maximum of \$60,000,000 of our common stock in this offering and 671,572 shares of our common stock issuable to Einstein immediately prior to the consummation of this offering and charged to research and development expenses in the statement of operations.

You should consider this table in conjunction with our financial statements and the notes to those financial statements included in this prospectus.

	As of September 30, 2017			
	Actual	Pro Forma (Minimum)	Pro Forma (Maximum)	
	(unaudited)	(unaudited)	(unaudited)	
Cash	\$ 3,400,481	\$ 40,319,615	\$ 59,269,610	
Total Debt	\$ —	\$ —	\$ —	
Stockholders' Equity:				
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding, actual; 10,000,000 shares authorized pro forma; no shares issued or outstanding pro forma;	_	_	_	
Common stock, \$0.001 par value; 50,000,000 shares authorized; 10,635,684 shares issued and outstanding, actual; 50,000,000 shares authorized and 16,640,590 shares issued and outstanding, pro forma (minimum), and 50,000,000 shares authorized and 19,307,256 shares				
issued and outstanding, pro forma (maximum)	10,636	16,641	19,307	
Additional paid-in capital	26,752,048	68,657,838	87,605,167	
Accumulated deficit	(22,381,994)	(27,418,784)	(27,418,784)	
Total stockholders' equity	4,380,690	41,255,695	60,205,690	
Total capitalization	\$ 4,380,690	\$ 41,255,695	\$ 60,205,690	

The above capitalization table excludes:

- 2,366,221 shares of our common stock reserved for issuance under stock option agreements issued pursuant to our 2016 Omnibus Incentive Plan and 2016 Non-Employee Equity Incentive Plan at a weighted average exercise price of \$3.50 per share;
- 370,370 shares of common stock reserved for issuance under outstanding warrants at a weighted average exercise price of \$2.70 per share;
- 803,779 shares of our common stock reserved for future issuance under our 2016 Omnibus Incentive Plan (for further information, see "Description of Capital Stock — Stock Options and Warrants" below);
- 130,000 shares of our common stock reserved for future issuance under our 2016 Non-Employee Equity Incentive Plan; and
- shares of our common stock issuable upon exercise of the warrant to be issued to the underwriter.

#### DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of common stock immediately after the completion of this offering. As of September 30, 2017, our net tangible book value was approximately \$4,205,690, or \$0.40 per share of common stock. Our net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of September 30, 2017. After giving effect to the issuance of 671,572 shares of common stock to Einstein prior to this offering and the sale of \$40,000,000 of common stock (minimum) or \$60,000,000 of common stock (maximum) in this offering at an initial public offering price of \$7.50 per share, and after deducting underwriting commissions and estimated offering expenses payable by us, but without adjusting for any other change in our pro forma net tangible book value subsequent to September 30, 2017, our pro forma net tangible book value would have been \$2,47 per share if the minimum amount of common stock is sold and \$3.11 per share if the maximum amount of common stock is sold. This represents an immediate increase in pro forma net tangible book value of \$2.10 per share to our existing stockholders and immediate dilution of \$5.03 to new investors purchasing shares at the proposed initial public offering price if the minimum of common stock is sold, and an immediate increase in pro forma net tangible book value of \$2.74 per share to our existing stockholders and immediate dilution of \$4.39 to new investors purchasing shares at the proposed initial public offering price if the maximum of common stock is sold. The following table illustrates this dilution:

	Minimum	Maximum
Public offering price	\$ 7.50	\$ 7.50
Net tangible book value per share as of September 30, 2017	0.40	0.40
Decrease attributable to shares issued to Einstein	(0.03)	(0.03)
Net tangible book value immediately prior to offering	0.37	0.37
Increase per share attributable to this offering	2.10	2.74
Pro forma tangible book value per share after this offering	2.47	3.11
Dilution per share to new investors in this offering	\$ 5.03	\$ 4.39

The number of shares of our common stock outstanding both before and after this offering is based on the number of shares outstanding as of September 30, 2017 and excludes:

- 2,366,221 shares of our common stock reserved for issuance under stock option agreements issued pursuant to our 2016 Omnibus Incentive Plan and 2016 Non-Employee Equity Incentive Plan at a weighted average exercise price of \$3.50 per share;
- 370,370 shares of common stock reserved for issuance under outstanding warrants at a weighted average exercise price of \$2.70 per share;
- 803,779 shares of our common stock reserved for future issuance under our 2016 Omnibus Incentive Plan (for further information, see "Description of Capital Stock — Stock Options and Warrants" below);
- 130,000 shares of our common stock reserved for future issuance under our 2016 Non-Employee Equity Incentive Plan; and
- shares of our common stock issuable upon exercise of the warrant to be issued to the underwriter.

The number of shares of our common stock to be outstanding after this offering includes shares of common stock that will be issued in this offering and 671,572 shares of our common stock issuable to Einstein immediately prior to the consummation of this offering pursuant to our license agreement with Einstein.

#### BUSINESS

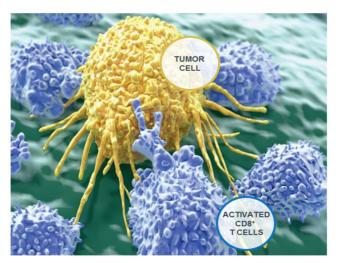
#### Overview

We are 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. While currently in preclinical development, we believe our CUE Biologics<sup>™</sup> platform provides a potentially transformative solution to the challenges facing prevailing immunotherapeutics. By directly engaging and modulating disease relevant T cells in the patient's body, we believe our biologic drug candidates will be able to realize the true potential of immune modulation. Through our proprietary CUE Biologics™ platform, we believe we are uniquely positioned to become a prominent and leading player in immuno-oncology, immunotherapy and autoimmune disease. Our proprietary platform is intended to allow us to efficiently design and develop drug candidates that specifically and selectively engage and modulate disease relevant T cells, providing therapeutic advantages while minimizing or eliminating the unwanted side effects. We have been aggressively seeking patent protection for our pioneering innovations and, combined with a license agreement with the Albert Einstein College of Medicine ("Einstein"), continue to build a robust intellectual property portfolio. This portfolio includes our core technology platform for the engineering of biologics to selectively control T cell activity, which we call CUE Biologics<sup>™</sup>, a growing portfolio of precision immuno-modulatory drug candidates, and two supporting technologies we call MOD<sup>™</sup> and viraTope<sup>™</sup> that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides, respectively.

#### Background

The human immune system comprises a number of specialized cell types which collectively function to identify and defend the body against foreign threats. Central to the proper functioning of the immune system are the coordinated activities and communications between two specialized cell types, antigen-presenting cells ("APCs") and T cells. APCs serve to capture and break the proteins from foreign organisms, (*e.g.*, bacteria and viruses), or abnormal proteins (*e.g.*, from genetic mutation in cancer cells) into smaller fragments suitable as signals for scrutiny by the larger immune system, including T cells. In particular, APCs break down proteins into small peptide fragments, which are then paired with a class of host molecules called the major histocompatibility complex ("MHC") and displayed on the cell surface. Cell surface display of an MHC together with a peptide fragment, also known as a T cell epitope, provides the underlying scaffold surveilled by T cells, allowing for specific recognition. The peptide fragments can be pathogen-derived, tumor-derived, or derived from natural host proteins (self-proteins). Moreover, APCs can recognize other foreign components, such as bacterial toxins, viral proteins, viral DNA, viral RNA, etc., whose presence denotes an escalated threat level. The APCs relay this information to T cells through additional costimulatory signals in order to generate a more effective response.

T cells recognize peptide-MHC ("pMHC") complexes through a specialized cell surface receptor, the T cell receptor ("TCR"). The TCR is unique to each T cell and, as a consequence, each T cell is highly specific for a particular pMHC target. In order to adequately address the universe of potential threats, a very large number (~10,000,000) of distinct T cells with distinct TCRs exist in the human body. Further, any given T cell, specific for a particular T cell peptide, is initially a very small fraction of the total T cell population. Although normally dormant and in limited numbers, T cells bearing specific TCRs can be readily activated and amplified by APCs to generate highly potent T cell responses that involve many millions of T cells. Such activated T cell responses are capable of attacking and clearing viral infections, bacterial infections, and other cellular threats including tumors, as illustrated below. Conversely, the broad, non-specific activation of overly active T cell responses against self or shared antigens can give rise to T cells inappropriately attacking and destroying healthy tissues or cells.



Activated T cells target tumor cells for killing through engagement of the TCR with its cognate pMHC.

TCR engagement by its specific or cognate pMHC delivers an activation signal to the T cell and defines the specificity of the response. However, robust and effective T cell activation requires that the TCR signal be accompanied by additional signals from the APC, collectively referred to as "costimulation." The sum of these interactions directs the quality and magnitude of the T cell response. Specific costimulatory (activating receptors), as well as coinhibitory signals (inhibitory receptors), may be delivered by the APC to the T cell through specific signaling molecules (ligands) at the interface of these two cells, shown below. Based upon the particular nature of the pMHC and costimulatory signal(s), the T cell may differentiate into a variety of cell types, each with a specialized defensive capability (*e.g.*, Tc1, Tc2, Th1, Th2, Th17, Treg, Tr1, etc.). Hence communication between APCs and T cells must be capable of precisely identifying threats and generating a response of appropriate quality and magnitude. An insufficient T cell response may result in a persistent pathogenic infection, or in the case of cancer, tumor persistence. Conversely, an excessive or inappropriate T cell response may damage the host acutely (*e.g.*, acute viral hepatitis) or chronically through autoimmune disease (*e.g.*, Type 1 diabetes, celiac disease, rheumatoid arthritis, Graves' disease, etc.).

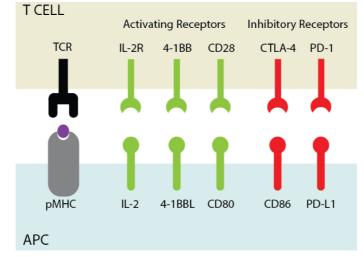


Illustration of the interaction between antigen presenting cells ("APCs") and T cells. Stimulatory signals are shaded green and inhibitory signals are shaded red.

Cancer is characterized by the uncontrolled proliferation of abnormal cells and is a leading cause of death in developed countries. Cancer cells arise when proteins responsible for regulating cell division, proliferation or death are altered and these changes can occur through several different mechanisms. Cancer cells may express particular proteins (antigens) at much higher levels than normal (collectively referred to as tumor associated antigens, *e.g.*, PSA-1 and Wilms Tumor 1) or express oncogenic (tumor-causing) viral proteins that are responsible for transformation, producing so-called cancer "drivers", such as HPV E7. Cells can also be rendered oncogenic by the damage of host proteins through mutation (*e.g.*, p53 and KRAS), which result in the expression of cancer neoantigens. Regardless of the nature of oncogenesis, cancer cells can display on their cell surface antigenic peptides, which are often recognized by the immune system.

In addition to being transformed, cancer cells have the ability to evade or modulate immune surveillance. This "immune escape" can be a key factor in their growth, spread, and persistence. Cancer cells employ a variety of approaches to escape immune surveillance or to suppress the effects of an immune response. One example of this is observed when cancer cells evade a normal immune response by expressing cell surface molecules that interact with and inhibit the attacking immune cells. These inhibitory interactions, called "immune checkpoints," provide the tumor with a shield or buffer from activated and tumor-specific T cells. Checkpoint pathway inhibitors are therapeutic antibodies in immuno-oncology that are designed to block the tumor's inhibitory shield; they have demonstrated promising clinical results. Another mechanism by which tumors can turn down the immune response is by stimulating the production of CD4<sup>+</sup> regulatory T cells ("Tregs"), which in turn inhibit the killer CD8+ T cells that would normally attack the cancer. Thus, through one or more of these different pathways, the cancer cells manipulate and bias the local tumor microenvironment in favor of immune cell suppression. To extend and enhance the observed clinical benefits of therapeutic checkpoint blockade, a concurrent means of specifically activating and expanding a tumor-specific CD8<sup>+</sup> T cell population is desired. Of interest, recent results from cancer trials that focus on activating a general (non-specific) immune response have shown that globally stimulated immune cells can attack "self" tissue. This therapeutically-induced autoimmune disease is frequently observed in patients as a consequence of their treatment and can limit further therapy.

In autoimmune and inflammatory diseases, components of the immune system are unable to effectively distinguish between foreign and "self" tissues and so the immune system mounts a response that can result in extensive destruction of normal tissue. Autoimmune and inflammatory diseases often occur in genetically predisposed individuals and can be triggered by select conditions, such as infection or tissue damage. The result is an immune response hyperactive against healthy tissue, amounting to the second highest cause of chronic illness in the United States and a leading cause of death for women under 65.

As described above, in order to attack cancer, the immune system needs to be amplified, whereas for the effective treatment of autoimmune and inflammatory diseases, the immune response needs to be specifically suppressed. Certain T cell populations are known to be critical to the development and persistence of T cell-mediated autoimmune diseases. In particular, effector T cells directly or indirectly damage or kill host cells. In the case of autoimmune diabetes, for example, CD8+ effector T cells directly kill insulin producing cells of the pancreas. Once most insulin-producing cells have been destroyed by the aberrant T cell response, the patient is no longer able to regulate blood glucose levels and develops diabetes. In addition to disease-causing T (or T effector) cells, there exist populations of T cells called Tregs, which act to inhibit such dangerous responses in normal individuals. Tregs are able to inhibit the destructive activity of effector T cells and are part of the immune system's control apparatus.

We believe that our technology can be used to specifically treat autoimmune disease. We are working on two different approaches: (1) the direct inhibition and/or deletion of the pathogenic autoimmune effector T cells and (2) the control of the effector T cells' function through the expansion and activation of Tregs.

#### Immunotherapy

During the last five years, there has been substantial scientific progress in therapeutically modifying the function of immune cells ("immunotherapies"), such as T cells, to either enhance tumor killing in the context of oncology, or protect tissue in the context of autoimmune disease. Immunotherapies are therefore increasingly recognized as an essential aspect of the emerging opportunities in the treatment of cancer and

autoimmune disease. Despite the tremendous promise of these therapies, there are a number of continuing challenges. For example, most of the currently used cancer immunotherapies rely on non-specific and general activation of T cells or the inhibition of costimulatory pathways (*e.g.*, checkpoint pathway inhibitors), both of which result in the global, non-specific stimulation of T cells. The global and nonspecific engagement by many current immunotherapeutics results in the activation of a large fraction of disease-irrelevant T cells, rather than selective activation of those T cells which can therapeutically affect the disease by virtue of their antigen-specific TCRs. The net effect of this approach is typically an extremely narrow therapeutic window in which many of the stimulated T cells are not selective towards the tumor, and often recognize "self antigens". This results in significant toxicity and serious side effects and, in severe cases (*e.g.*, Proleukin<sup>TM</sup> and Yervoy<sup>TM</sup>), fatalities. Similarly, for the treatment of autoimmune indications, previous immunotherapies have been non-specific and broadly suppress immune function (*e.g.*, Humira<sup>TM</sup>, cyclosporine and methotrexate) and thus potentially predispose patients to deadly infections, and cancer.

Checkpoint pathway inhibitors modulate the costimulatory pathways described and illustrated above by blocking the function of inhibitory receptors which would normally suppress the activation of T cells, so-called "immune checkpoints." Checkpoint blockade is predominantly achieved through the use of monoclonal antibodies ("mAbs") directed against the desired checkpoint protein (*e.g.*, mAbs to PD1 or CTLA-4). These mAbs can block the checkpoint proteins such as programmed cell death-1 (*e.g.*, PD-1, Pembrolizumab/ Keytruda (Merck)) and CTLA-4 (*e.g.*, Yervoy/Ipilimumab (Bristol-Myers Squibb)), and hence reactivate the inhibited anticancer T cell responses and stimulate T cell proliferation. The checkpoint inhibitors currently on the market have demonstrated significant and durable responses in some patients. However, immunotherapy with checkpoint inhibitors is still limited by modest to low response rates. For example, 34% of advanced melanoma patients respond to anti-CTLA-4. To enhance the proportion of responding patients, strategies, such as combinations with other existing cancer therapies, are currently being explored. While these strategies have promise, severe side effects including potentially life threatening immune-related adverse events can affect upwards of 24% of patients using anti-CTLA-4 therapy alone, or 54% when used in combination with anti-PD-L1 therapy (*e.g.*, Nivolumab).

An alternative approach to activate an immune response is through the use of bi-specific antibodies that concomitantly engage the TCR on a T cell and an antigen on the tumor cell, examples of which are BiTEs (*e.g.*, Amgen) or Darts (*e.g.*, Macrogenics). These bi-specific antibodies are distinct from the monoclonal antibodies described above in that they are engineered to simultaneously bind to two different types of antigen, rather than one. To activate the T cells, the bi-specific molecules are designed to engage a tumor antigen while also engaging a component of the T cell receptor, called CD3. Since CD3 is expressed on all T cells, dual engagement through bi-specific molecules results in a global, non-specific activation of T cells at the tumor or wherever the antigen is expressed. While a very small subset of the activated T cells would recognize tumor antigen and so would be expected to have the associated anti-tumor activity, the vast majority do not recognize tumor antigen, and as such, the activation of large T cell subsets can give rise to significant toxicity, thereby significantly limiting the acceptable dose and therapeutic range of this approach.

As described above, cancer cells can evade a normal immune response by expressing cell surface inhibitory molecules that interact with and suppress the attacking T cells within the tumor microenvironment. Consequently, more recent bi-specific approaches seek to decorate tumor cells with activating costimulatory signals to potentially overcome tumor resident immune cell suppression. This is achieved by targeting a tumor antigen with one arm and presenting a costimulatory signal for potential tumor resident T cell stimulation through the other. These bispecific molecules have been used in patients with, in some cases, good therapeutic results. However, there are significant limitations. For example, they must first localize to the tumor in order to exert their effects (*e.g.*, those from Altor, Sutro, Covagen, Roche, and Amgen) and have the added limitation of engaging only the subset of T cells which successfully traffic to the tumor within the treatment window. Notably, CUE biologics are designed to engage T cells directly, not requiring tumor targeting, and thus allow for T cell priming and activation in the periphery (*e.g.*, tumor draining lymph node) outside the suppressive tumor microenvironment. Lastly, the use of these tumor directed bi-specifics may be hampered by the drug's short half life in patients, thus requiring continuous infusion.

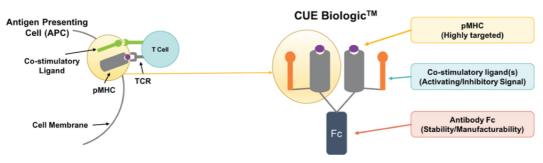
A different approach that has shown some promise in tumor therapy is to remove T cells from patients, activate and stimulate them outside the body (*ex vivo*), which expands them (usually over 7-14 days), and then infuse them back into the patients. These methods are termed cellular therapies, and include adoptive cell therapy ("ACT") and chimeric antigen receptor T cell ("CAR-T") therapy (*e.g.*, those from Juno and Kite). At the outset, this is an individualized patient-specific approach. In ACT, native (un-modified) T cells are extracted and purified from a patient, expanded *ex vivo* and re-introduced to the patient in order to increase the number of T cells available to kill the tumor cell. Similarly, in CAR-T therapy, patient T cells are extracted and purified; however, distinct from ACT, patient T cells are genetically modified to target tumor-specific antigens through the use of chimeric antigen receptors ("CARs") prior to patient infusion in an attempt to increase specificity. CARs are comprised of an external tumor-specific antibody fragment or engineered TCR (*e.g.*, Adaptimmune) linked to cytoplasmic signaling domains for T cell activation such that upon binding of the tumor antigens, the engineered T cells proliferate and attack cancer cells.

CAR-T-based immunotherapy has demonstrated complete responses of greater than 80% in recent clinical trials of acute lymphoblastic leukemia ("ALL") patients. However, potent CAR-T cell responses have produced life threatening cytokine release syndromes ("CRS") in 69% of high burden ALL adults. Severe toxicities and deaths led to a halt in JCAR015, Juno's lead CAR-T program, and potentially pose a safety challenge to the wider adoption of cellular therapies. Moreover, the technical requirements and expense associated with individualized T cell extraction, *ex vivo* amplification/modification, and patient re-infusion represent significant scaling and cost challenges that might limit broad usage and eventual commercialization of this therapeutic modality. Despite these safety and scalability considerations, the recent demonstration of impressive clinical survival in patients treated with cellular therapies deserves serious attention.

#### **Our Approach for Next Generation Immunotherapies**

We have developed a proprietary platform for the design and development of biologic drugs for *in vivo* (*e.g.*, directly in the patient's body) T cell based immunotherapy. In the context of cancer, CUE Biologics are being designed to selectively activate T cells which recognize cancer antigens (*e.g.*, peptides) expressed or amplified in cancer cells (tumor antigens or neoantigens). For the treatment of autoimmune diseases such as Type 1 diabetes, celiac disease, arthritis and others, CUE Biologics are designed to selectively dampen disease-causing T cell responses directed against self-antigens.

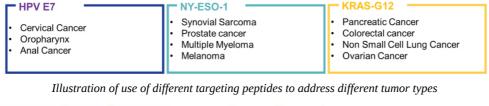
CUE Biologics are designed to mimic the signals, or "cues", of the immune system to generate highly focused T cell responses associated with disease. We accomplish this by the fusion of unique costimulatory signaling molecules (ligands) with a TCR targeting p-MHC complex ("pMHC"). This co-engagement of signals through the TCR and costimulatory receptor mimic and recapitulate the very signals delivered by APCs to T cells during an immune response. In this way CUE Biologics<sup>™</sup> allow for the precise targeting of distinct signaling ligands exclusive to the T cell population of interest, resulting in targeted T cell modulation. We call this platform CUE Biologics<sup>™</sup> for the Conditional and Unique Engagement<sup>™</sup> (CUE) of T cells.



CUE Biologics<sup>TM</sup> are designed to mimic Antigen Presenting Cells ("APCs")

Our therapeutic approach is designed to be administered directly in patients (*in vivo*) which differs markedly from other T cell therapeutic approaches such as ACT, requiring the patients' T cells to be first harvested, then stimulated and expanded outside the body before being reinfused in an activated state. Thus, we believe CUE Biologics represent a breakthrough approach as a disease-specific biologic T cell modulator administered *in vivo* (in body) rather than the *ex vivo* (outside the body) approach deployed by current cellular immune therapies. Furthermore, we believe the desired pharmacological effect in the patients will be more precisely controlled by directly administering CUE Biologics into the patient for selective modulation of disease relevant T cells.

The therapeutic properties and selective nature of Cue Biopharma's drug candidates result from the design and optimization of key functional parameters for a given therapeutic framework. Each framework harbors an MHC and one or more costimulatory element(s) optimized to drive a particular type of T cell response, such as stimulation and expansion of a cytolytic T cell response to kill cancer cells, or specific down-regulation and inhibition in the context of autoimmune disease. The targeting of the framework to specific T cell populations is dependent on the specific peptide linked to the MHC. Notably, more than 75 peptides that are expressed by different solid tumors are currently described in the clinical literature. Thus, after finalizing a therapeutic framework (pMHC-ligand-Fc) we believe different tumors can be addressed by changing the targeting peptide, presenting the promise of greatly reducing the time and cost associated with the generation of new CUE molecules to take forward through IND-enabling studies and, potentially, into the clinic.



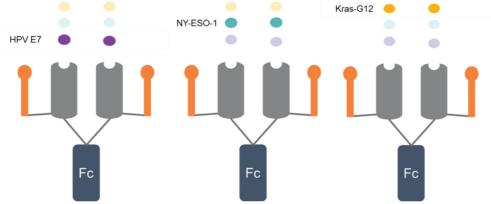


Illustration of use of different targeting peptides to address different indications

Using our CUE Biologics<sup>™</sup> platform, we believe we will be able to design biologics that will have certain advantages over existing immunotherapies. These advantages include increased specificity and reduced toxicity as described above under "Immunotherapy" and greater manufacturability as described above under "Immunotherapy" and below under "Manufacturing CUE Biologics<sup>™</sup>." As such, we believe our approach to designing and developing immuno-modulatory biologics represents a breakthrough, next-generation solution to realizing the promise of T cell based immunotherapies.

#### Competition

Immunotherapy technologies are advancing at a rapid pace and we anticipate competing with companies developing bi-specific antibodies (*e.g.*, Amgen, Inc., Hoffman-La Roche (Roche), Sutro Biopharma), CAR-T therapies (*e.g.*, Novartis A.G., Juno Therapeutics, Kite Pharma, Inc.), checkpoint

inhibitors (*e.g.*, Bristol-Myers Squibb, Merck & Co. and Pfizer, Inc.), and antibody drug conjugates ("ADCs") (*e.g.*, Seattle Genetics, Inc., ImmunoGen, Inc. and Sorrento Therapeutics), many of which have significantly greater financial and human resources than we have.

#### **CUE Biologics™ Drug Candidates**

The relative effectiveness of immunotherapies depends on whether a relevant or optimal therapeutic mechanism to engage the immune system has been addressed by the therapy, and it is likely that different immune stimulatory mechanisms will be required to optimally address certain cancers over others. The versatility of the CUE Biologics™ platform allows access to multiple distinct mechanisms with a series of biologic frameworks addressing a variety of conditions and requirements. We have currently designed two promising therapeutic frameworks to support distinct and potent mechanisms of T cell activation: our pMHC/IL-2 based CUE-100 series (to enhance overall numbers of tumor specific T cells) and our pMHC/CD80:4-1BBL based CUE-200 series (to reinvigorate exhausted T cells). We expect to be able to target antigen-specific T cell populations in a variety of indications by a simple peptide exchange into validated CUE Biologics™ frameworks. We continue to evaluate additional constructs from which we will launch further framework series in both oncology and autoimmunity.

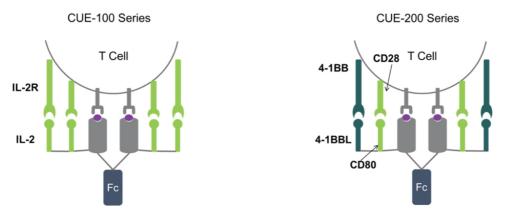
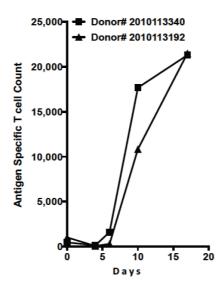
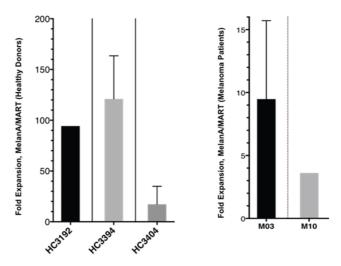


Illustration of CUE-100 and CUE-200 frameworks CUE-101

In furtherance of our efforts to design and test various frameworks addressing a variety of conditions, we are developing and implementing a complementary *ex vivo* (outside the body) human cancer model assay system for testing and evaluating CUE Biologics<sup>™</sup> molecules directly in cancer patient-derived T cells. The *ex vivo* assays have the potential to provide a powerful tool for demonstrating human translatability by evaluating preclinical proof of mechanism and proof of concept directly in human samples, as well as for defining relevant metrics and critical parameters informing clinical application(s). Through this assay system, we have recently tested various epitopes (CMV and MelanA/MART, shown below) on the CUE-101 framework to support the versatility and robustness of our CUE Biologics<sup>™</sup> platform.



Results from CUE-100 preliminary two-sample human ex vivo study, indicating treatment with CUE:CMV:IL-2 results in activation of antigen-specific T cells.



Results from CUE-100 human ex vivo study, indicating treatment with CUE-100 (MelanA/MART) results in activation of antigen-specific T cells in healthy donors and melanoma patients as measured by T cell expansion.

As exemplary of our CUE Biologics<sup>™</sup> platform, we continue to develop supporting data surrounding our current lead clinical candidate, CUE-101 (described below) and are utilizing our *ex vivo* assay capabilities to generate data for proof of concept demonstration with potent, tumor antigen-selective T cell activation. The *ex vivo* assays, utilizing clinical samples of peripheral blood mononuclear cells ("PBMCs") for testing and evaluating CUE-100, are expected to provide an informative and representative data set for guiding our assessment with respect to IND filing and clinical development strategy. By titrating drug levels and varying the duration of drug exposure, as well as altering the time of endpoint measurements (PD effect), drug concentration and duration of treatment can be correlated with the magnitude and duration of effects, such as antigen-specific T cell activation, expansion and tumor lysis. In addition to providing

potentially insightful data relating to the prospects of antitumor efficacy in patients, the assays also inform the drug exposure range for antitumor activity as well as provide evidence for clinical biomarker selection and the biopsy schedule for clinical proof of mechanism.

#### CUE-101

Our current lead drug candidate, CUE-101, uses the pMHC/IL-2 CUE-100 framework, and is a fusion of a variant form of the cytokine Interleukin-2 (IL-2) and a T cell antigen (pMHC). The targeting peptide contained in the pMHC that is currently used in CUE-101 is derived from the human papilloma virus E7 protein (HPV-E7). CUE-101 is a single, covalently-assembled biologic designed to target and activate T cells specific to HPV-related cancers. HPV-related cancers are an important unmet clinical need, which accounts for approximately 24,600 cases of cervical, head and neck, and genitoanal cancers in the United States every year leading to approximately 9,000 deaths annually. Notably, HPV-driven cancers lead to approximately 225,000 deaths worldwide each year. We believe our drug candidate CUE-101 has the potential to provide patients with a more effective and safer alternative in treating their HPV-driven cancers. While it is our current intention to file an IND for CUE-101 by the end of 2018, we plan to evaluate the completed *ex vivo* data prior to committing to proceed with clinical studies for CUE-101.

While CUE-101 targets the HPV-E7 TCR in cervical/head and neck cancers, we believe our CUE Biologics<sup>™</sup> platform may be used to target a large variety of alternative peptides which may allow us to address many tumors with high therapeutic need in the oncology patient population. In support of this, we have recently demonstrated highly potent efficacy in preclinical murine models targeting non-viral epitopes. These data together with the recent human *ex vivo* experiments using a melanoma specific epitope (MelanA/MART, shown above) in both healthy donor and melanoma patient samples support CUE-100 framework's ability to activate distinct T cell populations via a simple 9 amino acid peptide antigen exchange on an otherwise validated scaffold, which should reduce the time to clinic (and associated costs) of next-generation biologics. We are currently exploring multiple unique epitopes in the context of the CUE-100 series framework in human *ex vivo* assays to help guide prioritization of programs.

#### **Extension to Autoimmune Indications**

In addition to oncology, we are expanding our technology's reach to generate highly promising and novel immunotherapeutics for the treatment of debilitating autoimmune disorders. Autoimmune indications may be addressed with our technology through two general strategies: (1) depleting disease causing autoreactive T cells by selectively delivering inhibitory signals or (2) by delivering signals to induce and expand regulatory T cells, which subsequently act to inhibit disease-causing T cells (bystander protection).

CUE Biologics<sup>™</sup> 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 CUE Biologics<sup>™</sup> 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. Both pathogenic (*i.e.*, disease causing) and regulatory (disease limiting) CD4 T cell subsets are known to exist in autoimmune disease. Our CUE Biologics<sup>™</sup> frameworks in autoimmunity will therefore be intended to treat autoimmune disease by either depleting pathogenic CD4 T cells or amplifying regulatory CD4 T cell responses to specific disease relevant antigens. Potential autoimmune indications of interest include Type 1 diabetes, arthritis, autoimmune thyroiditis (*e.g.*, Graves' disease), celiac disease and CNS/neurological autoimmune disorders (*e.g.*, multiple sclerosis, Parkinson's disease, etc.).

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 certain of our 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. For further information, see below "Business — Our Collaboration Agreement with Merck".

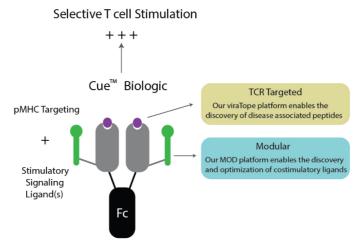
#### Manufacturing CUE Biologics<sup>™</sup>

Biologics are drugs in which the active substance is produced by or extracted from a biological source (in contrast to "small-molecule" drugs). Biologics are relatively recent, being for the most part recombinant proteins produced through genetic engineering; these include monoclonal antibodies (mAb), bi-specific antibodies, therapeutic proteins, and peptides. Biologics are very sensitive to their conditions of synthesis and handling, and a series of culturing and purification steps are required to produce a consistent, high-quality, active drug product.

Early cell culture processes for mAb production initially had low expression levels, with yields (titers) typically well below 1 g/L. The relatively recent advancement of recombinant technology based on a two-vector approach (*e.g.*, cloning and expression of the heavy and light chain antibody genes) in producer cell lines coupled with improvements in the production processes has resulted in increased expression levels, higher cell densities and much higher product titers (2-5 g/L). Of note, the titers observed in the manufacturing process will impact the drug substance manufacturing cost of goods (COG). Recombinant proteins designed to target multiple cell surface receptors (bi-specific antibodies) have historically resulted in unacceptably low titers (<1g/L). Bispecifics are typically generated through the use of a four-vector strategy (two heavy chains and two light chains) in one producer cell line. The individual components are free to associate stochastically which leads to mixtures of antibodies being produced. The difficulties in isolating the desired bi-specific antibody out of complex mixtures and the inherent poor yield (maximum of 12.5 to 25% depending on the assembly format used) make the production of a bi-specific 2 vector based strategy (*e.g.*, homo-dimeric IgG antibody scaffold) that more closely mimics natural IgG based mAbs. The use of a homo-dimeric scaffold should result in higher final titers, and resultant lower COG, than typically observed for traditional bi-specific T cell activators.

#### MOD<sup>™</sup> and viraTope<sup>™</sup> Technology Platforms

Supporting our CUE Biologics<sup>™</sup> platform are two companion discovery platforms: MOD<sup>™</sup>, a costimulatory optimization and discovery platform, and viraTope<sup>™</sup>, a T cell epitope discovery platform, both illustrated below.



The design of CUE Biologics<sup>™</sup> allows for incorporation of antigens identified by the viraTope<sup>™</sup> platform and costimulatory molecules discovered through the MOD<sup>TM</sup> platform to develop novel biologics to address new indications in oncology and autoimmune disorders.

We believe that the MOD<sup>TM</sup> technology platform has a unique ability to optimize existing costimulatory ligands for use in our biologics as well as discover as yet unknown costimulatory signaling molecules. The MOD<sup>TM</sup> platform represents a high throughput method for determining specific cell surface protein-protein interactions (*e.g.*, signaling receptor:ligand pair(s)). In brief, MOD<sup>TM</sup> allows for the detection of associations between distinct cell surface query proteins (*i.e.*, ligands) and cell surface

expression libraries (*i.e.*, receptors) to first identify molecular engagements and further allows for the mechanistic dissection of complex biochemical function by screening large numbers of mutant molecules. Taken together, we believe that MOD<sup>TM</sup> can provide powerful tools to first define novel protein-protein interactions associated with T cell activation. Secondly, MOD<sup>TM</sup> is designed to allow us to modulate these signaling ligands through the rapid screening of mutants in order to dissect biochemical function and alter binding properties (*i.e.*, altered affinities and specificities). A key component of our therapeutic design involves decreasing the binding of the costimulatory element while retaining its biological activity (*i.e.*, affinity attenuation). Affinity attenuation allows the pMHC to drive the engagement with the target T cells and limits off-target engagement and associated collateral toxicity.

The viraTope<sup>™</sup> platform addresses the historic difficulty of identifying disease associated T cell signatures through the monitoring of complex T cell repertoires. As discussed previously, at the core of the molecular events comprising a T cell-mediated immune response is the engagement of the T cell receptor ("TCR") with a small peptide antigen presented by an MHC molecule, referred to as a T cell epitope. This represents the immune system's targeting mechanism and is a requisite molecular interaction for T cell activation and function, and forms the basis of our targeted immunotherapeutics (i.e., TCR targeting). The viraTope platform is designed to achieve rapid, comprehensive, and quantitative immunomonitoring by interrogating primary T cells with a combinatorial library of pMHC in conjunction with deep sequencing. viraTope's™ libraries would query T cells with all possible mimotopes, leaving cognate pMHC bound to their respective T cells. Deep sequencing of the bound pMHC would comprehensively enumerate all T cell epitopes recognized by a given T cell sample. In this way, viraTope™ could allow the identification of novel epitopes differentially represented in diseased versus control patients and would further make the frequencies of all known and unknown T cell specificities accessible for prospective, in-study, and retrospective analyses of clinical trials. Thus, the ability to systematically identify the entire ensemble of epitopes for a given disease state represents a unique opportunity for the development of diagnostics and highly targeted therapeutics against infectious diseases, autoimmunity and cancers. We believe that viraTope<sup>™</sup> has the ability to comprehensively and quantitatively monitor T cell responses, which could lead to the discovery of novel drug candidates and biomarkers for internal use or to potentially license to strategic partners.

#### **Our Business Strategy**

Our primary objective is to become a leading, immunotherapeutics/biopharmaceutical company developing the next generation of highly specific and precisely regulated biotherapeutics. We plan to do this through coordinated and integrated strategic initiatives. Key elements of our strategy include:

- Modular and versatile platform allowing for efficient and rapid drug design, prototyping and optimization. We plan to leverage our CUE Biologics<sup>™</sup> platform's modular capabilities to rapidly and efficiently develop our drug candidates. We believe our platform will provide a highly productive portfolio of promising clinical drug candidates aimed at specifically targeting disease relevant T cells for effective immune modulation. The modular design of our CUE Biologics<sup>™</sup> platform provides the flexibility and versatility to construct drug frameworks comprised of various MOD combinations to elicit novel mechanisms of action. As described above under "Our Approach to Next Generation Immunotherapies," after we establish a successful framework that uses a specific peptide to target a particular disease indication, we expect to be able to use that framework to target additional disease indications by changing the targeting peptide. Therefore, by leveraging the previous work done to establish a framework, we believe we will be able to significantly compress the timeline (by as much as six to twelve months) and capital requirements associated with the development of additional drug candidates.
- Using preclinical data and efficient Phase I clinical study design to accelerate the development process. We recently demonstrated through ex vivo assays using human clinical samples that CUE:IL-2 activates T cells in an antigen specific manner. We plan to continue testing our biologic drug constructs in ex vivo studies with human clinical samples using various cancer relevant epitopes to demonstrate selective activation of T cells specific for various antigens spanning a range of oncology indications. We believe this approach provides meaningful validating data enhancing the quality of our preclinical data package for IND filing. This data also has the
  - 53

potential of increasing the probability for identifying relevant pharmacodynamic ("PD") biomarkers for patient monitoring and as a potential surrogate marker of anti-tumor activity in the clinical setting. Furthermore, we believe these ex vivo studies will supplement and potentially reduce our reliance on preclinical animal models, providing a more cost and time efficient means of testing our drug candidates' activities. Given the urgent medical needs we intend to address with our drug candidates, we are planning to design and conduct our Phase I clinical studies to generate safety data and a clinically meaningful data package around efficacy with the aim of approaching the FDA for an accelerated registration study.

- Using our process development and protein biochemistry capabilities as a competitive advantage.
  We anticipate devoting significant resources to optimizing drug design and process development, including protein engineering and optimization, which are key components to maximizing the value of our current and future drug candidates. Through our core competencies and proprietary CUE
  Biologics™, MOD™ and viraTope™ technology platforms, we are designing and developing a growing intellectual property portfolio of novel and proprietary immune modulatory biologics. We believe our modular approach to designing biologics, coupled with the protein engineering and optimization capabilities offered by our platform technologies, should enable us to more rapidly and cost-effectively design and optimize potential drug candidates, as compared to more traditional preclinical development processes. Although we have yet to advance any of our drug candidates into the clinic, we believe this efficient preclinical development process positions us well to potentially establish a leading position in the discovery and development of promising next generation immunotherapies.
- *Establishing key strategic partnerships with leading pharmaceutical companies.* We believe that our CUE Biologics<sup>™</sup> platform offers the promise of enabling us to develop multiple drug candidates that address a variety of potential indications. Accordingly, as we continue to evolve and progress our drug candidates through preclinical and early clinical development, we plan to establish strategic partnerships with leading pharmaceutical or biotechnology organizations, such as our partnership with Merck pursuant to the Collaboration Agreement described below. We believe that this will allow us to further enhance our capabilities and capacities to discover and develop multiple, promising drug candidates for unmet medical needs in oncology and autoimmunity in a highly productive and cost-effective manner.
- Leveraging our relationships with Einstein, our scientific founders and other scientific advisors. Our renowned scientific founders and Einstein, as well as our scientific and clinical advisors ("SAB/CABs"), have a history of seminal, pioneering discoveries and possess significant experience in oncology, immunotherapy, immunology, and biophysics, as well as clinical development. We plan to leverage our scientific founders' and SAB/CABs' scientific and clinical expertise and guidance as we develop our product pipeline and technologies.

#### **Our License Agreement with Einstein**

Our CUE Biologics<sup>™</sup>, viraTope<sup>™</sup> and MOD<sup>™</sup> platforms have all been developed from technology covered by core patent applications licensed to us from Albert Einstein College of Medicine ("Einstein") pursuant to a license agreement originally entered into on January 14, 2015 and amended and restated on July 31, 2017 (the "Einstein License"). The Einstein License covers certain patent rights relating to: (i) methods for high throughput receptor-ligand identification, which we refer to as our MOD<sup>™</sup> platform or technology, (ii) a cellular platform for rapid and comprehensive T cell immunomonitoring, which we refer to as our viraTope<sup>™</sup> platform or technology, (iii) CUE Fc fusion constructs and uses thereof, which we refer to as our CUE Biologics<sup>™</sup> platform or technology, and (iv) variant PD-L1 polypeptides, T cell modulatory multimeric polypeptides and methods and uses thereof (collectively, the "Patents"). We hold a worldwide exclusive 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 ("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 September 30, 2017, we had paid to Einstein an aggregate amount of \$125,000 in license signing 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 II clinical trials or foreign equivalent on a Licensed Product; (iv) initiation of Phase II clinical trials or foreign equivalent for a "new indication" for a Licensed Product; (v) initiation of Phase III clinical trials or foreign equivalent on a Licensed Product; (vi) initiation of Phase III clinical trials or foreign equivalent on a Licensed Product; (vii) initiation of Phase III clinical trials or foreign equivalent on 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 Product; 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 are required to issue Einstein 671,572 shares of our Common Stock immediately prior to completion of the offering contemplated by this prospectus.

The Einstein License commenced on January 14, 2015 and 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 I clinical trials on a Licensed Product within a number of years from the Effective Date;
- initiate Phase II clinical trials on a Licensed Product within a number of years from the Effective Date;
- initiate Phase III 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 II 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 "Collaboration Agreement") with Merck Sharp & Dohme Corp. ("Merck") for a partnership to research and develop certain of our proprietary biologics that target certain autoimmune disease indications (the "Initial Indications"). 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. The research program outlined in the Collaboration Agreement entails (1) our research, discovery and development of certain CUE Biologics™ 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 CUE Biologics™ 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, we have granted to Merck under the Collaboration 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 CUE Biologics<sup>™</sup> that are elected to be developed by Merck. From the effective date of the Collaboration Agreement until the earlier of (i) the first achievement of Proof of Mechanism for a Cue Biologic<sup>™</sup> drug candidate or (ii) 18 months after we notify the joint steering committee that the first Product Candidate has been synthesized under the research program, we are required to forebear from researching, developing or licensing to a third party rights related to any CUE Biologics<sup>™</sup> drug candidate for the treatment of autoimmune diseases other than pursuant to the Collaboration Agreement. 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 Collaboration Agreement. The Company is not required to forbear at any time, however, from developing other Cue Biologics<sup>™</sup> for use in therapeutic areas other than autoimmune diseases, e.g., for use in treating cancer or infectious diseases.

In exchange for the licenses and other rights granted to Merck under the Collaboration Agreement, we will receive 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 Collaboration 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.

The term of the Collaboration 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 Collaboration 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 Collaboration Agreement at any time upon 30 days' notice to the Company. The Collaboration 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 Intellectual Property**

We believe that our current 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 patent applications to which we have secured exclusive rights.

We own or have licensed 14 pending patent applications in the United States (including 11 pending U.S. provisional patent applications), four pending international PCT applications and 33 pending foreign patent applications intended to protect the intellectual property underlying our technology. Our patent applications describe certain features of our technologies, including our CUE Biologics<sup>™</sup> platform and drug candidates, viraTope<sup>™</sup>, MOD<sup>™</sup> screening, MOD<sup>™</sup> variants and combinations of MODs. 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 priority filing date, subject to available extensions. They are thus set to expire no earlier than dates ranging from 2032 to 2037, although there can be no assurance that any of the patent application will be granted.

#### **Target Markets**

Our initial focus and objective is to develop drug candidates for cervical/head and neck cancers, hepatocellular carcinomas, and melanoma. We expect that our future developmental roadmap will also focus on new drug candidates that target autoimmune disorders. We currently do not have any products that are developed such that they can be tested for clinical trials or commercial use. According to published reports, in 2016 oncology drugs were an \$87.5 billion global market and autoimmune drugs constituted a \$47.8 billion global market.

#### **Our Commercialization Strategy**

We are a preclinical stage company without a history of revenue or manufacturing, late stage clinical development or marketing experience. Because late stage clinical development, as well as establishing a full manufacturing and distribution structure, is expensive and time consuming, we intend to explore alternative commercialization strategies, including:

- developing drug candidates through the earlier stages of clinical development with the objectives of rapid, cost effective risk reduction and value creation and then establishing strategic partnership for late stage clinical development and subsequent commercialization;
- developing a robust pipeline of promising drug candidates at various stages of the development process to establish optionality and regular value inflection opportunities and revenue(s);
- strategically entering into co-development partnership(s) to retain potential for commercialization rights on selected drug candidate(s) and market opportunities; and
- partnering with industry participants to incorporate our technology into new and existing drugs.

We expect that partnering with pharmaceutical or biotherapeutic companies may accelerate product acceptance into our target market areas and gain the sales and marketing advantages of the partner's distribution infrastructure. We intend to continue to strengthen our market position and solidify our leadership position in immunotherapy by continuing to improve our technology, broadening our clinical and therapeutic applications, identifying new clinical and therapeutic applications and forming strategic partnerships.

#### **Government Regulation and Product Approval**

Therapeutic 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 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, governmental prohibitions on entering into supply contracts, 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 therapeutic approval, we will have to comply with the many requirements associated with preclinical and clinical trials, the FDA application process, the terms of any pre-certification protocols and agreements, FDA manufacturing requirements for prototypes, and testing. Upon approval of a Biologics License Application ("BLA") and similar approvals in other jurisdictions, there will be additional regulation relating to the packaging, distribution, marking, marketing and claims of our potential products. These later regulations are not only found in federal regulation but many states and, of course, foreign countries.

#### The FDA Process

The FDA regulates the clinical testing and design of therapeutics to ensure that medical products distributed in the United States are safe and effective for their intended uses. The application process for a new therapeutic is highly regulated.

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Our potential products will be regulated as biologics. With this classification, commercial production of our potential products will need to occur in registered and licensed facilities in compliance with current good manufacturing procedures ("cGMP") established by the FDA for biologics. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated, and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization.

Government authorities in the United States (at the federal, state and local levels) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution,

post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing. Our drug candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in a foreign country. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

#### **U.S. 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. 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 FDA has limited experience with commercial development of T cell therapies for cancer. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to 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;
- 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 proposed biological product 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
- FDA review and approval, or licensure, of the BLA.

Before testing any biological drug candidate, including our drug candidates, in humans, the drug 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 drug 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 drug 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 drug 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 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 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 therapeutic 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.

Human immunotherapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the 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 drug 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 drug candidate does not undergo unacceptable deterioration over its shelf life.

#### U.S. 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 product fee for biological products and an annual establishment fee on facilities used to manufacture prescription biological products. 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 user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

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 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. The request may be made at the time of IND submission and generally no later than the pre-BLA or pre-NDA 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 interaction and eligibility for rolling review and priority review. 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 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, the FDA will not recognize orphan drug exclusivity if a sponsor fails to demonstrate upon approval that the product is clinically superior to a previously approved product containing the same active moiety for the same orphan condition, regardless of whether or not the approved product was designated an orphan drug or had orphan drug exclusivity.



#### **Post-Approval Requirements**

Any potential products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping 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 legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, it is FDA's position that manufacturers may not market or promote 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 production 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.

#### 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.

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.

#### Employees

As of September 30, 2017, we had 26 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.

#### **Properties**

Our principal office is located in Cambridge, Massachusetts. We currently lease approximately 11,500 square feet of office and laboratory space under a lease that is due to expire in April 2018. The rent for our office space is \$177,500 per month.

#### Legal Proceedings

We are not a party to any pending legal proceedings.

#### General

We were incorporated as Imagen Biopharma, Inc. in Delaware on December 31, 2014. In October 2016, we changed our name to Cue Biopharma, Inc. The address of our corporate headquarters is 675 West Kendall Street, Cambridge, Massachusetts 02142 and our telephone number is (617) 949-2680. Our website can be accessed at www.cuebiopharma.com. The information contained on, or that may be obtained from, our website is not, and shall not be deemed to be, a part of this prospectus.

#### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with the section of this prospectus titled "Summary Selected Financial Information" and the Company's financial statements and related notes appearing elsewhere in this prospectus. In addition to historical information, this discussion and analysis here and throughout this prospectus contains forward-looking statements that involve risks, uncertainties and assumptions. The Company's actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth under "Risk Factors" and elsewhere in this prospectus.

#### 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 preclinical development, and the Company's activities are subject to significant risks and uncertainties, including the need for additional capital, as described below. The Company has not yet commenced any revenue-generating operations, does not have any cash flows from operations, and will need to raise additional capital to finance its operations.

#### **Plan of Operation**

The Company's technology is in the development phase. The Company believes that its licensed platforms have the potential for creating a robust pipeline of drug candidates addressing multiple medical indications. The Company intends to maximize the value and probability of commercialization of its CUE Biologics<sup>™</sup> immunotherapeutics 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. The Company intends to employ at least 12 scientists to conduct various planned experiments in furtherance of its technology. The Company plans to use the majority of the net proceeds from the initial public offering to fund these research and development efforts (see the section of this prospectus titled "Use of Proceeds").

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 would allow the Company to more fully exploit the potential of its technology platform, although no definitive agreement in that regard has been entered into as of the date of this prospectus.

#### **Going Concern**

The Company's financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any revenues from operations since inception, and does not expect to do so in the foreseeable future. The Company has experienced operating losses and negative operating cash flows since inception, and expects to continue to do so for at least the next few years. The Company has financed its working capital requirements during this period through the sale of its equity securities. At September 30, 2017, the Company had cash and a certificate of deposit totaling \$3,450,514 available to fund the Company's ongoing business activities.

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the financial statements are being issued. The Company's independent registered public accounting firm, in its report on the Company's financial statements for the year ended December 31, 2016, has also raised substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent on its ability to raise additional capital to fund its business activities, including its research and development program. The Company's objective is to complete an initial public offering in 2017 to provide the Company with additional financial resources to fund its operations, but there can be no assurances that the Company will be successful in this regard. Furthermore, 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 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. The Company's financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Because the Company is currently engaged in research at a relatively early stage, it will take a significant amount of time and resources to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years, and may never do so. In addition, to the extent that the Company is able to generate operating revenues, there can be no assurances that the Company will be able to achieve positive earnings and operating cash flows.

#### **Critical Accounting Policies**

The following discussion and analysis of financial condition and results of operations is based upon the Company's financial statements for the years ended December 31, 2016 and 2015 and for the nine months ended September 30, 2017 and 2016 presented elsewhere in this prospectus, which have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Certain accounting policies and estimates are particularly important to the understanding of the Company's financial position and results of operations and require the application of significant judgment by management or can be materially affected by changes from period to period in economic factors or conditions that are outside of the Company's control. As a result, these issues are subject to an inherent degree of uncertainty. In applying these policies, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on the Company's historical operations, the future business plans and the projected financial results, the terms of existing contracts, trends in the industry, and information available from other outside sources. For a more complete description of the Company's significant accounting policies, see Note 2 to the financial statements for the years ended December 31, 2016 and 2015 presented elsewhere in this prospectus.

#### **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 expensing schedule 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.

#### **Research and Development Funding Arrangements**

The Company's proprietary biologics are at an early stage and will require substantial time and funding to continue development. There can be no assurances that any of the Company's biologics will ultimately become commercially viable product candidates. In order to finance its research and development programs, the Company may periodically enter into collaboration agreements with third parties that provide funding for certain aspects of the Company's ongoing research and development activities. The Company considers various factors in determining the appropriate accounting treatment for such collaboration agreements, including, among others, the risks of and costs associated with the research and development program being funded, the stage of development of the proprietary biologics subject to the research and development program, the likelihood at initiation that the collaboration arrangement will result in an economically successful outcome to the third party, the continuing involvement of the Company in the research and development program and the expenditure of the funds, the transfer of the financial risk associated with the research and development program to the third party, the intended use of the funds and any restrictions thereon, and the probability of any repayment obligations or other forms of consideration if the proprietary biologics subject to the research and development program are not successfully developed and commercialized.

In accordance with ASC 730-20-25-8, to the extent that a collaboration agreement results in a substantive and genuine transfer of financial risk to a third party funding source because any economic benefit that the third party may receive depends solely on the research and development program successfully developing commercially viable product candidates having future economic benefit (which is uncertain at the initiation of the collaboration agreement), the Company will account for such collaboration agreement as a contract to perform research and development services for a third party. The funds received from the third party under such a collaboration agreement will initially be recorded as a deferred credit in the Company's balance sheet. As the related contractual research and development costs are incurred, the applicable amount of the deferred credit will be credited to operations and will be classified as an offset to such research and development costs in the Company's statement of operations.

#### 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. Patent expenses are included in general and administrative expenses in the Company's statement of operations.

#### Reclassification

Certain comparative figures for the years ended 2016 and 2015 have been adjusted to correct the classification of patent legal costs and intellectual property management fees from research and development expenses to general and administrative expenses. During the years ended December 31, 2016 and 2015, patent legal costs of \$366,131 and \$178,697, and intellectual property management fees of \$90,000 and \$38,182, aggregating \$456,131 and \$216,879, respectively, were reclassified from research and development costs to general and administrative costs. These changes did not impact loss from operations or net loss.

#### Licensing Fees and Costs

Licensing fees and costs consist primarily of costs relating to the acquisition of the Company's license agreement with the Albert Einstein College of Medicine, a division of Yeshiva University ("Einstein"), including related royalties, maintenance fees, milestone payments and product development costs. Licensing fees and costs are charged to operations as incurred.

#### Stock-Based Compensation

The Company periodically issues stock options 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, 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 vesting period. The fair value of stock options 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.

Stock options granted to members of the Company's Scientific and Clinical Advisory Board, non-employees and outside advisors and consultants are revalued each reporting period to determine the amount to be recorded as an expense in the respective period. As the stock options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the value on the date of vesting.

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**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). ASU 2014-09 will eliminate transactionand industry-specific revenue recognition guidance under current GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The FASB has issued ASU 2016-08, ASU 2016-10, ASU 2016-11, ASU 2016-12, and ASU 2016-20, all of which clarify certain implementation guidance within ASU 2014-09. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017, with early adoption permitted. Entities will be able to transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The Company will adopt the provisions of ASU 2014-09 in the quarter beginning January 1, 2018. As the Company is unlikely to generate any sustainable operating revenues in the next several years, the adoption of ASU 2014-09 is not currently expected to have any impact on the Company's financial statement presentation or disclosures.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes ("ASU 2015-17"). ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 was effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted as of the beginning of an interim or annual reporting period. The Company adopted the provisions of ASU 2015-17 in the quarter beginning January 1, 2017. The adoption of ASU 2015-17 did not have any impact on Company's financial statement presentation or disclosures.

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. 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 will adopt the provisions of ASU 2016-02 in the quarter beginning January 1, 2019. The Company generally does not finance purchases of property and equipment, but does lease its operating facilities. While the Company is continuing to assess the potential impact of ASU 2016-02, it currently expects that most of its lease commitments will be subject to ASU 2016-02 and accordingly, upon adoption will be recognized as lease liabilities and right-of-use assets in the Company's balance sheet.



In March 2016, the FASB issued Accounting Standards Update No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). ASU 2016-09 requires, among other things, that all income tax effects of awards be recognized in the statement of operations when the awards vest or are settled. ASU 2016-09 also allows for an employer to repurchase more of an employee's shares than it can today for tax withholding purposes without triggering liability accounting and allows for a policy election to account for forfeitures as they occur. ASU 2016-09 was effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted for any entity in any interim or annual period. The Company adopted the provisions of ASU 2016-09 in the quarter beginning January 1, 2017. The adoption of ASU 2016-09 did not have any impact on the Company's financial statement presentation or disclosures.

In July 2017, the FASB issued Accounting Standards Update No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The guidance in ASU 2017-11 can be applied using a full or modified retrospective approach. The adoption of ASU 2017-11 is not currently expected to have any impact on the Company's financial statement presentation or disclosures.

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.

## Acquisition of Trademark

On May 4, 2017, the Company entered into a settlement agreement with Cue BioLogics, LLC, an unrelated party, to acquire all 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 (collectively, the "CUE BIOLOGICS Mark"), in exchange for a cash payment by the Company of \$175,000.

Accounting Standards Codification ("ASC") 350-30-20 defines a defensive intangible asset as an acquired intangible asset in a situation in which an entity does not intend to actively use the asset but intends to hold (lock up) the asset to prevent others from obtaining access to the asset. The Company determined that the acquired intangible asset met the definition of a defensive intangible asset and has therefore accounted for the \$175,000 payment to Cue BioLogics, LLC for the CUE BIOLOGICS Mark as an acquired intangible asset.

As the Company can renew the underlying rights to the CUE BIOLOGICS trademark indefinitely at nominal cost, this acquired intangible asset has been classified as a non-amortizable intangible asset in Company's balance sheet at June 30, 2017. The Company evaluates the status of this intangible asset for amortization and impairment at each quarter end and year end reporting date.



## Significant Contracts and Agreements Related to Research and Development Activities

## 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, immunemodulatory drug 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 September 30, 2017, 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 September 30, 2017 and December 31, 2016.

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, 2016 and 2015, costs incurred with respect to the Einstein License aggregated \$31,250 and \$127,336, respectively, and for the nine months ended September 30, 2017 and 2016, costs incurred with respect to the Einstein License aggregated \$35,417 and \$25,000, respectively. Such costs are included in research and development costs in the statements of operations.

The Einstein License requires 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. A liquidity event includes, but is not limited to, an initial public offering of shares of the Company's common stock; a merger with a public reporting company under the Exchange Act, or a company whose shares are listed on a non-U.S. exchange or an affiliate thereof; a merger, consolidation, reorganization, or similar transaction whereby the Company's stockholders immediately prior to the consummation of the transaction; or a sale of substantially all of the Company's assets. Accordingly, the Company will be required to issue 671,572 shares of the Company. At September 30, 2017, a liquidity event had not occurred. Under the Einstein License, we must also use our best efforts to file a registration statement covering the resale of the 671,572 shares to be issued to Einstein no later than 180 days after the consummation of such an offering.

As the consummation of a liquidity event is outside the control of the Company, the Company will account for the issuance of these shares upon the occurrence of a liquidity event. Additionally, 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 Company will account for the issuance of such shares at their aggregate fair value on the date of issuance and, in accordance with ASC 730, Research and Development, will charge such amount to research and development expenses in the statements of operations. For basic earnings per share calculations, these shares will be treated as contingently issuable shares and will not be included in basic earnings per share until the shares have been issued.

## Service Agreement

On October 1, 2015, the Company entered into a service agreement (the "Service Agreement") with Einstein to support the Company's ongoing research and development activities. The initial term of the Service Agreement was for three months, which was amended in February 2016 to extend it for the period of time deemed necessary to complete the services pursuant to the terms of the Service Agreement. For the years ended December 31, 2016 and 2015, costs incurred with respect to the Service Agreement aggregated \$80,000 and \$200,000, respectively, and for the nine months ended September 30, 2017 and 2016, costs incurred with respect to the Service Agreement aggregated \$0 and \$80,000, respectively. Such costs are included in research and development expenses in the statements of operations.

#### Agreements with Catalent Pharma Solutions, LLC

Catalent Pharma Solutions, LLC ("Catalent") is a global provider of drug delivery technology and development solutions for drugs, biologics and consumer health products.

On March 7, 2017, the Company entered into an agreement with Catalent for Catalent to provide services on a sequential milestone basis with respect to the development and manufacture of the Company's lead drug candidate, CUE-101. The services under the agreement are designed to support the preparation and filing of an Investigational New Drug Application with the United States Food and Drug Administration to allow for the commencement of a Phase 1 clinical trial of CUE-101 in the United States. The Company currently estimates that it will incur total direct costs under this agreement aggregating approximately \$5,875,000, most of which the Company estimates will be incurred during the years ending December 31, 2017 and 2018. The Company expects that certain of these payments will consist of nonrefundable advance payments for which the Company anticipates receiving the contracted services within 12 months from the date of payment. Management periodically reviews and updates the project's estimated budget and timeline.

On July 5, 2017, the Company entered into a separate Master Services Agreement with Catalent that outlines the terms and conditions under which Catalent will provide contract services with respect to the Company's research and development activities for a period of five years. The Company may terminate this agreement without cause upon 90 days' prior written notice. Unless and until terminated, this agreement will automatically be extended for successive one-year periods.

With respect to the total estimated direct costs of approximately \$5,875,000, the Company had incurred \$1,263,384 of such costs as of September 30, 2017, of which \$1,158,925 was charged to research and development expenses in the condensed statement of operations for the nine months ended September 30, 2017, representing 11.7% of research and development expenses for such period. The remaining \$104,459 is reflected as research and development contract advances in the condensed balance sheet at September 30, 2017. The Company expects to receive the services related to such advance payments by March 31, 2018. Accordingly, advance payments at September 30, 2017 are classified as a current asset and are expected to be charged to research and development expenses in the statement of operations through March 31, 2018.

#### **Collaboration Agreement with Merck**

On November 14, 2017, we entered into an Exclusive Patent License and Research Collaboration Agreement (the "Collaboration Agreement") with Merck Sharp & Dohme Corp. ("Merck") for a partnership to research and develop certain of our proprietary biologics that target certain autoimmune

disease indications (the "Initial Indications"). 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. The research program outlined in the Collaboration Agreement entails (1) our research, discovery and development of certain CUE Biologics<sup>™</sup> 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 CUE Biologics<sup>™</sup> 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, we have granted to Merck under the Collaboration 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 CUE Biologics<sup>™</sup> that are elected to be developed by Merck. From the effective date of the Collaboration Agreement until the earlier of (i) the first achievement of Proof of Mechanism for a Cue Biologic<sup>™</sup> drug candidate or (ii) 18 months after we notify the joint steering committee that the first Product Candidate has been synthesized under the research program, we are required to forebear from researching, developing or licensing to a third party rights related to any CUE Biologics<sup>™</sup> drug candidate for the treatment of autoimmune diseases other than pursuant to the Collaboration Agreement. 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 Collaboration Agreement. The Company is not required to forbear at any time, however, from developing other Cue Biologics<sup>™</sup> for use in therapeutic areas other than autoimmune diseases, e.g., for use in treating cancer or infectious diseases.

In exchange for the licenses and other rights granted to Merck under the Collaboration Agreement, we will receive 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 Collaboration 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.

The term of the Collaboration 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 Collaboration 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 Collaboration Agreement at any time upon 30 days' notice to the Company. The Collaboration 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.

## **Results of Operations**

#### **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 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, 2016 and 2015

The Company's statements of operations for the years ended December 31, 2016 and 2015 as discussed herein are presented below.

		Years Ended December 31,		
	2016	2015		
Revenue	\$	\$		
Operating expenses:				
General and administrative	1,970,488	425,081		
Research and development	5,687,847	1,503,649		
Total operating expenses	7,658,335	1,928,730		
Loss from operations	(7,658,335)	(1,928,730)		
Interest income	52			
Net loss	\$(7,658,283)	\$(1,928,730)		

#### General and Administrative

General and administrative expenses totaled \$1,970,488 and \$425,081 for the years ended December 31, 2016 and 2015, respectively. This increase of \$1,545,407 was due primarily to the growth of the Company and its activities. General and administrative expenses for the year ended December 31, 2016 included expenses related to employee and board compensation of \$368,711, professional and consulting fees of \$768,586, rent of \$117,691, depreciation and amortization of \$4,630, stock-based compensation of \$439,366, investor relations of \$88,629, travel of \$63,746, and other expenses of \$119,129. General and administrative expenses for the year ended December 31, 2015 consisted of expenses related to employee and board compensation of \$42,000, professional and consulting fees of \$288,156, rent of \$42,455, depreciation and amortization of \$1,238, travel of \$9,948, and other expenses of \$41,284.

#### **Research and Development**

Research and development expenses totaled \$5,687,847 and \$1,503,649 for the years ended December 31, 2016 and 2015, respectively. This increase of \$4,184,198 was due primarily to the growth of the Company and its activities. Research and development expenses for the year ended December 31, 2016

included expenses related to employee and Scientific and Clinical Advisory Board compensation of \$1,330,625, depreciation and amortization of \$197,455, stock-based compensation of \$450,190, research and laboratory expenses of \$2,651,771, rent of \$846,818, licensing fees of \$69,465, other professional fees of \$103,407, and other expenses of \$38,116. Research and development expenses for the year ended December 31, 2015 included expenses related to employee and Scientific and Clinical Advisory Board compensation of \$415,683, depreciation and amortization of \$43,577, research and laboratory expenses of \$628,198, rent of \$319,091, licensing fees of \$94,167, and other expenses of \$2,933.

#### Loss from Operations

The Company's loss from operations was \$7,658,335 for the year ended December 31, 2016, as compared to \$1,928,730 for the year ended December 31, 2015.

#### Interest Income

Interest income was \$52 for the year ended December 31, 2016. The Company did not have any interest income for the year ended December 31, 2015.

#### Net Loss

As a result of the foregoing, the Company's net loss was \$7,658,283 for the year ended December 31, 2016, as compared to \$1,928,730 for the year ended December 31, 2015.

#### Nine Months Ended September 30, 2017 and 2016

The Company's unaudited condensed statements of operations for the nine months ended September 30, 2017 and 2016 as discussed herein are presented below.

	Nine Months Ended September 30,		
	2017	2016	
Revenue	\$ —	\$ —	
Operating expenses:			
General and administrative	2,914,452	1,193,527	
Research and development	9,880,529	3,622,409	
Total operating expenses	12,794,981	4,815,936	
Loss from operations	(12,794,981	) (4,815,936)	
Interest income		52	
Net loss	\$(12,794,981	) \$(4,815,884)	

## General and Administrative

General and administrative expenses totaled \$2,914,452 and \$1,193,527 for the nine months ended September 30, 2017 and 2016, respectively. This increase of \$1,720,925 was due primarily to the growth of the Company and its activities. General and administrative expenses for the nine months ended September 30, 2017 included expenses related to employee and board compensation of \$764,938, professional and consulting fees of \$723,401, investor relations of \$127,685, rent of \$172,773, depreciation and amortization of \$10,466, stockbased compensation of \$737,119, travel of \$131,911, and other expenses of \$246,159. General and administrative expenses for the nine months ended September 30, 2016 consisted of expenses related to employee and board compensation of \$210,227, professional and consulting fees of \$566,126, rent of \$63,818, depreciation and amortization of \$2,945, stock-based compensation of \$216,015, travel of \$44,592, and other expenses of \$89,804.

#### **Research and Development**

Research and development expenses totaled \$9,880,529 and \$3,622,409 for the nine months ended September 30, 2017 and 2016, respectively. This increase of \$6,258,120 was due primarily to the growth of the Company and its activities. Research and development expenses for the nine months ended September 30, 2017 included expenses related to employee and Scientific and Clinical Advisory Board compensation of \$2,242,260, depreciation and amortization of \$282,568, stock-based compensation of \$1,263,912, research and laboratory expenses of \$4,205,507, rent of \$1,297,909, licensing fees of \$78,616, other professional fees of \$373,451, and other expenses of \$136,306. Research and development expenses for the nine months ended September 30, 2016 included expenses related to employee and Scientific and Clinical Advisory Board compensation of \$895,394, depreciation and amortization of \$136,596, stock-based compensation of \$219,967, research and laboratory expenses of \$1,678,409, rent of \$574,364, licensing fees of \$49,176, other professional fees of \$52,000, and other expenses of \$16,503.

#### Loss from Operations

The Company's loss from operations was \$12,794,981 for the nine months ended September 30, 2017, as compared to \$4,815,936 for the nine months ended September 30, 2016.

#### **Interest Income**

Interest income was \$52 for the nine months ended September 30, 2016. The Company did not have any interest income for the nine months ended September 30, 2017.

#### Net Loss

As a result of the foregoing, the Company's net loss was \$12,794,981 for the nine months ended September 30, 2017, as compared to \$4,815,884 for the nine months ended September 30, 2016.

## Liquidity and Capital Resources — September 30, 2017 and December 31, 2016

The Company's financial statements are presented on a basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any revenues from operations since inception, and does not expect to do so in the foreseeable future. The Company has experienced operating losses and negative operating cash flows since inception, and expects to continue to do so. The Company has financed its working capital requirements during this period through the sale of equity securities. At September 30, 2017 and December 31, 2016, the Company had cash and a certificate of deposit totaling \$3,450,514 and \$14,975,853, 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 presented in this prospectus.

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the financial statements are being issued. The Company's independent registered public accounting firm, in its report on the Company's financial statements for the year ended December 31, 2016, has also raised substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above).

This offering is expected to generate gross proceeds of \$40,000,000 (or net proceeds of approximately \$36,875,000), if the minimum amount of common stock is sold, and gross proceeds of \$60,000,000 (or net proceeds of approximately \$55,825,000), if the maximum amount of common stock is sold. The Company intends to use the net proceeds from this offering as described in the section of this prospectus titled "Use of Proceeds".

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 the net proceeds from this offering (assuming that the minimum amount of common stock is sold), combined with its existing cash resources, will be sufficient to fund the Company's projected operating requirements for at least 12 months subsequent to the closing of this offering. However,

the expected net proceeds from this offering are not expected to be sufficient for the Company to be able to complete the development and commercialization of any of its drug candidates or platform technologies. 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.

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.

## **Operating Activities**

During the nine months ended September 30, 2017, the Company used cash of \$10,295,506 in operating activities, as compared to \$3,960,813 in operating activities during the nine months ended September 30, 2016. The difference between cash used in operating activities and net loss consisted primarily of depreciation and amortization, stock-based compensation, deferred rent, and changes in operating assets and liabilities.

During the year ended December 31, 2016, the Company used cash of \$5,968,411 in operating activities, as compared to \$1,657,567 in operating activities during the year ended December 31, 2015. The difference between cash used in operating activities and net loss consisted primarily of depreciation and amortization, stock-based compensation, and changes in operating assets and liabilities.

#### **Investing Activities**

During the nine months ended September 30, 2017, the Company used cash of \$1,185,705 in investing activities, consisting of \$1,010,705 for the purchase of office and laboratory equipment and \$175,000 for the purchase of the CUE BIOLOGICS Mark. During the nine months ended September 30, 2016, the Company used cash of \$421,141 for the purchase of office and laboratory equipment.

During the year ended December 31, 2016, the Company used cash of \$516,012 in investing activities, consisting of \$515,979 for the purchase of office and laboratory equipment and \$33 with respect to interest earned on the certificate of deposit. During the year ended December 31, 2015, the Company used cash of \$804,287, including \$754,287 for the purchase of office and laboratory equipment and \$50,000 for the purchase of a certificate of deposit.

#### **Financing Activities**

During the nine months ended September 30, 2017 the Company paid deferred offering costs of \$44,128. During the nine months ended September 30, 2016, the Company did not have any financing activities.

During the year ended December 31, 2016, the Company generated cash from financing activities of \$15,005,036, consisting of the net proceeds from the December 2016 common stock private placement. During the year ended December 31, 2015, the Company generated cash from financing activities of \$8,867,061, consisting of the proceeds from the issuance of common stock to the Company's founders of \$3,649, the net proceeds of \$8,862,412 from the June 2015 common stock private placement, and \$1,000 from the sale of warrants to the placement agent.



# **Principal Commitments**

## Leased Facilities

On July 29, 2015, the Company entered into an operating lease agreement for its laboratory space for the period from August 1, 2015 through April 30, 2018. The lease contains escalating payments during the lease period. The Company records monthly rent expense on the 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 November 14, 2016 and June 28, 2017, the Company entered into amendments to the operating lease agreement that each provided the Company with additional laboratory space. These amendments were effective beginning December 1, 2016 and July 1, 2017, respectively, and continue through the expiration of the lease on April 30, 2018. Subsequent to the expiration of this lease, the Company expects to enter into a new long-term operating lease for a similar facility in the same geographic area to house its operations and research activities.

On July 30, 2015, the Company entered into an operating lease agreement, as amended, for dedicated vivarium space for the period from August 1, 2015 through March 31, 2018. The operating lease agreement contains an option to increase the amount of space leased for an additional cost.

As of September 30, 2017, future minimum rental payments required under the operating leases for the years ended December 31 are presented below. Amounts reflected for 2017 represent amounts due at September 30, 2017 for the remainder of the 2017 fiscal year ending December 31, 2017.

Years Ending December 31,	
2017	\$ 676,500
2018	854,000
Total	\$1,530,500

## **Employment Agreements**

On August 29, 2016, the Company entered into an employment agreement with its President and Chief Executive Officer for an initial term ending on December 31, 2018 and continuing on a year-to-year basis thereafter, unless earlier terminated. Compensation under the agreement includes an annual salary of \$325,000, with annual review and adjustment at the discretion of the board of directors, a signing bonus of \$25,000 which was payable within 30 days of the effective date of the agreement, and an annual incentive bonus that may equal up to 30% of the annual salary based on performance standards established by the Compensation Committee of the Board of Directors. The agreement also provided for the grant of stock options to purchase shares of the Company's common stock. The agreement may be terminated by the Company without cause, as defined in the agreement, in which case, subject to certain requirements of the agreement, a severance payment would be due in a lump sum amount equal to (a) the target annual bonus prorated for the year of termination, plus (b) 12 months of base salary.

On May 31, 2017, the Company entered into an employment agreement with its Vice President of Translational Medicine for an initial term ending on December 31, 2018 and continuing on a year-to-year basis thereafter, unless earlier terminated. Compensation under the agreement includes an annual salary of \$250,000, with annual review and adjustment at the discretion of the Board of Directors, and an annual incentive bonus that may equal up to 30% of the annual salary based on performance standards established by the Compensation Committee of the Board of Directors. The agreement may be terminated by the Company without cause, as defined in the agreement, in which case, subject to certain requirements of the agreement, a severance payment would be due in a lump sum amount equal to (a) the target annual bonus prorated for the year of termination, plus (b) 6 months of base salary.

On November 15, 2017, the Company entered into an employment agreement with its Senior Vice President and General Counsel for an initial term ending on December 31, 2018 and continuing on a year-to-year basis thereafter, unless earlier terminated. Compensation under the agreement includes an annual salary of \$275,000, with annual review and adjustment at the discretion of the Board of Directors,

and an annual incentive bonus that may equal up to 20% of the annual salary based on performance standards established by the Compensation Committee of the Board of Directors. The agreement also provided for the grant of stock options to purchase shares of the Company's common stock. The agreement may be terminated by the Company without cause, as defined in the agreement, in which case, subject to certain requirements of the agreement, a severance payment would be due in a lump sum amount equal to (a) the highest annual bonus payable for the year of termination prorated for the year of termination, plus (b) 6 months of base salary.

#### Einstein License Agreement and Einstein Service Agreement

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

#### Agreements with Catalent

The Company's commitments with respect to its agreements with Catalent are summarized above at "Significant Contracts and Agreements Related to Research and Development Activities".

#### **Off-Balance Sheet Arrangements**

At September 30, 2017 and December 31, 2016, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

#### **Trends, Events and Uncertainties**

Research and development of new technologies are, by their nature, unpredictable. Although the Company will undertake development efforts with commercially reasonable diligence, there can be no assurance that the net proceeds from the initial public offering will be sufficient to enable the Company to develop its technology to the extent needed to create future sales to sustain operations as contemplated herein. If the net proceeds from the initial public offering are insufficient for this purpose, the Company will consider other options to continue its path to commercialization, including, but not limited to, additional financing through private placements, debt financing, co-development agreements, curtailment of operations, suspension of operations, sale or licensing of developed intellectual or other property, or other alternatives.

There can be no assurances that the Company's technology will be adopted or that the Company will ever achieve sustainable revenues sufficient to support its operations. Even if the Company is able to generate revenues, there can be no assurances that the Company will be able to achieve operating profitability or positive operating cash flows. There can be no assurances that the Company will be able to secure additional financing on acceptable terms or at all. If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to reduce or discontinue its technology and product development programs, or attempt to obtain funds, if available (although there can be no assurances), through strategic alliances that may require the Company to relinquish rights to certain of its potential products. 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.

Other than as discussed above and elsewhere in this prospectus, the Company is not currently aware of any trends, events or uncertainties that are likely to have a material effect on the Company's financial condition in the near term, although it is possible that new trends or events may develop in the future that could have a material effect on the Company's financial condition.



# DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth the names and ages of all of our directors and executive officers as well as the name and age of the chairman of our Scientific and Clinical Advisory Board.

Name	Age	Position
Daniel R. Passeri	57	Chief Executive Officer, President and Director
Gary Schuman	50	Interim Chief Financial Officer
Ken Pienta	57	Chief Medical Officer
Ronald Seidel, III	41	Executive Vice President, Head of Research and Development
Rodolfo Chaparro	45	Executive Vice President, Head of Immunology
Colin G. Sandercock	60	Senior Vice President and General Counsel
Peter A. Kiener	65	Chairman
Anthony DiGiandomenico	51	Director
Cameron Gray	47	Director
Christopher Marlett	53	Director
Steven McKnight	68	Director
Barry Simon	52	Director
Steven Almo	57	Chairman of Scientific and Clinical Advisory Board

Biographical information with respect to our executive officers and directors is provided below. There are no family relationships between any of our executive officers or directors.

## Daniel R. Passeri — Chief Executive Officer, President and Director

*Daniel R. Passeri, J.D.* joined Cue Biopharma in August 2016 as our Chief Executive Officer and President. He served as a director of Curis, Inc. (Nasdaq: CRIS) ("Curis"), a biotechnology company seeking to develop and commercialize drug candidates for the treatment of cancer, from September 2001 to June 2016. Mr. Passeri previously served as Chief Executive Officer of Curis from September 2001 until June 2014 and as Vice Chairman of its board of directors from June 2014 to June 2016, and additionally held the title of President from September 2001 to February 2013. Previously, from November 2000 to September 2001, Mr. Passeri served as the Senior Vice President, Corporate Development and Strategic Planning of Curis. From December 2014 to June 2015, Mr. Passeri served as Chief Officer of Technology Management and Business Development of the Jackson Laboratory for Genomic Medicine. From March 1997 to November 2000, Mr. Passeri was employed by GeneLogic Inc., a biotechnology company, most recently as Senior Vice President, Corporate Development and Strategic Planning. From February 1995 to March 1997, Mr. Passeri was employed by Boehringer Mannheim, a pharmaceutical, biotechnology and diagnostic company, as Director of Technology Management. Mr. Passeri received a J.D. from the National Law Center at George Washington University, an M.Sc. in biotechnology from the Imperial College of Science, Technology and Medicine at the University of London and a B.S. in biology from Northeastern University.

Mr. Passeri's qualifications to serve as a director of Cue Biopharma include his extensive service and experience as a director and executive officer of a public company as well as his extensive experience in corporate strategy and development, intellectual property strategy and oversight, and technology licensing, as each of these elements are critical to our overall business strategy.

## Gary Schuman — Interim Chief Financial Officer

*Gary Schuman* has been our Interim Chief Financial Officer since March 2015. He is also the Chief Financial Officer and Chief Compliance Officer of MDB. Mr. Schuman has been with MDB since November 2009. From May 2014 to November 2015, Mr. Schuman served as Chief Financial Officer of Pulse Biosciences, Inc. From 2010 to April 2017, Mr. Schuman served as Chief Financial Officer of Integrated Surgical Systems, Inc., now known as theMaven, Inc. From 2003 to 2008, Mr. Schuman was the Chief Financial Officer and Chief Compliance Officer of USBX Advisory Services, LLC, an investment

banking firm focused on mergers and acquisitions, and Chief Financial Officer of its parent company, USBX, Inc., from 2003 to 2009. Mr. Schuman received a Bachelor of Arts degree in Economics from UCLA and an MBA from the Marshall School of Business at the University of Southern California.

#### Ken Pienta — Chief Medical Officer

*Ken Pienta*, *M.D.* joined Cue Biopharma in April 2017 as our Chief Medical Officer. He has served as a director of Curis since March 2013. He is currently the Donald S. Coffey Professor of Urology and Professor of Oncology and Pharmacology and Molecular Sciences at the Johns Hopkins University School of Medicine and serves as the Director of Research for the Brady Urological Institute. From 1995 to 2013, Dr. Pienta was the Director of the Prostate Specialized Program of Research Excellence (SPORE) at The University of Michigan. He is a two-time American Cancer Society Clinical Research Professor Award recipient, is the author of more than 350 peer-reviewed articles, and has been the principle investigator on numerous local and national clinical trials. Dr. Pienta received a B.A. and an M.D. from the Johns Hopkins University.

#### Ronald Seidel, III — Executive Vice President, Head of Research and Development

*Ronald Seidel III, Ph.D.* is one of our Executive Vice Presidents and our Head of Research and Development. Dr. Seidel is a scientific co-founder of Cue Biopharma and co-inventor of our licensed core technologies. Prior to joining us, Dr. Seidel was a research Assistant Professor of Biochemistry and Director of the Macromolecular Therapeutic Development Facility (the "MTDF") at Einstein from 2008 to 2015. The function of the MTDF was to leverage high throughput technologies for the development, analysis and production of protein-based therapeutics. Additionally, through the MTDF, Dr. Seidel was the Associate Director of Eukaryotic Protein Production at the Northeast BioDefense Center from 2008 to 2013. He also served as a consultant to various companies in the biologics and protein production industries. Dr. Seidel holds a Bachelor of Sciences degree and Ph.D. in Biochemistry from the University of Georgia. He did his post-doctoral work at New York Structural Biology Center.

## Rodolfo Chaparro — Executive Vice President, Head of Immunology

*Rodolfo Chaparro, Ph.D.* is one of our Executive Vice Presidents and our Head of Immunology. Dr. Chaparro is a scientific co-founder of Cue Biopharma and co-inventor of our licensed core technologies. Prior to joining us, he served as research faculty in the Department of Biochemistry at Einstein from 2010 to 2014 with research expertise in immune profiling and immunotherapeutics, and became Head of Immunology within the MTDF. He began working at Einstein as a postdoctoral fellow in 2004 and joined the MTDF in 2010. Dr. Chaparro holds a Bachelor of Sciences degree in Biology from the University of California at Irvine and a Ph.D. in Immunology from Stanford University.

## Colin G. Sandercock — Senior Vice President and General Counsel

*Colin Sandercock* has been our Senior Vice President and General Counsel since December 4, 2017. Prior to joining Cue Biopharma, he was a partner at Perkins Coie LLP since July 2010, practicing in the areas of patent litigation, procurement, management and enforcement of domestic and foreign patent portfolio, licensing disputes, trademark disputes, and opinions relating to infringement, validity and freedom to operate. Mr. Sandercock holds a B.S. from Moravian College, an M.S.E. from the University of Pennsylvania and a J.D. from Catholic University, Columbus School of Law.

## Peter Kiener — Chairman

*Peter Kiener* joined our board of directors in March 2016. Dr. Kiener has served as the Chief Scientific Officer and Head of Research and Development of Sucampo Pharmaceuticals, Inc. ("Sucampo"), a global biopharmaceutical company, since 2014. Prior to joining Sucampo, Dr. Kiener served as the Chief Scientific Officer of Ambrx, Inc., a clinical-stage biopharmaceutical company focused on the development of antibody-drug conjugates since 2013. From 2009 to 2013, he was President and co-founder of Zyngenia Inc., an early-stage biopharmaceutical company. Dr. Kiener holds a Bachelor's Degree in Chemistry from

the University of Lancaster and a Doctorate of Philosophy in Biochemistry from the University of Oxford. Dr. Kiener's extensive executive leadership experience and his in-depth knowledge of the biopharmaceutical industry make him well qualified to serve on our board of directors as Chairman.

#### Anthony DiGiandomenico — Director

Anthony DiGiandomenico joined our board of directors in June 2015. He has also served on the board of directors of ENDRA Life Sciences Inc. (Nasdaq: NDRA), a developer of enhanced ultrasound technology, since July 2013. Since he co-founded MDB in 1997, Mr. DiGiandomenico has been enabling investment into early-stage disruptive technologies. He has worked alongside a wide range of companies in the biotechnology, medical devices, high technology, and renewable energy spaces. Mr. DiGiandomenico holds an MBA from the Haas School of Business at the University of California, Berkeley and a BS in Finance from the University of Colorado. Mr. DiGiandomenico's financial expertise, general business acumen and significant executive leadership experience position him well to make valuable contributions to our board of directors.

## Cameron Gray — Director

*Cameron Gray, Ph.D., J.D.* has been a member of our board of directors since January 2015 and served as our Chief Executive Officer from June 2015 to August 2016. He is also a Managing Director at MDB. Dr. Gray has been with MDB since September 2013. Prior to joining MDB, Dr. Gray served as Chief Executive Officer and a member of the board of directors of Endeavor IP, Inc., an intellectual property services and patent licensing company, from May 2013 through January 2014. He was self-employed from January 2012 through May 2013 and prior to that he was Senior Vice President at ICAP Patent Brokerage, LLC where he managed its life sciences and Asia Pacific businesses from January 2009 through January 2012. Dr. Gray has a Juris Doctor degree from George Washington University School of Law, a Ph.D. in biophysics from the University of Virginia, and a Bachelor of Arts degree in physics from Princeton University. Dr. Gray's extensive industry, executive and board experience position him well to serve as a member of our board of directors.

#### **Christopher Marlett — Director**

*Christopher Marlett* joined our board of directors in June 2015. Mr. Marlett is, and has been since 1997, the Chief Executive Officer and a co-founder of MDB. He has also served on the board of directors of theMaven, Inc., a developer of a network of professionally-managed online media channels, since April 2008. Mr. Marlett has over twenty-seven years of investment banking experience, including all phases of corporate finance, such as the completion of initial public offerings, secondary offerings, PIPEs and strategic consulting. He holds a Bachelor of Science degree in Business Administration from the University of Southern California. Mr. Marlett's leadership and financial experience position him well to serve as a member of our board of directors.

#### Steven McKnight — Director

*Professor Steven McKnight* joined our board of directors in March 2016. Dr. McKnight is the founder and chairman of the Scientific Advisory Board of Peloton Therapeutics, Inc., a clinical-stage biotechnology company that discovers and develops first-in-class, small molecule cancer therapies targeting unexploited molecular vulnerabilities, which he founded in 2011, and founded Neuroprotective Therapeutics, Inc. in 2017. He also serves as a professor and the Chairman of the Department of Biochemistry at UT Southwestern Medical Center, where he has led an active research laboratory since 1996. He is a member of the National Academy of Sciences, the National Academy of Medicine, and the American Academy of Arts and Sciences. Dr. McKnight is the recipient of many awards, including induction into the Hall of Honor at The University of Texas at Austin, College of Natural Sciences and the Monsanto Award from the National Academy of Sciences. Dr. McKnight holds a B.S. in Biology from The University of Texas at Austin and a Ph.D. in Biology from the University of Virginia. His extensive academic accomplishments and pertinent research experience position him well to serve on our board of directors.



## Barry Simon — Director

*Barry J. Simon, M.D.* joined our board of directors in March 2016. He has served as a member of the board of directors of Nantkwest Inc., a clinical-stage immunotherapy company, since 2007 and as its President and Chief Operating Officer since 2015. From 2007 to 2015, Dr. Simon was also Nantkwest Inc.'s President and Chief Executive Officer. Prior to this, he held various senior management and advisory positions at Roche Labs, Inc., a pharmaceuticals company, F. Hoffmann-La Roche AG, a global healthcare company, Connetics Corporation, a specialty pharmaceutical company, Immunomedics, Inc., a biopharmaceutical company, HealthPro BioVentures, LLC, a healthcare and life sciences investment bank, and NorthSound Capital, LLC, a U.S.-based hedge fund. Dr. Simon has attended corporate training programs by the London School of Business and the Amos Tuck School of Business at Dartmouth College. He is clinically trained in infectious diseases, anesthesiology, and internal medicine and received his M.D. from the SUNY Downstate, Health Sciences Center in New York. Dr. Simon's many years of management and director experience make him well-qualified to serve on our board of directors.

## Steven Almo — Chairman of Scientific and Clinical Advisory Board

*Steven C. Almo, Ph.D.* is the Chairman of our Scientific and Clinical Advisory Board, which he joined in January 2015. Dr. Almo has been a professor in the Department of Biochemistry and Department of Physiology & Biophysics at Einstein since 1992. Prior to joining Einstein, Dr. Almo was a post-doctoral fellow at Johns Hopkins School of Medicine from 1990 to 1992. Dr. Almo also serves as Director of the Macromolecular Therapeutics Development Facility at Einstein and since July 2017 has served as the President of the Institute for Protein Innovation (a 503(c) non-profit organization located in Harvard Medical School). He received his Ph.D. in Biophysics at Harvard University and has published more than 300 peer-reviewed publications.

#### **Director Independence**

Upon the completion of this offering, we anticipate that our common stock will be listed on the Nasdaq Capital Market ("Nasdaq"). Under the listing requirements and rules of Nasdaq, independent directors must constitute a majority of a listed company's board of directors within 12 months after its initial public offering. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

We intend to rely on the phase-in rules of Nasdaq with respect to the independence of our board of directors. In accordance with this phase-in provision, a majority of our board of directors will be independent within one year of the effective date of the registration statement of which this prospectus is a part.

Our board of directors has determined that each of Peter Kiener, Steven McKnight and Barry Simon are "independent directors" as such term is defined by Nasdaq Marketplace Rule 5605(a)(2). We have established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each of Peter Kiener, Steven McKnight and Barry Simon serve as members of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. Our board of directors has determined that Peter Kiener is an audit committee financial expert, as defined under the applicable rules of the SEC, and that all members of the Audit Committee are "independent" within the meaning of the applicable Nasdaq listing standards and the independence standards of Rule 10A-3 of the Securities Exchange Act of 1934. Each of the members of the Audit Committee meets the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq Stock Market.



# EXECUTIVE COMPENSATION

Our compensation philosophy is to offer our executive officers compensation and benefits that are competitive and meet our goals of attracting, retaining and motivating highly skilled management, which is necessary to achieve our financial and strategic objectives and create long-term value for our stockholders. We believe the levels of compensation we provide should be competitive, reasonable and appropriate for our business needs and circumstances. The principal elements of our executive compensation program have to date included base salary and long-term equity compensation in the form of stock options. We believe successful long-term Company performance is more critical to enhancing stockholder value than short-term results. For this reason and to conserve cash and better align the interests of management and our stockholders, we emphasize long-term performance-based equity compensation over base annual salaries.

The following table sets forth information concerning the compensation earned by the individuals that served as our Principal Executive Officer during 2016 and our two most highly compensated executive officers other than the individual who served as our Principal Executive Officer during 2016 (collectively, the "named executive officers"):

## **Summary Compensation Table**

Name & Position	Fiscal Year	Salary (\$)	Bonus (\$)	Option Awards (\$) <sup>(1)</sup>	Total (\$)
Daniel R. Passeri Chief Executive Officer	2016 <sup>(2)</sup>	112,027	57,500	2,289,178	2,458,705
Rodolfo J. Chaparro Executive Vice President, Head of Immunology	2016 2015	203,333 90,000	50,000 30,000 <sup>(3)</sup>	504,135 —	757,468 120,000
Ronald D. Seidel Executive Vice President, Head of Research & Development	2016 2015	203,333 90,000	50,000 30,000 <sup>(3)</sup>	504,135 —	757,468 120,000

(1) The amounts shown in this column indicate the grant date fair value of option awards granted in the subject year computed in accordance with FASB ASC Topic 718. For additional information regarding the assumptions made in calculating these amounts, see notes 2 and 5 to our audited financial statements included herein.

- (2) Represents a partial year of employment. Mr. Passeri joined us on August 29, 2016.
- (3) Represents amount paid to each of Mr. Chaparro and Mr. Seidel for relocation.

## **Outstanding Equity Awards at 2016 Fiscal Year-End**

The following table provides information regarding equity awards held by the named executive officers as of December 31, 2016.

	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise	Option Expiration
Name & Principal Position	(#)	(#)	Price (\$)	Date
Daniel R. Passeri Chief Executive Officer	_	544,732 <sup>(1)</sup>	\$2.86	08/29/2023
Rodolfo Chaparro Executive Vice President, Head of Immunology	—	120,000 <sup>(2)</sup>	\$2.86	09/07/2023
Ronald Seidel Executive Vice President, Head of Research & Development	_	120,000 <sup>(2)</sup>	\$2.86	09/07/2023



- (1) These options vest in eight equal semi-annual installments beginning on February 28, 2017.
- (2) These options vest in eight equal semi-annual installments beginning on March 7, 2017.

#### **Employment Agreements**

The following is a summary of the employment arrangements with our named executive officers as currently in effect.

**Daniel R. Passeri.** We entered into an employment agreement with Mr. Passeri effective August 29, 2016. The initial term of the employment agreement continues through December 31, 2018 and, unless terminated sooner pursuant to the terms of the employment agreement, continues on a year-to-year basis thereafter. Mr. Passeri's current annual base salary is \$325,000, and he is eligible for an annual incentive bonus of up to 30% of his base salary based upon achievement of performance-based objectives established by our board of directors. Upon entering into the employment agreement, Mr. Passeri received a one-time cash payment of \$25,000, which amount is forfeitable if Mr. Passeri terminates his employment without Good Reason or is terminated by the Company for Cause (as such terms are defined in Mr. Passeri's employment agreement) prior to the first anniversary of his employment. Pursuant to Mr. Passeri's employment agreement, he was granted a seven-year option to purchase a number of shares of our common stock equal to 5% of the common stock issued and outstanding as of the effective date of the employment agreement. Mr. Passeri's stock option becomes exercisable over four years in eight equal semi-annual installments beginning six months after the option's date of grant.

If Mr. Passeri's employment is terminated due to his death or disability, Mr. Passeri will be entitled to receive (i) any unpaid salary through the date of termination, (ii) any annual bonus earned but unpaid prior to the date of termination, (iii) reimbursement of any business expenses incurred through the date of termination, (iv) any accrued but unused vacation time, (v) all other payments, benefits or fringe benefits to which Mr. Passeri is entitled under the terms of any applicable compensation arrangement or benefit plan, and (vi) an annual bonus for the year in which such termination occurs, determined and payable as though no such termination had occurred. If Mr. Passeri's employment is terminated without Cause or for Good Reason, he will be entitled to receive each of the benefits described in the foregoing clauses (i)-(v) and, subject to the terms and provisions of the employment agreement, a lump sum cash payment in an amount equal to (A) the annual bonus, prorated based on the number of days that Mr. Passeri's employment is terminated for Cause or without Good Reason, he will be entitled to receive (i) any unpaid salary through the date of termination, (ii) reimbursement of any business expenses incurred through the date of termination plus (B) twelve (12) months of base salary. If Mr. Passeri's employment is terminated for Cause or without Good Reason, he will be entitled to receive (i) any unpaid salary through the date of termination, (ii) reimbursement of any business expenses incurred through the date of termination, (iii) any accrued but unused vacation time, and (iv) all other payments, benefits or fringe benefits to which Mr. Passeri is entitled under the terms of any applicable compensation arrangement or benefit plan.

Under his employment agreement, Mr. Passeri is subject to confidentiality, noncompetition and nonsolicitation provisions that survive the term of his employment.

**Rodolfo Chaparro**. Effective as of the closing of the private placement of our common stock on June 15, 2015, the Company entered into an employment agreement with Dr. Chaparro. The employment agreement has no specific term and constitutes at-will employment. Under the employment agreement Mr. Chaparro is being paid an annual salary of \$250,000. Under the employment agreement, Mr. Chaparro is entitled to bonus compensation and equity award grants with the value and terms generally commensurate with those of other senior executives of the Company, including incentive stock options in an amount customary for senior executives of biotechnology companies as determined by the board of directors in its sole discretion.

If Mr. Chaparro's employment is terminated by the Company for any reason other than Cause, death or Disability or if Mr. Chaparro resigns for Good Reason (as such terms are defined in the employment agreement), Mr. Chaparro will be entitled to receive six months' continuation of his then-current base salary and a cash lumpsum payment in an amount equal to accrued unpaid bonuses through the end of the fiscal half year in which the termination occurs. Additionally, any unvested portion of any options will vest



immediately upon such termination or resignation and will remain exercisable thereafter for the period prescribed in the applicable equity award plan. If Mr. Chaparro elects continuation healthcare coverage under COBRA, the Company will reimburse his monthly premiums until the earlier of Mr. Chaparro and his dependents regaining coverage under a healthcare plan or the date upon which Mr. Chaparro is no longer eligible for coverage under COBRA.

Mr. Chaparro is eligible to receive benefits that are substantially similar to those of the Company's other senior executive officers and is also reimbursed for pre-approved expenses incurred in furtherance of his duties under the employment agreement. Mr. Chaparro is also entitled paid vacation of not less than four weeks per year, two weeks of which may be rolled over to the following year, provided that accrued unused vacation in any one year does not exceed six weeks. Mr. Chaparro is subject to certain restrictive covenants, including non-solicitation of employees for a period of one year following termination of his employment with the Company and non-competition for a period of six months following termination of his employment with the Company. Mr. Chaparro has also entered into our standard inventions assignment and confidentiality agreement.

**Ronald Seidel.** Effective as of the closing of the private placement of our common stock on June 15, 2015, the Company entered into an employment agreement with Dr. Seidel. The employment agreement has no specific term and constitutes at-will employment. Under the employment agreement, Mr. Seidel is being paid an annual salary of \$250,000. Under the employment agreement, Mr. Seidel is entitled to bonus compensation and equity award grants with the value and terms generally commensurate with those of other senior executives of the Company, including incentive stock options in an amount customary for senior executives of biotechnology companies as determined by the board of directors in its sole discretion.

If Mr. Seidel's employment is terminated by the Company for any reason other than Cause, death or Disability or if Mr. Seidel resigns for Good Reason (as such terms are defined in the employment agreement), Mr. Seidel will be entitled to receive six months' continuation of his then-current base salary and a cash lump-sum payment in an amount equal to accrued unpaid bonuses through the end of the fiscal half year in which the termination occurs. Additionally, any unvested portion of any options will vest immediately upon such termination or resignation and will remain exercisable thereafter for the period prescribed in the applicable equity award plan. If Mr. Seidel elects continuation healthcare coverage under COBRA, the Company will reimburse his monthly premiums until the earlier of Mr. Seidel and his dependents regaining coverage under a healthcare plan or the date upon which Mr. Seidel is no longer eligible for coverage under COBRA.

Mr. Seidel is eligible to receive benefits that are substantially similar to those of the Company's other senior executive officers and is also reimbursed for pre-approved expenses incurred in furtherance of his duties under the employment agreement. Mr. Seidel is also entitled paid vacation of not less than four weeks per year, two weeks of which may be rolled over to the following year, provided that accrued unused vacation in any one year does not exceed six weeks. Mr. Seidel is subject to certain restrictive covenants, including non-solicitation of employees for a period of one year following termination of his employment with the Company and non-competition for a period of six months following termination of his employment with the Company. Mr. Seidel has also entered into our standard inventions assignment and confidentiality agreement.

#### **Director Compensation**

In 2016, independent members of our board of directors received a one-time grant of stock options for their service as directors since their appointment to the board of directors. These stock options vest in five annual installments beginning in March 2017. On July 27, 2016, we adopted a director compensation policy pursuant to which our independent directors receive on an annual basis a \$30,000 retainer paid in cash. Pursuant to the director compensation policy, as revised on June 14, 2017, an independent director who also serves as Chairman of the board of directors receives on an annual basis an additional \$45,000 retainer paid in cash.

The following table sets forth information with respect to compensation earned by or awarded to each of our independent directors who served on our board of directors during the year ended December 31, 2016. Our non-independent directors do not receive any compensation for serving on our board of directors.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) <sup>(1)</sup>	All Other Compensation (\$)	Total (\$)
Peter A. Kiener	23,250	535,182		558,432
Steven McKnight	23,250	535,182	—	558,432
Barry Simon	23,250	535,182	—	558,432

(1) The amounts shown in this column indicate the grant date fair value of option awards granted in the subject year computed in accordance with FASB ASC Topic 718. For additional information regarding the assumptions made in calculating these amounts, see the notes to our audited financial statements included herein. The following table shows the number of shares subject to outstanding option awards held by each non-employee director as of December 31, 2016:

Name	Shares subject to Outstanding Stock Option Awards (#)
Peter A. Kiener	125,920
Steven McKnight	125,920
Barry Simon	125,920

## DESCRIPTION OF CAPITAL STOCK

The following is a brief description of our capital stock. This summary does not purport to be complete in all respects. This description is subject to and qualified entirely by the terms of our amended and restated certificate of incorporation (the "Certificate of Incorporation"), and our amended and restated bylaws (the "Bylaws"), each of which we plan to adopt prior to the completion of this offering and copies of which have been filed with the SEC and are also available upon request from us.

## **Authorized Capitalization**

We have 60,000,000 shares of capital stock authorized under our Certificate of Incorporation, consisting of 50,000,000 shares of common stock with a par value of \$0.001 per share and 10,000,000 shares of preferred stock with a par value of \$0.001 per share. As of September 30, 2017, we had 10,635,684 shares of common stock outstanding and no shares of preferred stock outstanding. Our authorized but unissued shares of common stock and preferred 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 in the future.

#### **Common Stock**

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

Each holder of our 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.

In the event of our liquidation, dissolution or winding up, the holders of our common stock are entitled to receive pro rata our assets, which are legally available for distribution, after payments of all debts and other liabilities. All of the outstanding shares of our common stock are fully paid and non-assessable. The shares of common stock offered by this prospectus will also be fully paid and non-assessable.

#### **Stock Options and Warrants**

As of September 30, 2017, we had reserved the following shares of common stock for issuance pursuant to stock options, warrants and equity plans:

- 2,366,221 shares of our common stock reserved for issuance under stock option agreements issued pursuant to our 2016 Omnibus Incentive Plan and 2016 Non-Employee Equity Incentive Plan at a weighted average exercise price of \$3.50 per share;
- 370,370 shares of common stock reserved for issuance under outstanding warrants at a weighted average exercise price of \$2.70 per share;
- 803,779 shares of our common stock reserved for future issuance under our 2016 Omnibus Incentive Plan;
- 130,000 shares of our common stock reserved for future issuance under our 2016 Non-Employee Equity Incentive Plan.

In addition, we have agreed to sell to the underwriters, for nominal consideration, warrants to purchase 533,333 shares (if the minimum amount of common stock is sold), to 800,000 shares (if the maximum amount of common stock is sold), as additional consideration to the underwriters in this offering.

## Stock Incentive Plan and Other Employment Related Options

We have adopted the 2016 Omnibus Incentive Plan (the "Omnibus Plan") and the 2016 Non-Employee Equity Incentive Plan (the "Non-Employee Plan"), which provide for the grant of incentive stock options and non-qualified stock options to purchase shares of our common stock, restricted stock and restricted stock units, performance awards and other share-based awards. The purpose of the plans is to enhance the Company's ability to attract and retain highly qualified officers, non-employee directors, key employees and consultants, and to motivate such persons to serve the Company and to expend maximum effort to improve the business results and earnings of the Company, by providing to such persons an opportunity to acquire or increase a direct proprietary interest in the operations and future success of the Company.

In August 2017, our board of directors approved an amendment and restatement of the Omnibus Plan. We have reserved 2,800,000 shares of common stock under the Omnibus Plan and 500,000 shares of our common stock under the Non-Employee Plan. The Omnibus 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 the Omnibus 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 Omnibus Plan equals 20.0% 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 determined by our board of directors.

All officers, directors and employees and certain consultants to our company are eligible to participate under the plan. The plans provide that options may not be granted at an exercise price less than the fair market value of our common shares on the date of grant. The plan is administered by the board of directors or a committee thereof, which currently is the Compensation Committee. The board of directors and the committee have the discretion to determine the nature of the awards and the number of shares subject to an award, the exercise price, vesting provisions, and the term of the award. Awards under the plans are intended to be exempt from Section 16 of the Exchange Act, and will be administered to achieve this objective.

As of September 30, 2017, under the Omnibus Plan we have granted options to purchase an aggregate of 1,996,221 shares of our common stock at a weighted average exercise price of \$3.28 per share and have available for future grants 803,779 shares (subject to stockholder approval of the amendment and restatement of our Omnibus Plan approved by our board of directors in August 2017). As of September 30, 2017, under the Non-Employee Plan we have granted options to purchase an aggregate of 370,000 shares of our common stock at a weighted average exercise price of \$4.65 per share and have available for future grants 130,000 shares.

## **Contingent Issuance of Shares to Einstein**

Pursuant to the terms of our license agreement with Einstein, immediately prior to the consummation of this offering, we are required to issue to Einstein 671,572 shares of our Common Stock.

#### **Anti-Dilution Rights**

Our number of outstanding shares of common stock could change in the future due to the anti-dilution rights of holders of 3,282,980 shares of our outstanding common stock, who have anti-dilution protection that could result in additional dilution to our stockholders generally. These investors acquired their shares in our December 2016 private placement at a price of \$5.00 per share. The anti-dilution protection provides that, if at any time on or prior to December 31, 2019, we issue additional shares of common stock without consideration, or for a consideration per share less than the Effective Per Share Purchase Price (as described below) deemed to be in effect immediately prior to such issuance, then concurrently with such issuance, we shall issue to each of these investors, for no additional consideration, a number of additional shares of common stock to replicate the issuance of shares to such investors at such lower price (subject to a minimum per share price of \$2.50). Notwithstanding the foregoing, no shares will be issued to these investors as the result of an issuance or deemed issuance of additional shares of common



stock if we receive written notice from a number of these investors who purchased at least a majority of shares sold in the December 2016 private placement (the "Majority Investors") agreeing that no such issuance will be made as the result of such issuance or deemed issuance of such additional shares. Initially, the "Effective Per Share Purchase Price" is \$5.00. Following any issuance as a result of the foregoing anti-dilution rights, the Effective Per Share Purchase Price will be adjusted to equal the per share price associated with such issuance.

Pursuant to an Irrevocable Waiver and Amendment to Securities Purchase Agreements entered into on December 4, 2017, the Majority Investors agreed that no shares shall be issuable pursuant to these anti-dilution rights in connection with any issuance of common stock occurring after the Company's initial public offering.

#### **Registration Rights**

Holders of 7,357,054 shares of our common stock, including those issuable upon the exercise of outstanding warrants, will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of a registration rights agreement dated as of June 15, 2015 among us and the holders of securities issued in the June 2015 private placement, as supplemented by a joinder and amendment to registration rights agreement, dated as of December 22, 2016, among us and the holders of securities issued in the December 2016 private placement (the "Registration Rights Agreement"). The holders of securities issued in the June 2015 private placement and the December 2016 private placement are referred to, collectively, as the "Private Placement Holders".

Pursuant to the Registration Rights Agreement, beginning 180 days after we become a reporting company under the Exchange Act, if we register any of our securities, the Private Placement Holders will be entitled to include in the registration their shares that are subject to the Registration Rights Agreement. Additionally, Private Placement Holders who collectively hold more than 50% of the shares subject to the Registration Rights Agreement have a one-time right to demand that we register for resale their shares that are subject to the Registration Rights Agreement. MDB, one of the Private Placement Holders, also has a one-time right under the Registration Rights Agreement to demand that we register for resale its shares that are subject to the registration rights agreement.

The rights under the Registration Rights Agreement are subject to certain cutback provisions and customary suspension provisions. We have agreed to pay all registration expenses (excluding underwriting fees, discounts and selling commissions) under the Registration Rights Agreement.

Additionally, pursuant to the terms of our license agreement with Einstein, we must use our best efforts to file a registration statement covering the resale of the 671,572 shares to be issued to Einstein immediately prior to this offering no later than 180 days after the consummation of the offering.

#### **Preferred Stock**

Our board of directors has the authority, without further action by the 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 change in our control or other corporate action. No shares of preferred stock are outstanding, and we have no present plan to issue any shares of preferred stock.

## **Anti-Takeover Provisions**

The provisions of Delaware law, our Amended and Restated Certificate of Incorporation and Bylaws to be in effect upon completion of this offering, could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. 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, 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 662/3% 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.

In general, Section 203 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**

Our Certificate of Incorporation and Bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our Company. 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 our Company 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.* Our 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.* Our 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.* Our 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 General Corporation Law of the State of Delaware. 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. Our 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. Our 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 our Company.

*Supermajority Voting for Amendments to Our Governing Documents.* Any amendment to our Certificate of Incorporation will require the affirmative vote of at least 66 2/3% of the voting power of all shares of our capital stock then outstanding. Our Certificate of Incorporation provides that the board of directors is expressly authorized to adopt, amend or repeal our Bylaws and that our stockholders may amend our 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.* Our 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 Delaware General Corporation Law, or any other provision of Title 8 of the Delaware Code, confers jurisdiction upon the Court of Chancery.

## **Transfer Agent**

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

# SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

We have set forth in the following table certain information regarding our common stock beneficially owned by (i) each stockholder we know to be the beneficial owner of 5% or more of our outstanding common stock, (ii) each of our directors and named executive officers, and (iii) all executive officers and directors as a group. Generally, a person is deemed to be a "beneficial owner" of a security if that person has or shares the power to dispose or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities of which the person has the right to acquire beneficial ownership within 60 days pursuant to options, warrants, conversion privileges or similar rights. Unless otherwise indicated, ownership information is as of September 30, 2017, and is based on 10,635,684 shares of common stock outstanding on that date (plus the number, if any, of shares of common stock which a person has the right to acquire beneficial ownership within 60 days thereof).

	Shares of Common Stock	Shares Underlying Options	Shares Underlying Warrants <sup>(2)</sup>	Number of Shares Beneficially Owned <sup>(3)</sup>	Percentage Owned Prior to the Offering	Percentage Owned After the Offering (Minimum) <sup>(4)</sup>	Percentage Owned After the Offering (Maximum) <sup>(4)</sup>
Directors and Executive Officers <sup>(1)</sup>							
Daniel R. Passeri	40,000	136,183	_	176,183	1.6%	1.1%	*
Gary Schuman	66,750	—	11,111	77,861	*	*	*
Ken Pienta	-	20,000	_	20,000	*	*	*
Ronald D. Seidel	445,000	30,000	_	475,000	4.5%	2.8%	2.5%
Rodolfo J. Chaparro	445,000	30,000	_	475,000	4.5%	2.8%	2.5%
Colin G. Sandercock	—	—	_		*	*	*
Peter Kiener	-	25,184	_	25,184	*	*	*
Anthony DiGiandomenico <sup>(5)</sup>	_	—	_		*	*	*
Cameron Gray	667,500	—	61,111	728,611	6.8%	4.4%	3.8%
Christopher Marlett <sup>(6)</sup>	1,017,973	—	185,185	1,203,158	11.1%	7.2%	6.2%
Steven McKnight	_	25,184	_	25,184	*	*	*
Barry Simon	—	25,184	—	25,184	*	*	*
Directors and Executive Officers as a group (12 persons)	2,682,223	291,735	257,407	3,231,365	28.9%	18.8%	16.3%
Five Percent Stockholders							
MDB Capital Group, LLC <sup>(7)</sup>	1,017,973	—	185,185	1,203,158	11.1%	7.2%	6.2%
Albert Einstein College of Medicine <sup>(8)</sup>	671,572	_	_	671,572	6.3%	4.0%	3.5%
Steven C. Almo <sup>(9)</sup>	534,000	40,122	_	574,122	5.4%	3.4%	3.0%
Mark Strome <sup>(10)</sup>	615,556 <sup>(</sup>	<sup>11)</sup> —	_	615,556	5.8%	3.7%	3.2%
Peter A. Appel <sup>(12)</sup>	655,556	_	_	655,556	6.2%	3.9%	3.4%

\* Less than one percent.

(1) The address of each officer and director is 675 W. Kendall St., Cambridge, Massachusetts 02142.

- (2) On June 15, 2015, in connection with the consummation of a private placement of common stock, the Company issued to MDB a warrant exercisable for 370,370 shares of common stock at an exercise price of \$2.70 per share. MDB subsequently assigned one-half of the warrant, or a portion exercisable for 185,185 shares of common stock, among eight MDB employees, three of whom are officers or directors of the Company.
- (3) We have determined beneficial ownership in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended, which is generally determined by voting power and/or dispositive power with respect to securities. Unless otherwise noted, the shares of common stock listed above are owned as of September 30, 2017, and are owned of record by each individual named as beneficial owner and such individual has sole voting and dispositive power with respect to the shares of common stock owned by each of them, unless otherwise noted.
- (4) Percentage ownership after this offering is based on 16,640,590 shares (if the minimum amount of common stock is sold) and 19,307,256 shares (if the maximum amount of common stock is sold) of

common stock issued and outstanding immediately after the closing of this offering, which amounts include the 671,572 shares issuable to Einstein immediately prior to the consummation of the offering, and assumes that none of the beneficial owners named above purchases shares in this offering.

- (5) This row does not include shares owned by MDB, of which Mr. DiGiandomenico is a co-founder. See the section of this prospectus below titled "Underwriting (Conflicts of Interest)".
- (6) Shares represented in this row are owned by MDB, of which Mr. Marlett is Chief Executive Officer and a co-founder. Mr. Marlett has sole voting and dispositive power with respect to these shares. Mr. Marlett disclaims any beneficial ownership of the shares included in the table above except to the extent of his respective pecuniary interests therein, and this prospectus shall not be deemed an admission that Mr. Marlett is the beneficial owner of such securities.
- (7) The address of MDB is 2425 Cedar Springs Road, Dallas, Texas 75201.
- (8) Beneficial ownership information of Einstein includes 671,572 shares of common stock issuable to Einstein immediately prior to the consummation of the offering pursuant to the license agreement described in the section of this prospectus titled "Business—Our License Agreement with Einstein". The address of Einstein is 1300 Morris Park Avenue, Bronx, New York 10461.
- (9) The address of Steven C. Almo is 1300 Morris Park Avenue, Bronx, New York 10461. Mr. Almo is also the Chairman of our Scientific and Clinical Advisory Board.
- (10) The address of Mark Strome is 100 Wilshire Boulevard, Suite 1750, Santa Monica, California 90401.
- (11) Consists of (a) 555,556 shares of common stock held by Mark and Tammy Strome Family Trust (as to which Mr. Strome has voting and investment power); and (b) 60,000 shares of common stock held by Strome Mezzanine Fund, LP (as to which Mr. Strome has voting and investment power).
- (12) The address of Peter A. Appel is 3505 Main Lodge Drive, Coconut Grove, Florida 33133.

# CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

## **Director Independence**

We have applied for the listing of our common stock on the Nasdaq Capital Market; therefore, our determination of the independence of directors is made using the definition of "independent" contained in the listing standards of the Nasdaq Capital Market. Under the listing requirements and rules of the Nasdaq Capital Market ("Nasdaq"), independent directors must constitute a majority of a listed company's board of directors within 12 months after its initial public offering. Under the rules of the Nasdaq Capital Market, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

We intend to rely on this phase-in rule with respect to the independence of our board of directors. In accordance with this phase-in provision, a majority of our board of directors will be independent within one year of the effective date of the registration statement of which this prospectus is a part.

On the basis of information solicited from each director, the board has determined that each of Peter Kiener, Steven McKnight and Barry Simon has no material relationship with the Company and is independent within the meaning of such rules.

#### **Related Transactions**

SEC regulations define the related person transactions that require disclosure to include any transaction, arrangement or relationship in which the amount involved exceeds the lesser of \$120,000 or one percent of the average of the Company's total assets at year end for the last two completed fiscal years in which we were or are to be a participant and in which a related person had or will have a direct or indirect material interest. A related person is: (i) an executive officer, director or director nominee of the Company, (ii) a beneficial owner of more than 5% of our common stock, (iii) an immediate family member of an executive officer, director or director nominee or beneficial owner of more than 5% of our common stock, or (iv) any entity that is owned or controlled by any of the foregoing persons or in which any of the foregoing persons has a substantial ownership interest or control.

For the period from January 1, 2015, through the date of this prospectus, described below are certain transactions or series of transactions between us and certain related persons.

In January 2015, we issued 3,649,000 shares of our Common Stock to MDB and certain of our founders who are our directors, officers or 5% stockholders and are listed below for an aggregate consideration of \$3,649, at a purchase price of approximately \$0.001 per share, in connection with the initial formation of the Company, as follows:

Name	Shares of Common Stock	Relationship to Us
MDB Capital Group, LLC	1,045,750	5% Stockholder
Cameron Gray	667,500	Director
Steven C. Almo	534,000	5% Stockholder and Chairman of the Scientific and Clinical Advisory Board
Ronald D. Seidel	445,000	Officer
Rodolfo J. Chaparro	445,000	Officer
Gary Schuman	66,750	Officer

In April 2015, we entered into an engagement agreement with MDB, pursuant to which we appointed MDB as our exclusive placement agent for private placements and public offerings of our securities during the term of the agreement. We agreed that, in connection with any offering pursuant to the engagement agreement, we would pay MDB a cash fee equal to 10 percent of the gross proceeds of such offering and issue MDB warrants to purchase the type of equity securities issued in such offering, in an amount equal to 10 percent of the aggregate securities issued in such offering, such warrants being exercisable for 7 years and

being priced at not less than 120 percent of the offering price per share. We also agreed to reimburse certain reasonable costs and expenses, including reasonable travel, printing and legal fees and expenses, incurred by MDB in connection with any offering pursuant to the engagement agreement. We are required to indemnify MDB and their related persons in connection with engagement agreement and MDB's services under the engagement agreement.

In June 2015, we issued and sold an aggregate of 3,703,704 shares of our common stock for an aggregate consideration of \$10,000,000 to certain accredited investors pursuant to securities purchase agreements entered into with these investors. In connection with the June 2015 private placement, and pursuant to the terms of our engagement agreement with MDB, we paid MDB \$1,000,000 in cash and issued to MDB a warrant to purchase up to 370,370 shares of common stock at an exercise price of \$2.70 per share. The warrant has a term of seven years. We also reimbursed MDB for approximately \$75,000 of its costs and expenses incurred in connection with the June 2015 private placement.

In June 2015, MDB assigned one-half of the warrant among eight MDB employees. Two such employees are officers or directors of the Company and received a warrant exercisable for the following amounts of common stock: Cameron Gray, 61,111 shares; and Gary Schuman, 11,111 shares.

In July 2016, we granted Mr. Almo, Chairman of our Scientific and Clinical Advisory Board, options to purchase 80,243 shares of common stock at an exercise price of \$2.86 per share. Mr. Almo's award has a term of five years and vests in 12 equal quarterly installments. The option award was granted under our 2016 Omnibus Plan.

In December 2016, we issued and sold an aggregate of 3,282,980 shares of our common stock at a purchase price of \$5.00 per share for an aggregate consideration of \$16,414,900 to certain accredited investors pursuant to securities purchase agreements entered into with these investors. Daniel Passeri, our Chief Executive Officer, purchased 40,000 shares of common stock in this private placement.

In December 2016, we entered into a letter agreement with MDB, waiving the cash and warrant compensation payable pursuant to the MDB engagement agreement in connection with the December 2016 private placement. Instead, pursuant to the letter agreement, we paid MDB \$1,320,745 in cash. We also reimbursed MDB for approximately \$17,000 of its costs and expenses incurred in connection with the December 2016 private placement.

Certain of our directors and officers are employees of MDB. See the section of this prospectus below titled "Underwriting (Conflicts of Interest)".

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for shares of our common stock. Future sales of substantial amounts of shares of common stock, including shares issued upon the exercise of outstanding warrants and options, in the public market after this offering, or the possibility of these sales occurring, could adversely affect the then prevailing market price for our common stock or impair our ability to raise equity capital.

Upon the completion of this offering, a total of 16,640,590 shares of common stock will be outstanding if the minimum amount of common stock is sold or 19,307,256 shares if the maximum amount of common stock is sold, which amounts include the 671,572 shares issuable to Einstein immediately prior to the consummation of the offering. All shares of common stock sold in this offering by us will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act.

The remaining shares of common stock are denominated "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

Subject to the lock-up agreements described below and the provisions of Rules 144 and 701 under the Securities Act, 3,242,980 of these restricted securities will be available for sale in the public market beginning 90 days after the date of this prospectus after the expiration of a three-month lock-up, 3,703,704 of these restricted securities will be available for sale in the public market beginning 180 days after the date of this prospectus after the expiration of a 4,360,572 shares of these restricted securities will be available for sale in the public market beginning one year after the date of this prospectus after the expiration of a 12-month lock-up, which amount includes the 671,572 shares issuable to Einstein immediately prior to the consummation of the offering.

#### Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least six, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described below, within any three-month period beginning 90 days after the date of this prospectus, a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding; or
- the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

## Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been one of our affiliates during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits our affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. However, all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701.

## Lock-Up Agreements

We, all of our directors, officers, employees and the holders of substantially all of our common stock or securities exercisable for or convertible into our common stock outstanding immediately prior to this offering have entered into lock-up agreements with respect to the disposition of their shares. See "Underwriting (Conflicts of Interest) — Lock-Up Agreements" for additional information.

#### **Registration Rights**

Upon the completion of this offering, the holders of 8,028,626 shares of common stock (including 671,572 shares issuable to Einstein and 370,370 shares of common stock underlying warrants) or their permitted assigns will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming freely tradable under the Securities Act immediately upon the effectiveness of the registration, except for shares held by affiliates. See "Description of Capital Stock — Registration Rights" for additional information.

## **Registration Statements on Form S-8**

We intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of common stock to be issued or reserved for issuance under our 2016 Omnibus Incentive Plan and 2016 Non-Employee Equity Incentive Plan. Shares covered by that registration statement will be eligible for sale in the public market, upon the expiration or release from the terms of the lock-up agreements and subject to vesting of such shares.

## UNDERWRITING (CONFLICTS OF INTEREST)

MDB Capital Group, LLC ("MDB") and Feltl and Company, Inc. ("Feltl") are acting as the underwriters of this offering. Subject to the terms and conditions set forth in an underwriting agreement between us and the underwriters, the underwriters have agreed to sell up to \$60,000,000 of common stock on a best efforts basis.

MDB acted as our placement agent in connection with the placements of our shares of common stock that were consummated on June 15, 2015 and December 22, 2016.

The underwriters are under no obligation to purchase any shares of our common stock for their own account nor may they purchase shares in order to guarantee that the offering minimum is met. As a "best efforts" offering, there can be no assurance that the offering contemplated hereby will ultimately be consummated.

We have been advised by the underwriters that they propose to offer shares of our common stock directly to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers that are members of the Financial Industry Regulatory Authority, Inc., or FINRA. The underwriters have informed us that they may provide an allowance not in excess of  $[\bullet]$  per share to other dealers out of the underwriters' commission.

The underwriters will receive the underwriting commissions, set forth on the cover of this prospectus. The amount of the commission paid to the underwriters will equal 4.8% of the gross proceeds of this offering, exclusive of the fee paid to Feltl as the qualified independent underwriter. The gross proceeds of this offering will be deposited at JP Morgan Chase, in an escrow account established by us, until we have sold a minimum of \$40,000,000 of common stock and otherwise satisfy the listing conditions to trade our common stock on the Nasdaq Capital Market. Once we satisfy the minimum stock sale and Nasdaq Capital Market listing conditions, the funds will be released to us.

None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus and any other offering material or advertisements in connection with the offer and sales of any of our common stock, be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of our common stock and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy any of our common stock included in this offering in any jurisdiction where that would not be permitted or legal.

## **Conflict of Interest**

MDB and persons who are associated or employed by MDB together own beneficially an aggregate of 2,233,000 shares of common stock of the Company, representing an aggregate of 21.0% of the actual (nonbeneficial basis) issued and outstanding common stock of the Company immediately prior to this offering. Therefore, MDB is deemed to be an affiliate of the Company and to have a "conflict of interest" under Rule 5121 of FINRA. Accordingly, this offering will be made in compliance with the applicable provisions of Rule 5121, which requires that a "qualified independent underwriter," as defined by FINRA, participate in the preparation of the registration statement and exercise the usual standard of due diligence with respect to the registration statement that an underwriter would exercise on its own behalf. Feltl has agreed to act as the "qualified independent underwriter" within the meaning of Rule 5121 in connection with this offering. Feltl will receive \$275,000 for serving as a qualified independent underwriter in connection with this offering. We have agreed to indemnify Feltl against liabilities incurred in connection with acting as qualified independent underwriter, including liabilities under the Securities Act. In accordance with Rule 5121, MDB will not sell shares of our common stock to discretionary accounts without the prior written approval from the account holder.

The table below sets forth the actual, direct ownership of our common stock by MDB and its affiliates and employees. The table is prepared on the basis of the current, actual ownership of the common stock and not the beneficial ownership of the common stock, although the other holdings of the person or entity are footnoted.

Name	Shares of Common Stock Actually Owned Prior to Offering
MDB Capital Group, LLC	1,017,973
Cameron Gray	667,500
Amy En-Mei Wang	333,750
Gary Schuman	66,750
George Brandon	63,625
Kevin Cotter	55,625
Edgardo Rayo	9,259
Ivonne Bordas	9,259
Carlos Herrera	9,259
Total	2,233,000

Additionally, Anthony DiGiandomenico and Christopher Marlett, members of our board of directors, are cofounders of MDB. Mr. DiGiandomenico holds a 24.99% ownership stake in MDB but has no dispositive or voting power over our shares held by MDB.

## **Underwriting Commissions and Expenses**

The following table summarizes the underwriting commissions to be paid to the underwriters by us.

	Total Minimum Offering	Total Maximum Offering
Public offering price	\$ 40,000,000	\$60,000,000
Underwriting commissions to be paid to the underwriters	\$ 1,920,000	\$ 2,880,000
Qualified independent underwriter fee	\$ 275,000	\$ 275,000
Net proceeds, before other Company expenses	\$ 37,805,000	\$56,845,000

We have agreed to pay the underwriters a non-accountable expense allowance of 0.45% of the gross proceeds of the offering. We estimate that the total expenses of this offering, excluding underwriting commissions, will be approximately \$750,000.

## **Determination of Offering Price**

There is no current market for our common stock. The underwriters are not obligated to make a market in our securities, and even if they choose to make a market, the market making can discontinue at any time without notice. Neither we nor the underwriters can provide any assurance that an active and liquid trading market in our securities will develop or, if developed, that the market will continue.

The public offering price of the shares offered by this prospectus has been determined by negotiation between us and the underwriters. Among the factors considered in determining the public offering price of the shares are:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares. We cannot assure you that the shares can be resold at or above the public offering price.

## Subscription and Escrow

To purchase shares of our common stock in this offering, investors must complete and sign a subscription agreement. Investors will be required to pay for their shares of common stock by wire for the full purchase price of the shares, payable to "Continental Stock Transfer & Trust Company as Agent for Cue Biopharma and MDB Capital Group Escrow Account"

Subscriptions will be effective only upon our acceptance of the subscriptions, and we reserve the right to reject any subscriptions in whole or in part. In compliance with Rule 15c2-4 under the Exchange Act, we and the underwriters will instruct investors to deliver all monies in the form of wire transfers to the escrow agent. Upon the escrow agent's receipt of such monies, they shall be credited to the escrow account. Pursuant to an escrow agreement among us, the underwriters and Continental Stock Transfer & Trust Company, as escrow agent, the funds received in payment for the shares of common stock purchased in this offering will be wired to a non-interest bearing escrow account at JP Morgan Chase and held until the escrow agent determines that the amount in the escrow account is equal to at least the minimum amount required to close this offering. Upon confirmation of receipt of the requested minimum subscription amount and the satisfaction of listing conditions to trade our common stock on the Nasdaq Capital Market, the escrow agent will release the funds in accordance with the written instructions provided by us and the underwriters, indicating the date on which the shares of common stock purchased in this offering are to be delivered to the investors and the date the net proceeds are to be delivered to us. Unless investors instruct us otherwise, we will deliver the shares of common stock being issued to the investors electronically.

#### **Underwriter's Warrant**

We have agreed to issue to MDB a warrant to purchase shares of our common stock (in an amount up to 10% of the shares of common stock sold in this offering). This warrant is exercisable at a per share price equal to 125% of the price of common stock sold in this offering, commencing on the effective date of this offering and expiring five years from the effective date of this offering. The warrant and the shares of common stock underlying the warrant have been deemed compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. MDB (or its permitted assignees under Rule 5110(g)(2)) will not sell, transfer, assign, pledge, or hypothecate this warrant or the securities underlying this warrant, nor will it engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of this warrant or the underlying securities for a period of 180 days from the effective date of the offering.

#### Lock-Up Agreements

All of our officers, directors, employees and MDB and certain of its affiliates have agreed that, until the oneyear anniversary of the date of the underwriting agreement we will enter into in conjunction with this offering, they will not sell, contract to sell, grant any option for the sale or otherwise dispose of any of our equity securities, or any securities convertible into or exercisable or exchangeable for our equity securities, without the consent of MDB, except for exercise or conversion of currently outstanding warrants, options and convertible securities, as applicable; and exercise of options (the "One-Year Lock-Up"). The number of currently outstanding shares of common stock subject to the One-Year Lock-Up totals 3,689,000. Additionally, the 2,366,221 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2017 will be subject to the One-Year Lock-Up.

The purchasers of our common stock in the June 2015 private placement are subject to lock-up requirements for a period that may last no more than 180 days following the date of this prospectus (the "180 Days Lock-Up"). The number of shares of common stock that are subject to the 180 Days Lock-Up totals 3,703,704, and the number of shares underlying warrants subject to the 180 Days Lock-Up totals 370,370. The warrant to purchase up to 10% of the shares of common stock sold in this offering that we have agreed to issue to the underwriters in connection with this offering will also be subject to the 180 Days Lock-Up.

The purchasers of our common stock in the December 2016 private placement are subject to lock-up requirements for a period that may last no more than 90 days following the date of this prospectus (the "90 Days Lock-Up"). The number of shares of common stock that are subject to the 90 Days Lock-Up totals 3,242,980.

MDB may consent to an early release from the lock-up periods if, in its opinion, the market for the common stock would not be adversely impacted by sales and in cases of a financial emergency of an officer, director or other stockholder. MDB is not required to obtain a consent of any other party to so grant a release. We are unaware of any security holder who intends to ask for consent to dispose of any of our equity securities during the relevant lock-up period.

## Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including certain liabilities arising under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

## **Electronic Distribution**

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by the underwriters or an affiliate thereof. In those cases, prospective investors may view offering terms online and, depending upon the underwriter, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations.

Other than the prospectus in electronic format, information on the website of an underwriter and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any of the underwriters in their capacity as an underwriter and should not be relied upon by investors. Compensation to the underwriters in connection with this offering is limited to the fees and expenses described above under "Underwriting Commissions and Expenses."

# LEGAL MATTERS

K&L Gates LLP, with an office at Hearst Tower, 47th Floor, 214 North Tryon Street, Charlotte, North Carolina 28202, will pass upon the validity of the shares of common stock offered by this prospectus and certain other legal matters. LKP Global Law, LLP, with an office at 1901 Avenue of the Stars, Suite 480, Los Angeles, California 90067, is legal counsel to MDB Capital Group, LLC. Certain employees of LKP Global Law, LLP participated in the June 2015 and December 2016 private placements of our common stock as investors.

## EXPERTS

The financial statements of Cue Biopharma, Inc. as of December 31, 2016 and 2015 and for each of the years in the two-year period ended December 31, 2016 included in this prospectus have been audited by Gumbiner Savett Inc., independent registered public accounting firm. We have included these financial statements in this prospectus in reliance upon the report of Gumbiner Savett Inc., given on their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act that registers the shares of our common stock to be sold in this offering. Our SEC filings are and will become available to the public over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street N.E., Washington, D.C. 20549. You can also obtain copies of the documents upon the payment of a duplicating fee to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. Some items are omitted in accordance with the rules and regulations of the SEC. You should review the information and exhibits included in the registration statement for further information about us and the securities we are offering. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements.

## DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the Company, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

# CUE BIOPHARMA, INC.

# INDEX TO FINANCIAL STATEMENTS (INCLUDING REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM) Years Ended December 31, 2016 and 2015

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Cue Biopharma, Inc. (the "Company") as of December 31, 2016 and 2015, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2016. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully discussed in Note 1 to the financial statements, the Company is subject to the risks and uncertainties associated with a new business and has incurred losses from operations since inception. Funding for the Company's operations has come through the issuance of equity securities. The Company has no committed sources of capital and is not certain whether additional financing will be available when needed on terms that are acceptable, if at all. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Gumbiner Savett Inc. September 21, 2017 Santa Monica, California

# CUE BIOPHARMA, INC. BALANCE SHEETS

	December 31,		
	2016	2015	
ASSETS			
Current assets:			
Cash	\$14,925,820	\$ 6,405,207	
Certificate of deposit	50,033	50,000	
Prepaid expenses and other current assets	162,398	51,447	
Total current assets	15,138,251	6,506,654	
Property and equipment, net	1,023,366	709,472	
Deposits	117,000	98,500	
Total assets	\$16,278,617	\$ 7,314,626	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable and accrued expenses	\$ 549,963	\$ 177,815	
Accrued compensation and related expenses	408,559	118,935	
Current portion of deferred rent	109,091	45,455	
Total current liabilities	1,067,613	342,205	
Deferred rent, net of current portion	36,364	34,090	
Total liabilities	1,103,977	376,295	
Commitments and contingencies			
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 – 10,635,684 shares and 7,352,704 shares at December 31, 2016 and 2015 recreatively.	10.626	7 252	
and 2015, respectively	10,636	7,353	
Additional paid-in capital	24,751,017	8,859,708	
Accumulated deficit	(9,587,013)	(1,928,730	
Total stockholders' equity	15,174,640	6,938,331	
Total liabilities and stockholders' equity	\$16,278,617	\$ 7,314,626	

See accompanying notes to financial statements.

# CUE BIOPHARMA, INC. STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2016 2015	
Revenue	\$	\$ —
Operating expenses:		
General and administrative	1,970,488	425,081
Research and development	5,687,847	1,503,649
Total operating expenses	7,658,335	1,928,730
Loss from operations	(7,658,335)	(1,928,730)
Interest income	52	
Net loss	\$(7,658,283)	\$(1,928,730)
Net loss per common share – basic and diluted	\$ (1.03)	\$ (0.34)
Weighted average common shares outstanding – basic and diluted	7,433,433	5,658,282

See accompanying notes to financial statements.

# CUE BIOPHARMA, INC.

# STATEMENT OF STOCKHOLDERS' EQUITY Years Ended December 31, 2016 and 2015

	Common Stock		Common Stock Additional Paid-in Accumulated		Total Stockholders'
	Shares	Par Value	Capital	Deficit	Equity
Common stock issued to founders	3,649,000	\$ 3,649	\$ —	\$ —	\$ 3,649
Common stock issued in private placement	3,703,704	3,704	9,996,296		10,000,000
Costs incurred in connection with private placement					
of common stock			(1,911,529)		(1,911,529)
Proceeds from sale of placement agent warrants		_	1,000		1,000
Fair value of warrants issued in connection with					
private placement of common stock	—		773,941		773,941
Net loss				(1,928,730)	(1,928,730)
Balance, December 31, 2015	7,352,704	7,353	8,859,708	(1,928,730)	6,938,331
Common stock issued in private placement	3,282,980	3,283	16,411,617		16,414,900
Costs incurred in connection with private placement					
of common stock	—	—	(1,409,864)		(1,409,864)
Stock-based compensation		_	889,556		889,556
Net loss				(7,658,283)	(7,658,283)
Balance, December 31, 2016	10,635,684	\$10,636	\$24,751,017	\$(9,587,013)	\$15,174,640

See accompanying notes to financial statements.

## CUE BIOPHARMA, INC.

# STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$(7,658,283)	\$(1,928,730
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	202,085	44,815
Deferred rent	65,910	79,545
Stock-based compensation	889,556	_
Changes in operating assets and liabilities:		
(Increase) decrease in –		
Prepaid expenses and other current assets	(110,951)	(51,447
Deposits	(18,500)	(98,500
Increase (decrease) in –		
Accounts payable and accrued expenses	372,148	177,815
Accrued compensation and related expenses	289,624	118,935
Net cash used in operating activities	(5,968,411)	(1,657,567
Cash flows from investing activities:		
Increase in certificate of deposit	(33)	(50,000
Purchases of property and equipment	(515,979)	(754,287
Net cash used in investing activities	(516,012)	(804,287
Cash flows from financing activities:		
Proceeds from issuance of common stock to founders		3,649
Proceeds from private placements of common stock	16,414,900	10,000,000
Proceeds from sale of placement agent warrants	_	1,000
Cash payments made for costs incurred in connection with sale of common stock	(1,409,864)	(1,137,588
Net cash provided by financing activities	15,005,036	8,867,061
Cash:		
Net increase	8,520,613	6,405,207
Balance at beginning of year	6,405,207	
Balance at end of year	\$14,925,820	\$ 6,405,207
Supplemental disclosures of cash flow information:		
Cash paid for –		
Interest	\$	\$
Income taxes	\$	\$ —
Non-cash financing activities:		
Fair value of warrants issued in connection with private placement of common stock	\$	\$ 773,941
See accompanying notes to financial statements.		
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# CUE BIOPHARMA, INC. NOTES TO FINANCIAL STATEMENTS Years Ended December 31, 2016 and 2015

## 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.

On January 14, 2015, in order to implement its business plans, the Company entered into a license agreement with the Albert Einstein College of Medicine, a division of Yeshiva University ("Einstein"), for certain patent rights, as described in Note 4.

The Company is a pre-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 and autoimmune disorders.

#### **Going Concern**

The Company's financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any revenues from operations since inception, and does not expect to do so in the foreseeable future. The Company has experienced operating losses and negative operating cash flows since inception, and expects to continue to do so for at least the next few years. The Company has financed its working capital requirements during this period through the sale of its equity securities. At December 31, 2016, the Company had cash and a certificate of deposit totaling \$14,975,853 available to fund the Company's ongoing business activities.

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the financial statements are being issued. The Company's independent registered public accounting firm, in its report on the Company's financial statements for the year ended December 31, 2016, has also raised substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent on its ability to raise additional capital to fund its business activities, including its research and development program. The Company's objective is to complete an initial public offering in 2017 to provide the Company with additional financial resources to fund its operations, but there can be no assurances that the Company will be successful in this regard. Furthermore, 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 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. The Company's financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Because the Company is currently engaged in research at a relatively early stage, it will take a significant amount of time and resources to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years, and may never do so. In addition, to the extent that the Company is able to generate operating revenues, there can be no assurances that the Company will be able to achieve positive earnings and operating cash flows.

## Reclassifications

Certain comparative figures for the years ended 2016 and 2015 have been adjusted to correct the classification of patent legal costs and intellectual property management fees from research and development expenses to general and administrative expenses. During the years ended December 31, 2016

and 2015, patent legal costs of \$366,131 and \$178,697 and intellectual property management fees of \$90,000 and \$38,182, aggregating \$456,131 and \$216,879, respectively, were reclassified from research and development costs to general and administrative costs. These changes did not impact loss from operations or net loss.

## 2. Summary of Significant Accounting Policies

#### Use of Estimates

The preparation of financial statements in conformity with United States Generally Accepted Accounting Principles ("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 the accounting for potential liabilities, the assumptions utilized in valuing stock-based compensation issued for services, the realization of deferred tax assets, and the impairment of long-lived assets and intangibles. Actual results could differ from those estimates.

### **Risks and Uncertainties**

The Company's operations are subject to a number of factors that may affect its operating results and financial condition. Such factors include, but are not limited to: the Company's ability to determine candidates for clinical testing, the results of clinical testing and trial activities of the Company's product candidates, the Company's ability to obtain regulatory approval to market its product candidates, the Company's intellectual property, competition from products manufactured and sold or being developed by other companies, the price of, and demand for, the Company's product candidates if approved for sale, the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its product candidates, and the Company's ability to raise capital.

The Company currently has no commercially approved product candidates and there can be no assurance that the Company's research and development programs will be successfully commercialized. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval, as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and consultants and obtaining and protecting its intellectual property.

#### **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.

### **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 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.

## **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 expensing schedule 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.

## 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, 2016 and 2015, patent expenses were \$366,131 and \$178,697, 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, 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. As of December 31, 2016 and 2015, the Company had not deemed any long-lived assets as impaired, and was not aware of the existence of any indicators of impairment at such dates.

## **Rent Expense and Deferred Rent Liability**

Operating lease agreements which contain provisions for future rent increases or periods in which rent payments are reduced or abated are recorded in monthly rent expense in the amount of the total payments over the lease term divided by the number of months of the lease term. The difference between rent expense recorded and the amount paid is credited or charged to a deferred rent liability account. The current portion of deferred rent is included in current liabilities, and the remaining amount is shown in the balance sheet as a non-current liability. Accordingly, rent expense is recorded on a straight-line basis.

## Stock-Based Compensation

The Company periodically issues stock options 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, 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 vesting period. The fair value of stock options 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.

Stock options granted to members of the Company's Scientific and Clinical Advisory Board, non-employees and outside consultants are revalued each reporting period to determine the amount to be recorded as an expense in the respective period. As the stock options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the value on the date of vesting.

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. During the years ended December 31, 2016 and 2015, 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, 2016 or 2015.

### **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. 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). The Company did not have any items of comprehensive income (loss) for the years ended December 31, 2016 and 2015.

## 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 antidilutive.

At December 31, 2016 and 2015, 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. The information shown below does not include any shares that may be issuable under the down round protection provisions as described in Note 6.

	Decem	ber 31,
	2016	2015
Common stock warrants	370,370	370,370
Common stock options	1,663,221	—
Total	2,033,591	370,370

## 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.

There were no financial instruments that were measured and recorded at fair value on the Company's balance sheet at December 31, 2016 and 2015.

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 May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). ASU 2014-09 will eliminate transactionand industry-specific revenue recognition guidance under current GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The FASB has issued ASU 2016-08, ASU 2016-10, ASU 2016-11, ASU 2016-12, and ASU 2016-20, all of which clarify certain implementation guidance within ASU 2014-09. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017, with early adoption permitted. Entities will be able to transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The Company will adopt the provisions of ASU 2014-09 in the quarter beginning January 1, 2018. As the Company is unlikely to generate any sustainable operating revenues in the next several years, the adoption of ASU 2014-09 is not currently expected to have any impact on the Company's financial statement presentation or disclosures.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes ("ASU 2015-17"). ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted as of the beginning of an interim or annual reporting period. The Company will adopt the provisions of ASU 2015-17 in the quarter beginning January 1, 2017. The adoption of ASU 2015-17 is not expected to have any impact on Company's financial statement presentation or disclosures.

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. 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 will adopt the provisions of ASU 2016-02 in the quarter beginning January 1, 2019. The Company generally does not finance purchases of property and equipment, but does lease its operating facilities. While the Company is continuing to assess the potential impact of ASU 2016-02, it currently expects that most of its lease commitments will be subject to ASU 2016-02 and accordingly, upon adoption will be recognized as lease liabilities and right-of-use assets in the Company's balance sheet.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). ASU 2016-09 requires, among other things, that all income tax effects of awards be recognized in the statement of operations when the awards vest or are settled. ASU 2016-09 also allows for an employer to repurchase more of an employee's shares than it can today for tax withholding purposes without triggering liability accounting and allows for a policy election to account for forfeitures as they occur. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted for any entity in any interim or annual period. The Company will adopt the provisions of ASU 2016-09 in the quarter beginning January 1, 2017. The adoption of ASU 2016-09 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In July 2017, the FASB issued Accounting Standards Update No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The guidance in ASU 2017-11 can be applied using a full or modified retrospective approach. The adoption of ASU 2017-11 is not currently expected to have any impact on the Company's financial statement presentation or disclosures.

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. Property and Equipment

Property and equipment as of December 31, 2016 and 2015 is summarized as follows:

	Deceml	December 31,	
	2016	2015	
Laboratory equipment	\$1,194,473	\$735,013	
Furniture and fixtures	1,832	1,832	
Computer equipment	44,166	17,442	
Leasehold improvements	29,795	—	
	1,270,266	754,287	
Less accumulated depreciation and amortization	(246,900)	(44,815)	
Net property and equipment	\$1,023,366	\$709,472	

Depreciation and amortization expense for the years ended December 31, 2016 and 2015 was included in the statement of operations as follows:

	Years Ended	Years Ended December 31,		
	2016	2015		
General and administrative	\$ 4,630	\$ 1,238		
Research and development	197,455	43,577		
Total	\$202,085	\$44,815		

## 4. 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, 2016, 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, 2016 and 2015.

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 Company accounts for the costs incurred in connection with the Einstein License in accordance with Accounting Standards Codification ("ASC") 730, Research and Development. For the years ended December 31, 2016 and 2015, costs incurred with respect to the Einstein License aggregated \$31,250 and \$127,336 (including related legal fees of \$35,669), respectively, and are included in research and development expenses in the statements of operations.

The Einstein License requires 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 6. A liquidity event includes, but is not limited to, an initial public offering of shares of the Company's common stock; a merger with a public reporting company under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or a company whose shares are listed on a non-U.S. exchange or an affiliate thereof; a merger, consolidation, reorganization, or similar transaction whereby the Company's stockholders immediately prior to the consummation of the transaction; or a sale of substantially all of the Company's assets. Accordingly, the Company will be required to issue 671,572 shares of the Company's common stock to Einstein immediately prior to the consummation of an initial public offering by the Company. At December 31, 2016, a liquidity event had not occurred. The common stock issuable to Einstein upon the occurrence of a liquidity event has certain registration rights, as described in Note 9.

As the consummation of a liquidity event is outside the control of the Company, the Company will account for the issuance of these shares upon the occurrence of a liquidity event. Additionally, 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 Company will account for the issuance of such shares at their aggregate fair value on the date of issuance and, in accordance with ASC 730, Research and Development, will charge such amount to research and development expenses in the statement of operations. For basic earnings per share calculations, these shares will be treated as contingently issuable shares and will not be included in basic earnings per share until the shares have been issued.

#### Service Agreement

On October 1, 2015, the Company entered into a service agreement (the "Service Agreement") with Einstein to support the Company's ongoing research and development activities. The initial term of the Service Agreement was for three months, which was amended in February 2016 to extend it for the period of time deemed necessary to complete the services pursuant to the terms of the Service Agreement. For the years ended December 31, 2016 and 2015, costs incurred with respect to the Service Agreement aggregated \$80,000 and \$200,000, respectively, and are included in research and development expenses in the statement of operations.

#### 5. 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 and 500,000 shares of common stock, respectively. At December 31, 2016, stock options for 1,603,221 shares of common stock had been granted and 396,779 shares of common stock were reserved for future grants under the Omnibus Plan, and stock options for 60,000 shares of common stock had been granted and 440,000 shares of common stock were reserved for future grants under the Non-Employee Plan. In the aggregate, at December 31, 2016, stock options for a total of 1,663,221 shares of common stock had been granted and 836,779 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.

Pursuant to the plans, during the year ended December 31, 2016, the Company granted stock options to purchase 1,663,221 shares of the Company's common stock, of which 377,760 were granted to independent members of the Board of Directors, 300,729 to members of the Scientific and Clinical Advisory Board, 784,732 to members of management, and 200,000 to other employees. The stock options granted to independent members of the Board of Directors and to members of the Scientific and Clinical Advisory Board effective March 23, 2016 and November 16, 2016, representing stock options to purchase an aggregate of 678,489 shares of the Company's common stock, were non-qualified stock options, whereas all other stock options were incentive stock options. The stock options are exercisable at \$2.86 per share, which was deemed to be the fair value of the Company's common stock on the respective grant dates during March through November 2016. However, because the Company subsequently sold shares of common stock in a private placement at \$5.00 per share on December 22, 2016, the Company recalculated the fair value of the stock options utilizing the \$5.00 per share purchase price as the fair value of the Company's common stock. The stock options vest in equal monthly installments over the vesting term.

A summary of stock options granted is as follows:

	Number of Shares Under	Life of	Vesting	Fair Value at 1	Date of Grant
Grant of Date	Option	Option	Period	Total	Per Share
March 23, 2016	240,729	5 years	3 years	\$1,023,791	\$4.25
March 23, 2016	377,760	7 years	5 years	1,605,546	\$4.25
August 29, 2016	544,732	7 years	4 years	2,289,178	\$4.20
September 7, 2016	440,000	7 years	4 years	1,848,496	\$4.20
November 16, 2016	60,000	7 years	1 year	265,367	\$4.42
	1,663,221			\$7,032,378	

For stock options requiring an assessment of value during the year ended December 31, 2016, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model utilizing the following assumptions:

Risk-free interest rate	1.07 to 2.25%
Expected dividend yield	0%
Expected volatility	104% to 112%
Expected life	4.25 to 7 years
Stock price per share	\$5.00

The fair value of \$5.00 per share was determined by reference to the sale price of the Company's common stock in its December 2016 private placement.

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, 2016 and 2015 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Granted			
Exercised			
Expired			
Stock options outstanding at December 31, 2015			
Granted	1,663,221	\$2.86	
Exercised		_	
Expired			
Stock options outstanding at December 31, 2016	1,663,221	\$ 2.86	6.22
Stock options exercisable at December 31, 2016	60,183	\$ 2.86	4.21

The Company recognized \$889,556 and \$0 in stock-based compensation during the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, total unrecognized stock-based compensation was approximately \$6,100,000, which is expected to be recognized as an operating expense in the Company's statement of operations through March 2021.

The intrinsic value of exercisable but unexercised in-the-money stock options at December 31, 2016 was approximately \$129,000, based on a fair value of \$5.00 per share on December 31, 2016.

There was no stock-based compensation for the year ended December 31, 2015. Stock-based compensation for the year ended December 31, 2016 was included in the statement of operations as follows:

General and administrative	\$439,366
Research and development	450,190
Total	\$889,556

## 6. 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, 2016 and 2015. 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 10,635,684 shares and 7,352,704 shares were issued and outstanding at December 31, 2016 and 2015, respectively.

*Issuance of Shares to Founders.* In conjunction with the formation and initial capitalization of the Company, 3,649,000 shares of common stock were issued to its founding stockholders for cash consideration of \$3,649, representing the par value of the common stock. Of the total shares issued to founding stockholders, 2,225,000 shares (61%) were issued to MDB Capital Group, LLC ("MDB") and its affiliated persons (see Note 7), and 1,424,000 shares (39%) were issued to the inventors of patents licensed to the Company (see Note 4).

*June 15, 2015 Private Placement of Common Stock.* On June 15, 2015, the Company sold 3,703,704 shares of common stock in a private placement to accredited investors at \$2.70 per share, resulting in gross cash proceeds of \$10,000,000. Direct costs of the private placement consisted of a 10% placement agent fee to the placement agent, MDB, of \$1,000,000, and related legal fees and reimbursable expenses of \$137,588.

In conjunction with this private placement, the Company issued warrants to the placement agent to purchase 370,370 shares of common stock, exercisable at issuance for a period of seven years at \$2.70 per share, for a cash consideration of \$1,000. The placement agent warrants had a fair value of \$773,941, calculated pursuant to the Black-Scholes option-pricing model. Issuance costs of the private placement, including the fair value of placement agent warrants of \$773,941, aggregated \$1,911,529 and were charged directly to additional paid-in capital. The common stock sold and the placement agent warrants issued in this private placement have certain registration rights, as described in Note 9.

*December 22, 2016 Private Placement of Common Stock.* On December 22, 2016, the Company sold 3,282,980 shares of common stock in a private placement to accredited investors at \$5.00 per share, resulting in gross cash proceeds of \$16,414,900. Direct costs of the private placement consisted of a placement agent fee to the placement agent, MDB, of \$1,320,745 and related legal fees and reimbursable expenses of \$89,119. Issuance costs of the private placement aggregated \$1,409,864 and were charged directly to additional paid-in capital. The common stock sold in this private placement has certain registration rights, as described in Note 9.

Down Round Protection. The Company provided investors in the December 22, 2016 private placement of common stock with certain limited protections resulting from one or more issuances of shares of common stock at a per share purchase price below that paid by the investors in the private placement, terminating on December 31, 2019. If the Company issues additional shares of common stock without consideration, or for a consideration per share less than the effective per share purchase price deemed to be in effect immediately prior to such issuance, then concurrently with such issuance, the Company is required to issue to each investor, for no additional consideration, the number of additional common shares equal to: (i) the amount invested by the investor divided by an amount equal to the greater of (A) the consideration per share received by the Company for such issuance or deemed issuance of the additional shares of common stock, and (B) \$2.50 (the "Trigger Price"), less (ii) the number of common shares initially purchased by such investor, plus any additional common shares previously issued to such investor. Notwithstanding the foregoing, no common shares will be issued to an investor as the result of an issuance or deemed issuance of additional shares of common stock if the Company receives written notice from the investors who purchased at least a majority of the common shares in the private placement agreeing that no such issuance will be made as the result of such issuance or deemed issuance of such additional shares of common stock. Initially, the effective per share purchase price will be equal to \$5.00; provided that, in no event, will the Trigger Price be reduced below \$2.50. Following the issuance of any additional shares of common stock to the investors, the effective per share purchase price will be adjusted to equal the Trigger Price associated with such issuance.

The Company considered the following elements of the down round protection in its analysis of the accounting for this contingency: The down round protection has a fixed floor price of \$2.50 per share, as a result of which a maximum of 6,565,960 shares of common stock are issuable under this private placement, including up to 3,282,980 shares of common stock under the down round protection. The Company has sufficient authorized but unissued shares of common stock to fully fund its maximum obligation under the down round protection. The down round protection has a finite life, terminating on December 31, 2019. The down round protection is non-detachable and non-transferable. The shares of common stock issued in the private placement qualify for classification in stockholders' equity as permanent equity, as the Company has no obligation to deliver cash to the investors under any circumstances and no contractual obligation to deliver an indeterminately variable number of shares. Accordingly, the Company will account for the down round protection as a component of the actual price per common share paid by the investors in the private placement when the amount of any additional shares issuable to the investors is known. Any adjustment to the initial number of shares issued under this provision will be accounted for within stockholders' equity as an increase to common stock at par value and an offsetting decrease to additional paid-in capital. For basic earnings per share, the shares associated with the down round protection will be treated as contingently issuable shares and will not be included in basic earnings per share until the final number of shares issuable in this private placement is known and the shares have been issued.

#### **Common Stock Warrants**

In conjunction with the private placement of common stock on June 15, 2015 at \$2.70 per share, the Company issued warrants to the placement agent to purchase 370,370 shares of common stock, exercisable

at issuance for a period of seven years at \$2.70 per share, for a cash consideration of \$1,000. MDB assigned onehalf of the warrants to its employees, three of which are officers or directors of the Company. The placement agent warrants have standard anti-dilution protections and cashless exercise rights. The placement agent warrants have certain registration rights, as described in Note 9.

The placement agent warrants were valued pursuant to the Black-Scholes option-pricing model at \$773,941, based on the following inputs: risk-free interest rate — 2.11%; expected dividend yield — 0%; expected volatility — 88%; expected life — 7 years; fair value of common stock — \$2.70 per share. The expected volatility was determined by reference to the volatility factors of several comparable bio pharmaceutical public companies. These warrants were considered a cost of the private placement offering.

A summary of warrant activity for the years ended December 31, 2016 and 2015 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Issued	370,370	\$ 2.70	
Exercised	_	—	
Expired			
Warrants outstanding at December 31, 2015	370,370	\$ 2.70	
Issued	_	—	
Exercised	_	_	
Expired			
Warrants outstanding at December 31, 2016	370,370	\$ 2.70	5.46
Warrants exercisable at December 31, 2016	370,370	\$ 2.70	5.46

The intrinsic value of exercisable but unexercised in-the-money common stock warrants at December 31, 2016 was approximately \$851,900, based on a fair value of \$5.00 per share on December 31, 2016.

## 7. Related Party Transactions

During the years ended December 31, 2016 and 2015, MDB provided investment banking services to the Company (see Note 6). For those services, the Company paid MDB cash placement agent fees of \$1,320,745 and \$1,000,000 in 2016 and 2015, respectively. In 2015, the Company also issued to MDB placement agent warrants to purchase 370,370 shares of the Company's common stock for a cash consideration of \$1,000, exercisable for seven years at \$2.70 per share.

MDB assigned one-half of the warrants that it acquired in conjunction with the June 15, 2015 private placement (see Note 6) to eight employees of MDB, three of which are also current officers or directors of the Company, who received a total of 120,333 of such warrants as part of the normal distribution of warrants received by MDB to its employees.

During the years ended December 31, 2016 and 2015, the Company incurred expenses amounting to \$60,000 and \$38,182, respectively, for patent-related services provided by MDB, which is included in general and administrative expenses in the statement of operations. At December 31, 2016 and 2015, \$26,152 and \$38,182, respectively, of amounts payable to MDB relating to reimbursable expenses and patent-related services were included in accounts payable.

Beginning in June 2015, the interim Chief Financial Officer of the Company, who is also the Chief Financial Officer of MDB, has been compensated at a rate of \$6,000 per month, reflecting an aggregate charge to operations for the years ended December 31, 2016 and 2015 of \$72,000 and \$42,000, respectively.

Information with respect to payments under the Einstein License and the Service Agreement is described in Note 4.

## 8. Income Taxes

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, 2016 and 2015 are as follows:

	Decem	December 31,		
	2016	2015		
Deferred tax assets:				
Net operating loss carryforwards	\$ 3,607,000	\$ 816,000		
Research and other credits	364,000	54,000		
Reserves and accruals	315,000	39,000		
Other intangibles	9,000	9,000		
Total gross deferred tax assets	4,295,000	918,000		
Less valuation allowance	(4,190,000)	(873,000)		
Total deferred tax assets	105,000	45,000		
Deferred tax liability:				
Depreciation	(105,000)	(45,000)		
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, 2016 and 2015, 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, 2016 and 2015 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, 2016 and 2015 is as follows:

	Years Ended D	Years Ended December 31,	
	2016	2015	
U. S. Federal statutory tax rate	(35)%	(35)%	
Change in valuation allowance	36%	37%	
Tax credits	(3)%	(3)%	
Other	2%	1%	
Effective tax rate	0.0%	0.0%	

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, 2016 and 2015, the Company had unrecognized tax benefits related to Federal and state research tax credits of approximately \$157,000 and \$21,000, 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, 2016, the Company has available net operating loss carryforwards for Federal and state income tax purposes of approximately \$8,400,000 and \$8,400,000, respectively, which, if not utilized

earlier, will begin to expire in 2035. The Company has Federal research credits of approximately \$392,000, which, if not utilized earlier, will begin to expire in 2035, and state research credits of approximately \$150,000, which, if not utilized earlier, will begin to expire in 2032.

## 9. Commitments and Contingencies

#### **Einstein License and Service Agreement**

The Company's commitments with respect to the Einstein License and the Service Agreement are summarized in Note 4.

## Leased Facilities

On July 29, 2015, the Company entered into an operating lease agreement for its laboratory space for the period from August 1, 2015 through April 30, 2018. The lease contains escalating payments during the lease period. The Company records monthly rent expense on the 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 November 14, 2016, the Company entered into an amended lease agreement that provided the Company with additional laboratory space. This amendment was effective beginning December 1, 2016 and continues through the expiration of the lease on April 30, 2018.

On July 30, 2015, the Company entered into an operating lease agreement, as amended, for dedicated vivarium space for the period from August 1, 2015 through March 31, 2018. The operating lease agreement contains an option to increase the amount of space leased for an additional cost.

Future minimum lease payments under these leases at December 31, 2016 are as follows:

Years Ending December 31,	
2017	\$2,650,000
2018	854,000
Total	\$3,504,000

Total lease expense, excluding the dedicated vivarium space, for the years ended December 31, 2016 and 2015 was included in the statement of operations as follows:

	Years Ended	Years Ended December 31,	
	2016	2015	
General and administrative	\$117,691	\$ 42,455	
Research and development	846,818	319,091	
Total	\$964,509	\$361,546	

#### Legal Contingencies

The Company may be subject to various legal proceedings from time to time as part of its business. As of December 31, 2016, 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. Information with respect to the settlement agreement with Cue BioLogics, LLC is presented in Note 10.

### **Registration Statement Filing Obligations**

In conjunction with the sale of common stock on June 15, 2015 (see Note 6), including placement agent warrants issued to MDB, the Company granted the investors and MDB certain piggy-back registration rights commencing 180 days after the date that the Company becomes a reporting company under the Exchange Act, and for a period of five years thereafter, and a one-time demand registration right commencing 180 days after the date that the Company under the Exchange

Act, which shall terminate on the earliest of when all the underlying securities either (i) have been sold pursuant to a registration statement, (ii) have been covered by an effective registration statement which has been effective for an aggregate period of 16 months, or (iii) sold by the holder pursuant to Rule 144 of the Securities Act of 1933, as amended.

In conjunction with the sale of common stock on December 22, 2016 (see Note 6), the Company granted the investors certain piggy-back and demand registration rights with respect to the common stock commencing six months after an initial public offering by the Company, by joinder to the registration rights agreement entered into by the Company and investors in connection with the Company's June 15, 2015 private placement of common stock.

Upon the completion of an initial public offering, the Company is required to use its best efforts to file a registration statement covering the resale of the shares of common stock issued to Einstein (see Note 4) as soon as practicable, but no later than 180 calendar days from the date of the initial public offering, and to cause such registration statement to be declared effective by the United States Securities and Exchange Commission within 120 calendar days from the dates.

#### Agreement with MDB

Effective April 13, 2015, the Company entered into an agreement with MDB to engage such firm as its exclusive placement agent in connection with one or more offerings of the Company's securities. As consideration for the services to be provided under the agreement, MDB was entitled to a cash fee equal to 10% of the gross proceeds raised in a financing, and warrants for up to 10% of the aggregate securities sold in an offering, exercisable for seven years at 100% of the offering price per share in a private offering and at not less than 120% of the offering price per share in a public offering, each for a cash consideration of \$1,000. The agreement provided for the reimbursement of legal expenses incurred by MDB in conjunction with a securities offering.

Effective December 22, 2016, the Company amended the agreement with MDB to modify the consideration that MDB is entitled to receive for its placement agent services, to provide for a cash fee equal to 10% of the initial \$10,000,000 of gross proceeds raised in a financing and 5% of the amount in excess of \$10,000,000 in gross proceeds raised in a financing, and that MDB shall receive no placement agent warrants.

#### **Employment Agreement**

On August 29, 2016, the Company entered into an employment agreement with its President and Chief Executive Officer for an initial term ending on December 31, 2018 and continuing on a year-to-year basis thereafter, unless earlier terminated. Compensation under the agreement includes an annual salary of \$325,000, with annual review and adjustment at the discretion of the Board of Directors, a signing bonus of \$25,000 which was payable within 30 days of the effective date of the agreement, and an annual incentive bonus that may equal up to 30% of the annual salary based on performance standards established by the Compensation Committee of the Board of Directors. The agreement also provided for the grant of stock options to purchase 544,732 of shares of the Company's common stock exercisable for a period of seven years, vesting over four years in eight equal semi-annual installments beginning six months after the stock option grant date (see Note 5). The agreement may be terminated by the Company without cause, as defined in the agreement, in which case, subject to certain requirements of the agreement, a severance payment would be due in a lump sum amount equal to (a) the target annual bonus prorated for the year of termination, plus (b) 12 months of base salary.

#### 10. Subsequent Events

## 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.

## Settlement Agreement with Cue BioLogics, LLC

The Company received a legal letter dated on or about February 2, 2017 from Cue Biologics, LLC, an unrelated party, asserting that it had rights in the CUE BIOLOGICS trademark. On May 4, 2017, the Company entered into a settlement agreement with Cue BioLogics, LLC to acquire all 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 (collectively, the "CUE BIOLOGICS Mark"), in exchange for a cash payment by the Company of \$175,000 by May 12, 2017. Such payment was timely made.

ASC 350-30-20 defines a defensive intangible asset as an acquired intangible asset in a situation in which an entity does not intend to actively use the asset but intends to hold (lock up) the asset to prevent others from obtaining access to the asset. The Company determined that the acquired intangible asset met the definition of a defensive intangible asset. The Company will account for the \$175,000 payment to Cue BioLogics, LLC for the CUE BIOLOGICS Mark as an acquired intangible asset as of the closing of the settlement agreement (e.g., the date that the cash payment was made), as that was the date that the settlement agreement became effective and the CUE BIOLOGICS trademark was assigned and transferred to the Company.

As the Company can renew the underlying rights to the CUE BIOLOGICS trademark indefinitely at nominal cost, this acquired intangible asset will be classified as a non-amortizable intangible asset in the Company's balance sheet at June 30, 2017. The Company will evaluate the status of this intangible asset for amortization and impairment at each quarter end and year end reporting date.

## Agreements with Catalent Pharma Solutions, LLC

Catalent Pharma Solutions, LLC ("Catalent") is a global provider of drug delivery technology and development solutions for drugs, biologics and consumer health products.

On March 7, 2017, the Company entered into an agreement with Catalent for Catalent to provide services on a sequential milestone basis with respect to the development and manufacture of the Company's lead drug candidate, CUE-101. The services under the agreement are designed to support the preparation and filing of an Investigational New Drug Application with the United States Food and Drug Administration to allow for the commencement of a Phase 1 clinical trial of CUE-101 in the United States. The Company currently estimates that it will incur total direct costs under this agreement aggregating approximately \$5,875,000, most of which the Company estimates will be incurred during the years ending December 31, 2017 and 2018. The Company expects that certain of these payments will consist of nonrefundable advance payments for which the Company anticipates receiving the contracted services within 12 months from the date of payment. Management will periodically review and update the project's estimated budget and timeline.

On July 5, 2017, the Company entered into a separate Master Services Agreement with Catalent that outlines the terms and conditions under which Catalent will provide contract services with respect to the Company's research and development activities for a period of five years. The Company may terminate this agreement without cause upon 90 days prior written notice. Unless and until terminated, this agreement will automatically be extended for successive one-year periods.

## Amendment to Einstein License

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, as described in Note 4.

## Amendment and Restatement of 2016 Omnibus Incentive Plan

On August 13, 2017, the Company's Board of Directors approved an amendment and restatement of the Company's 2016 Omnibus Incentive Plan (see Note 5) 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 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.

## **Employment Agreement**

On May 31, 2017, the Company entered into an employment agreement with its Vice President of Translational Medicine for an initial term ending on December 31, 2018 and continuing on a year-to-year basis thereafter, unless earlier terminated. Compensation under the agreement includes an annual salary of \$250,000, with annual review and adjustment at the discretion of the Board of Directors, and an annual incentive bonus that may equal up to 30% of the annual salary based on performance standards established by the Compensation Committee of the Board of Directors. The agreement may be terminated by the Company without cause, as defined in the agreement, in which case, subject to certain requirements of the agreement, a severance payment would be due in a lump sum amount equal to (a) the target annual bonus prorated for the year of termination, plus (b) 6 months of base salary.

# CUE BIOPHARMA, INC.

# INDEX TO CONDENSED FINANCIAL STATEMENTS Nine Months Ended September 30, 2017 and 2016

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# CUE BIOPHARMA, INC.

# CONDENSED BALANCE SHEETS

	September 30, 2017	December 31, 2016	
	(Unaudited)		
ASSETS			
Current assets:			
Cash	\$ 3,400,481	\$14,925,820	
Certificate of deposit	50,033	50,033	
Research and development contract advances	294,206		
Prepaid expenses and other current assets	145,068	162,398	
Deferred offering costs	240,823		
Total current assets	4,130,611	15,138,251	
Property and equipment, net	1,741,037	1,023,366	
Trademark	175,000	_	
Long-term service contract	23,282		
Deposits	225,500	117,000	
Total assets	\$ 6,295,430	\$16,278,617	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable and accrued expenses	\$ 772,245	\$ 549,963	
Accrued compensation and related expenses	725,196	408,559	
Accrued deferred offering costs	196,694		
Research and development contract liabilities	156,969		
Current portion of deferred rent	63,636	109,091	
Total current liabilities	1,914,740	1,067,613	
Deferred rent, net of current portion		36,364	
Total liabilities	1,914,740	1,103,977	
Commitments and contingencies			
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 – 10,635,684 shares	10,636	10,636	
Additional paid-in capital	26,752,048	24,751,017	
Accumulated deficit	(22,381,994)	(9,587,013)	
Total stockholders' equity	4,380,690	15,174,640	
Total liabilities and stockholders' equity	\$ 6,295,430	\$16,278,617	

See accompanying notes to condensed financial statements.

# CUE BIOPHARMA, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

	Nine Months Ended September 30,			I
	2017		20	)16
Revenue	\$	_	\$	
Operating expenses:				
General and administrative	2,9	14,452	1,1	93,527
Research and development	9,88	9,880,529		22,409
Total operating expenses	12,79	94,981	4,8	15,936
Loss from operations	(12,79	94,981)	(4,8	15,936)
Interest income				52
Net loss	\$(12,79	94,981)	\$(4,8	15,884)
Net loss per common share – basic and diluted	\$	(1.20)	\$	(0.65)
Weighted average common shares outstanding – basic and diluted	10,635,684 7,352,7		52,704	

See accompanying notes to condensed financial statements.

# CUE BIOPHARMA, INC. CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited) Nine Months Ended September 30, 2017

	Common	Stock	Additional		Total
	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Equity
Balance, December 31, 2016	10,635,684	\$10,636	\$24,751,017	\$ (9,587,013)	\$ 15,174,640
Stock-based compensation	_	_	2,001,031	_	2,001,031
Net loss	—	_	—	(12,794,981)	(12,794,981)
Balance, September 30, 2017	10,635,684	\$10,636	\$26,752,048	\$(22,381,994)	\$ 4,380,690

See accompanying notes to condensed financial statements.

# CUE BIOPHARMA, INC. CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

(Chaudhed)	Nine Month	s Fnded	
	Nine Months Ended September 30,		
	2017	2016	
Cash flows from operating activities:			
Net loss	\$(12,794,981)	\$(4,815,884)	
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	293,034	139,541	
Deferred rent	(81,819)	93,183	
Stock-based compensation	2,001,031	435,982	
Changes in operating assets and liabilities:			
(Increase) decrease in –			
Research and development contract advances	(294,206)		
Prepaid expenses and other current assets	(5,952)	(110,891)	
Deposits	(108,500)	(9,283)	
Increase (decrease) in –	222.204		
Accounts payable and accrued expenses	222,281	117,327	
Accrued compensation and related expenses	316,637	189,212	
Research and development contract liabilities	156,969		
Net cash used in operating activities	(10,295,506)	(3,960,813)	
Cash flows from investing activities:			
Acquisition of trademark	(175,000)		
Purchases of property and equipment	(1,010,705)	(421,141)	
Net cash used in investing activities	(1,185,705)	(421,141)	
Cash flow from financing activities:			
Payment of deferred offering costs	(44,128)		
Payment of deferred private sale of common stock		(7,685)	
Net cash used in financing activities:	(44,128)	(7,685)	
Cash:			
Net decrease	(11,525,339)	(4,389,639)	
Balance at beginning of period	14,925,820	6,405,207	
Balance at end of period	\$ 3,400,481	\$ 2,015,568	
Supplemental disclosures of cash flow information:			
Cash paid for –			
Interest	\$ —	\$ —	
Income taxes	\$	\$ —	
Non-cash financing activities:			
Accrual of deferred offering costs	\$ 196,694		
See accompanying notes to condensed financial stateme	nts.		

## CUE BIOPHARMA, INC. NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited) Nine Months Ended September 30, 2017 and 2016

## 1. Organization and Basis of Presentation

The condensed financial statements of Cue Biopharma, Inc. (the "Company") at September 30, 2017, and for the nine months ended September 30, 2017 and 2016, are unaudited. In the opinion of management of the Company, all adjustments, including normal recurring accruals, have been made that are necessary to present fairly the financial position of the Company as of September 30, 2017, the results of its operations for the nine months ended September 30, 2017 and 2016, the statement of stockholders' equity for the nine months ended September 30, 2017, and its cash flows for the nine months ended September 30, 2017 and 2016. Operating results for the interim periods presented are not necessarily indicative of the results to be expected for a full fiscal year. The balance sheet at December 31, 2016 has been derived from the Company's audited financial statements at such date.

The unaudited condensed financial statements and related notes have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to such rules and regulations. These condensed financial statements should be read in conjunction with the Company's audited financial statements for the fiscal year ended December 31, 2016.

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.

On January 14, 2015, in order to implement its business plans, the Company entered into a license agreement with the Albert Einstein College of Medicine, a division of Yeshiva University ("Einstein"), for certain patent rights, as described in Note 4.

The Company is a pre-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 and autoimmune disorders.

## **Going Concern**

The Company's financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any revenues from operations since inception, and does not expect to do so in the foreseeable future. The Company has experienced operating losses and negative operating cash flows since inception, and expects to continue to do so for at least the next few years. The Company has financed its working capital requirements during this period through the sale of its equity securities. At September 30, 2017, the Company had cash and a certificate of deposit totaling \$3,450,514 available to fund the Company's ongoing business activities.

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the financial statements are being issued. The Company's independent registered public accounting firm, in its report on the Company's financial statements for the year ended December 31, 2016, has also raised substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent on its ability to raise additional capital to fund its business activities, including its research and development program. The Company's objective is to complete an initial public offering in 2017 to provide the Company with additional financial resources to fund its operations, but there can be no assurances that the Company will be successful in this regard. Furthermore, 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 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. The Company's financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Because the Company is currently engaged in research at a relatively early stage, it will take a significant amount of time and resources to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years, and may never do so. In addition, to the extent that the Company is able to generate operating revenues, there can be no assurances that the Company will be able to achieve positive earnings and operating cash flows.

## 2. Summary of Significant Accounting Policies

### Use of Estimates

The preparation of financial statements in conformity with United States Generally Accepted Accounting Principles ("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 the accounting for potential liabilities, the assumptions utilized in valuing stock-based compensation issued for services, the realization of deferred tax assets, and the impairment of long-lived assets and intangibles. Actual results could differ from those estimates.

#### **Risks and Uncertainties**

The Company's operations are subject to a number of factors that may affect its operating results and financial condition. Such factors include, but are not limited to: the Company's ability to determine candidates for clinical testing, the results of clinical testing and trial activities of the Company's product candidates, the Company's ability to obtain regulatory approval to market its product candidates, the Company's intellectual property, competition from products manufactured and sold or being developed by other companies, the price of, and demand for, the Company's product candidates if approved for sale, the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its product candidates, and the Company's ability to raise capital.

The Company currently has no commercially approved product candidates and there can be no assurance that the Company's research and development programs will be successfully commercialized. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval, as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and consultants and obtaining and protecting its intellectual property.

## Concentrations

The Company periodically contracts with organizations to provide consulting services related to the Company's research and development activities. Agreements for these services can be for a specific time period or for a specific project or task. The only such contract that represents (or is expected to represent) 10% or more of general and administrative or research and development costs during the year ending December 31, 2017 is summarized below and described in more detail at Note 9.

On March 7, 2017, the Company entered into an agreement with Catalent Pharma Solutions, LLC ("Catalent") for Catalent to provide services on a sequential milestone basis with respect to the development and manufacture of the Company's lead drug candidate, CUE-101. The services under the agreement are designed to support the preparation and filing of an Investigational New Drug Application with the United States Food and Drug Administration to allow for the commencement of a Phase 1 clinical trial of CUE-101 in the United States. The Company currently estimates that it will incur total direct costs under this agreement aggregating approximately \$5,875,000, most of which the Company estimates will be

incurred during the years ending December 31, 2017 and 2018. The Company expects that certain of these payments will consist of nonrefundable advance payments for which the Company anticipates receiving the contracted services within 12 months from the date of payment. Management periodically reviews and updates the project's estimated budget and timeline.

With respect to the total estimated direct costs of approximately \$5,875,000, the Company had incurred \$1,263,384 of such total estimated direct costs as of September 30, 2017, of which \$1,158,925 was charged to research and development expenses in the condensed statement of operations for the nine months ended September 30, 2017, representing 11.7% of research and development expenses for such period. The remaining \$104,459 is reflected as research and development contract advances in the condensed balance sheet at September 30, 2017. The Company expects to receive the services related to such advance payments by March 31, 2018. Accordingly, advance payments at September 30, 2017 are classified as a current asset and are expected to be charged to research and development expenses in the statement of operations through March 31, 2018.

## **Research and Development Funding Arrangements**

The Company's proprietary biologics are at an early stage and will require substantial time and funding to continue development. There can be no assurances that any of the Company's biologics will ultimately become commercially viable product candidates. In order to finance its research and development programs, the Company may periodically enter into collaboration agreements with third parties that provide funding for certain aspects of the Company's ongoing research and development activities. The Company considers various factors in determining the appropriate accounting treatment for such collaboration agreements, including, among others, the risks of and costs associated with the research and development program being funded, the stage of development of the proprietary biologics subject to the research and development program, the likelihood at initiation that the collaboration arrangement will result in an economically successful outcome to the third party, the continuing involvement of the Company in the research and development program and the expenditure of the funds, the transfer of the financial risk associated with the research and development program to the third party, the intended use of the funds and any restrictions thereon, and the probability of any repayment obligations or other forms of consideration if the proprietary biologics subject to the research and development program are not successfully developed and commercialized.

In accordance with ASC 730-20-25-8, to the extent that a collaboration agreement results in a substantive and genuine transfer of financial risk to a third party funding source because any economic benefit that the third party may receive depends solely on the research and development program successfully developing commercially viable product candidates having future economic benefit (which is uncertain at the initiation of the collaboration agreement), the Company will account for such collaboration agreement as a contract to perform research and development services for a third party. The funds received from the third party under such a collaboration agreement will initially be recorded as a deferred credit in the Company's balance sheet. As the related contractual research and development costs are incurred, the applicable amount of the deferred credit will be credited to operations and will be classified as an offset to such research and development costs in the Company's statement of operations.

### **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.

## **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 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 non-amortizable intangible asset in the Company's balance sheet at September 30, 2017. The Company evaluates the status of this intangible asset for amortization and impairment at each quarter end and year end reporting date.

## **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 expensing schedule 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.

#### 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 and patent portfolio

management fees and other costs are charged to operations as incurred. For the nine months ended September 30, 2017 and 2016, patent expenses were \$390,236 and \$257,113, 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 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. As of September 30, 2017 and December 31, 2016, the Company had not deemed any long-lived assets as impaired, and was not aware of the existence of any indicators of impairment at such dates.

## **Rent Expense and Deferred Rent Liability**

Operating lease agreements which contain provisions for future rent increases or periods in which rent payments are reduced or abated are recorded in monthly rent expense in the amount of the total payments over the lease term divided by the number of months of the lease term. The difference between rent expense recorded and the amount paid is credited or charged to a deferred rent liability account. The current portion of deferred rent is included in current liabilities, and the remaining amount is shown in the balance sheet as a non-current liability. Accordingly, rent expense is recorded on a straight-line basis.

#### Stock-Based Compensation

The Company periodically issues stock options 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, 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 vesting period. The fair value of stock options 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.

Stock options granted to members of the Company's Scientific and Clinical Advisory Board, non-employees and outside consultants are revalued each reporting period to determine the amount to be recorded as an expense in the respective period. As the stock options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the value on the date of vesting.

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. During the nine months ended September 30, 2017 and 2016, 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 September 30, 2017 and December 31, 2016.

### **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. 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). The Company did not have any items of comprehensive income (loss) for the nine months ended September 30, 2017 and 2016.

### 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 antidilutive 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 September 30, 2017 and 2016, 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. The information shown below does not include any shares that may be issuable under the down round protection provisions as described in Note 7.

	Septen	September 30,	
	2017	2016	
Common stock warrants	370,370	370,370	
Common stock options	2,366,221	1,603,221	
Total	2,736,591	1,973,591	

### 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.

There were no financial instruments that were measured and recorded at fair value on the Company's balance sheet at September 30, 2017 and December 31, 2016.

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.

## **Deferred Offering Costs**

Costs incurred in connection with equity financings, including legal fees, are deferred until the related financing is either completed or abandoned.

Costs related to abandoned equity financings are charged to operations in the period of abandonment. Costs related to completed equity financings are charged directly to additional paid-in capital.

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). ASU 2014-09 will eliminate transactionand industry-specific revenue recognition guidance under current GAAP and replace

it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The FASB has issued ASU 2016-08, ASU 2016-10, ASU 2016-11, ASU 2016-12, and ASU 2016-20, all of which clarify certain implementation guidance within ASU 2014-09. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017, with early adoption permitted. Entities will be able to transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The Company will adopt the provisions of ASU 2014-09 in the quarter beginning January 1, 2018. As the Company is unlikely to generate any sustainable operating revenues in the next several years, the adoption of ASU 2014-09 is not currently expected to have any impact on the Company's financial statement presentation or disclosures.

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. 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 will adopt the provisions of ASU 2016-02 in the quarter beginning January 1, 2019. The Company generally does not finance purchases of property and equipment, but does lease its operating facilities. While the Company is continuing to assess the potential impact of ASU 2016-02, it currently expects that most of its lease commitments will be subject to ASU 2016-02 and accordingly, upon adoption will be recognized as lease liabilities and right-of-use assets in the Company's balance sheet.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). ASU 2016-09 requires, among other things, that all income tax effects of awards be recognized in the statement of operations when the awards vest or are settled. ASU 2016-09 also allows for an employer to repurchase more of an employee's shares than it can today for tax withholding purposes without triggering liability accounting and allows for a policy election to account for forfeitures as they occur. ASU 2016-09 was effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted for any entity in any interim or annual period. The Company adopted the provisions of ASU 2016-09 in the quarter beginning January 1, 2017. The adoption of ASU 2016-09 did not have any impact on the Company's financial statement presentation or disclosures.

In July 2017, the FASB issued Accounting Standards Update No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to

earnings. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The guidance in ASU 2017-11 can be applied using a full or modified retrospective approach. The adoption of ASU 2017-11 is not currently expected to have any impact on the Company's financial statement presentation or disclosures.

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. Property and Equipment

Property and equipment as of September 30, 2017 and December 31, 2016 is summarized as follows:

	September 30, 2017	December 31, 2016
Laboratory equipment	\$ 2,147,152	\$1,194,473
Furniture and fixtures	9,606	1,832
Computer equipment	70,496	44,166
Leasehold improvements	53,717	29,795
	2,280,971	1,270,266
Less accumulated depreciation and amortization	(539,934)	(246,900)
Net property and equipment	\$ 1,741,037	\$1,023,366

Depreciation and amortization expense for the nine months ended September 30, 2017 and 2016 is included in the condensed statement of operations as follows:

		Nine Months Ended September 30,	
	2017	2016	
General and administrative	\$ 10,466	\$ 2,945	
Research and development	282,568	136,596	
Total	\$293,034	\$139,541	

#### 4. 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 September 30, 2017, 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 September 30, 2017 and December 31, 2016.

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 Company accounts for the costs incurred in connection with the Einstein License in accordance with ASC 730, Research and Development. For the nine months ended September 30, 2017 and 2016, costs incurred with respect to the Einstein License aggregated \$35,417 and \$25,000, respectively, and are included in research and development expenses in the condensed statements of operations.

The Einstein License requires 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 7. A liquidity event includes, but is not limited to, an initial public offering of shares of the Company's common stock; a merger with a public reporting company under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or a company whose shares are listed on a non-U.S. exchange or an affiliate thereof; a merger, consolidation, reorganization, or similar transaction whereby the Company's stockholders immediately prior to the consummation of the transaction; or a sale of substantially all of the Company's assets. Accordingly, the Company will be required to issue 671,572 shares of the Company's common stock to Einstein immediately prior to the consummation of an initial public offering by the Company. At September 30, 2017, a liquidity event had not occurred. The common stock issuable to Einstein upon the occurrence of a liquidity event has certain registration rights, as described in Note 9.

As the consummation of a liquidity event is outside the control of the Company, the Company will account for the issuance of these shares upon the occurrence of a liquidity event. Additionally, 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 Company will account for the issuance of such shares at their aggregate fair value on the date of issuance and, in accordance with ASC 730, Research and Development, will charge such amount to research and development expenses in the statement of operations. For basic earnings per share calculations, these shares will be treated as contingently issuable shares and will not be included in basic earnings per share until the shares have been issued.

#### Service Agreement

On October 1, 2015, the Company entered into a service agreement (the "Service Agreement") with Einstein to support the Company's ongoing research and development activities. The initial term of the Service Agreement was for three months, which was amended in February 2016 to extend it for the period of time deemed necessary to complete the services pursuant to the terms of the Service Agreement. For the nine months ended September 30, 2017 and 2016, costs incurred with respect to the Service Agreement aggregated \$0 and \$80,000, respectively, and are included in research and development expenses in the condensed statement of operations.

# 5. Acquisition of Trademark

On May 4, 2017, the Company entered into a settlement agreement with Cue BioLogics, LLC, an unrelated party, to acquire all 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 (collectively, the "CUE BIOLOGICS Mark"), in exchange for a cash payment by the Company of \$175,000.

Accounting Standards Codification ("ASC") 350-30-20 defines a defensive intangible asset as an acquired intangible asset in a situation in which an entity does not intend to actively use the asset but intends to hold (lock up) the asset to prevent others from obtaining access to the asset. The Company determined that the acquired intangible asset met the definition of a defensive intangible asset and has therefore accounted for the \$175,000 payment to Cue BioLogics, LLC for the CUE BIOLOGICS Mark as an acquired intangible asset.

#### 6. 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 and 500,000 shares of common stock, respectively. At September 30, 2017, stock options for 1,996,221 shares of common stock had been granted and 803,779 shares of common stock had been granted and 130,000 shares of common stock were reserved for future grants under the Omnibus Plan, and stock options for 370,000 shares of common stock had been granted and 130,000 shares of common stock were reserved for future grants under the Non-Employee Plan. In the aggregate, at September 30, 2017, stock options for a total of 2,366,221 shares of common stock were reserved for future grants of common stock were reserved for future grants and end 933,779 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.

Effective March 23, 2016, the Company granted non-qualified stock options to purchase 240,729 shares of its common stock to members of the Company's Scientific and Clinical Advisory Board. The stock options are exercisable for a period of five years from date of grant at \$2.86 per share, which was deemed to be the fair value of the Company's common stock on the date of grant. The stock options vest in equal quarterly installments over a three-year vesting term. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$1,023,791 (\$4.25 per share). The Company re-measures the non-vested options to fair value at the end of each reporting period. The unvested portion of the fair value of the stock options is being charged to operations ratably over the term of the service period from March 15, 2016 through March 15, 2019. During the nine months ended September 30, 2017 and 2016, the Company recorded a charge to operations of \$319,076 and \$181,457, respectively, with respect to these stock options.

Effective March 23, 2016, the Company granted non-qualified stock options to purchase 377,760 shares of its common stock to independent members of the Company's Board of Directors. The stock options are exercisable for a period of seven years from date of grant at \$2.86 per share, which was deemed to be the fair value of the Company's common stock on the date of grant. The stock options vest in equal annual installments over a five-year vesting term. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$1,605,546 (\$4.25 per share). The unvested portion of the fair value of the stock options is being charged to operations ratably from March 23, 2016 through March 23, 2021. During the nine months ended September 30, 2017 and 2016, the Company recorded a charge to operations of \$240,832 and \$168,323, respectively, with respect to these stock options.

On August 29, 2016, the Company entered into an employment agreement with its President and Chief Executive Officer pursuant to which the Company granted incentive stock options to purchase 544,732 shares of its common stock. The stock options are exercisable for a period of seven years from date of grant at \$2.86 per share, which was deemed to be the fair value of the Company's common stock on the date of grant. The stock options vest in equal semi-annual installments over a four-year vesting term. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$2,289,178 (\$4.20 per share). The unvested portion of the fair value of the stock options is being charged to operations ratably from August 29, 2016 through August 29, 2020. During the nine months ended September 30, 2017 and 2016, the Company recorded a charge to operations of \$429,221 and \$47,691, respectively, with respect to these stock options.

Effective September 7, 2016, the Company granted incentive stock options to purchase 440,000 shares of its common stock to the Company's management and employees. The stock options are exercisable for a period of seven years from date of grant at \$2.86 per share, which was deemed to be the fair value of the Company's common stock on the date of grant. The stock options vest in equal semi-annual installments over a four-year vesting term. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$1,848,496 (\$4.20 per share). The unvested portion of the fair value of the stock options is being charged to operations ratably from September 7, 2016 through September 7, 2020. During the nine months ended September 30, 2017 and 2016, the Company recorded a charge to operations of \$346,588 and \$38,511, respectively, with respect to these stock options.

Effective November 16, 2016, the Company granted non-qualified stock options to purchase 60,000 shares of its common stock to members of the Company's Scientific and Clinical Advisory Board. The stock options are exercisable for a period of seven years from date of grant at \$2.86 per share, which was deemed to be the fair value of the Company's common stock on the date of grant. The stock options vest over a one-year vesting term. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$265,367 (\$4.42 per share). The Company re-measures the non-vested options to fair value at the end of each reporting period. The unvested portion of the fair value of the stock options is being charged to operations ratably from November 16, 2016 through November 16, 2017. During the nine months ended September 30, 2017, the Company recorded a charge to operations of \$261,032 with respect to these stock options.

Effective as of January 1, 2017, the Company entered into a consulting agreement with its Chief Medical Officer pursuant to which, effective as of April 17, 2017, the Company granted non-qualified stock options to purchase 150,000 shares of its common stock. The stock options are exercisable for a period of seven years from date of grant at \$5.00 per share, which was deemed to be the fair value of the Company's common stock on the date of grant. The stock options vest over a four-year vesting term. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$821,621 (\$5.48 per share). The unvested portion of the fair value of the stock options is being charged to operations from April 17, 2017 through December 31, 2020. During the nine months ended September 30, 2017, the Company recorded a charge to operations of \$154,054 with respect to these stock options.

Effective March 15, 2017, the Company granted incentive stock options to purchase 173,000 shares of its common stock to the Company's employees. The stock options are exercisable for a period of seven years from date of grant at \$5.00 per share, which was deemed to be the fair value of the Company's common stock on the date of grant. The stock options vest in equal semi-annual installments over a four-year vesting term. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$846,950 (\$4.90 per share). The unvested portion of the fair value of the stock options is being charged to operations ratably from March 15, 2017 through March 15, 2021. During the nine months ended September 30, 2017, the Company recorded a charge to operations of \$114,691 with respect to these stock options.

Effective May 31, 2017, the Company entered into an employment agreement with its Vice President of Translational Medicine, pursuant to which the Company granted incentive stock options to purchase 135,000 shares of its common stock on June 14, 2017. The stock options are exercisable for a period of seven years from date of grant at \$5.00 per share, which was deemed to be the fair value of the Company's

common stock on the date of grant. The stock options vest in equal semi-annual installments over a four-year vesting term. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$658,950 (\$4.88 per share). The unvested portion of the fair value of the stock options is being charged to operations ratably from June 14, 2017 through June 14, 2021. During the nine months ended September 30, 2017, the Company recorded a charge to operations of \$48,048 with respect to these stock options.

Effective June 14, 2017, the Company granted non-qualified stock options to purchase 100,000 shares of its common stock under a consulting agreement to the Company's Senior Scientific and Technical Advisor. The stock options are exercisable for a period of seven years from date of grant at \$5.00 per share, which was deemed to be the fair value of the Company's common stock on the date of grant. The stock options vest over a four-year vesting term. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$547,101 (\$5.47 per share). The Company will re-measure the non-vested options to fair value at the end of each reporting period. The unvested portion of the fair value of the stock options ratably from June 14, 2017 through June 14, 2021. During the nine months ended September 30, 2017, the Company recorded a charge to operations of \$39,893 with respect to these stock options.

Effective June 14, 2017, the Company granted non-qualified stock options to purchase 60,000 shares of its common stock to an independent member of the Company's Board of Directors. The stock options are exercisable for a period of seven years from date of grant at \$5.00 per share, which was deemed to be the fair value of the Company's common stock on the date of grant. The stock options vest over a five-year vesting term. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$297,341 (\$4.96 per share). The unvested portion of the fair value of the stock options is being charged to operations ratably from June 14, 2017 through June 14, 2022. During the nine months ended September 30, 2017, the Company recorded a charge to operations of \$17,345 with respect to these stock options.

Effective June 14, 2017, the Company granted incentive stock options to purchase 85,000 shares of its common stock to the Company's employees. The stock options are exercisable for a period of seven years from date of grant at \$5.00 per share, which was deemed to be the fair value of the Company's common stock on the date of grant. The stock options vest in equal semi-annual installments over a four-year vesting term. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$414,895 (\$4.88 per share). The unvested portion of the fair value of the stock options is being charged to operations ratably from June 14, 2017 through June 14, 2021. During the nine months ended September 30, 2017, the Company recorded a charge to operations of \$30,251 with respect to these stock options.

#### Amendment and Restatement of 2016 Omnibus Incentive Plan

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 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.

For stock options requiring an assessment of value during the nine months ended September 30, 2017, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model utilizing the following assumptions:

Risk-free interest rate	1.48 to 2.17%
Expected dividend yield	0%
Expected volatility	80.90% to 82.97%
Expected life	3.46 to 7 years
Stock price per share	\$7.00

The fair value of \$7.00 per share was determined by reference to the midpoint of the range of the Company's current estimate of the selling price of its common stock (\$6.00 to \$8.00 per share) in its planned initial public offering in 2017.

For stock options requiring an assessment of value during the nine months ended September 30, 2016, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model utilizing the following assumptions:

Risk-free interest rate	1.01 to 1.50%
Expected dividend yield	0%
Expected volatility	112.36%
Expected life	4.46 to 5 years
Stock price per share	\$5.00

The fair value of \$5.00 per share was determined by reference to the sale price of the Company's common stock in its December 2016 private placement.

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 nine months ended September 30, 2017 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2016	1,663,221	\$2.86	
Granted	703,000	\$ 5.00	
Exercised			
Expired		—	
Stock options outstanding at September 30, 2017	2,366,221	\$ 3.50	5.81
Stock options exercisable at December 31, 2016	60,183	\$ 2.86	
Stock options exercisable at September 30, 2017	463,726	\$ 2.96	5.24

The Company recognized \$2,001,031 and \$435,982 in stock-based compensation during the six months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, total unrecognized stock-based compensation was approximately \$8,048,000, which is expected to be recognized as an operating expense in the Company's statement of operations through June 2022.

A summary of the exercise prices of common stock options outstanding and exercisable at September 30, 2017 is as follows:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
\$2.86	1,663,221	442,101
\$5.00	703,000	
	2,366,221	463,726

The intrinsic value of exercisable but unexercised in-the-money stock options at September 30, 2017 was approximately \$1,874,000, based on a fair value of \$7.00 per share on September 30, 2017, which is the midpoint of the Company's current estimate of the range of the selling price of its common stock (\$6.00 to \$8.00 per share) in its planned initial public offering in 2017.

Outstanding options to acquire 1,902,495 shares of the Company's common stock had not vested at September 30, 2017.

The Company expects to satisfy such stock obligations through the issuance of authorized but unissued shares of common stock.

Stock-based compensation for the nine months ended September 30, 2017 and 2016 is included in the condensed statement of operations as follows:

		Nine Months Ended September 30,	
	2017	2016	
General and administrative	\$ 737,119	\$216,015	
Research and development	1,263,912	219,967	
Total	\$2,001,031	\$435,982	

# 7. 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 September 30, 2017 and December 31, 2016. 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 10,635,684 shares were issued and outstanding at September 30, 2017 and December 31, 2016.

*December 22, 2016 Private Placement of Common Stock.* On December 22, 2016, the Company sold 3,282,980 shares of common stock in a private placement to accredited investors at \$5.00 per share, resulting in gross cash proceeds of \$16,414,900. Direct costs of the private placement consisted of a placement agent fee to the placement agent, MDB Capital Group, LLC ("MDB"), of \$1,320,745 and related legal fees and reimbursable expenses of \$89,119. Issuance costs of the private placement aggregated \$1,409,864 and were charged directly to additional paid-in capital. The common stock sold in this private placement has certain registration rights, as described in Note 9.

*Down Round Protection.* The Company provided investors in the December 22, 2016 private placement of common stock with certain limited protections resulting from one or more issuances of shares of common stock at a per share purchase price below that paid by the investors in the private placement, terminating on December 31, 2019. If the Company issues additional shares of common stock without consideration, or for a consideration per share less than the effective per share purchase price deemed to be in effect immediately prior to such issuance, then concurrently with such issuance, the Company is required to issue to each investor, for no additional consideration, the number of additional common shares equal to:

(i) the amount invested by the investor divided by an amount equal to the greater of (A) the consideration per share received by the Company for such issuance or deemed issuance of the additional shares of common stock, and (B) \$2.50 (the "Trigger Price"), less (ii) the number of common shares initially purchased by such investor, plus any additional common shares previously issued to such investor. Notwithstanding the foregoing, no common shares will be issued to an investor as the result of an issuance or deemed issuance of additional shares of common stock if the Company receives written notice from the investors who purchased at least a majority of the common shares in the private placement agreeing that no such issuance will be made as the result of such issuance or deemed issuance of such additional shares of common stock. Initially, the effective per share purchase price will be equal to \$5.00; provided that, in no event, will the Trigger Price be reduced below \$2.50. Following the issuance of any additional shares of common stock to the investors, the effective per share purchase price will be adjusted to equal the Trigger Price associated with such issuance.

The Company considered the following elements of the down round protection in its analysis of the accounting for this contingency: The down round protection has a fixed floor price of \$2.50 per share, as a result of which a maximum of 6,565,960 shares of common stock are issuable under this private placement, including up to 3,282,980 shares of common stock under the down round protection. The Company has sufficient authorized but unissued shares of common stock to fully fund its maximum obligation under the down round protection. The down round protection has a finite life, terminating on December 31, 2019. The down round protection is non-detachable and non-transferable. The shares of common stock issued in the private placement qualify for classification in stockholders' equity as permanent equity, as the Company has no obligation to deliver cash to the investors under any circumstances and no contractual obligation to deliver an indeterminately variable number of shares. Accordingly, the Company will account for the down round protection as a component of the actual price per common share paid by the investors in the private placement when the amount of any additional shares issuable to the investors is known. Any adjustment to the initial number of shares issued under this provision will be accounted for within stockholders' equity as an increase to common stock at par value and an offsetting decrease to additional paid-in capital. For basic earnings per share, the shares associated with the down round protection will be treated as contingently issuable shares and will not be included in basic earnings per share until the final number of shares issuable in this private placement is known and the shares have been issued. See Note 10.

#### **Common Stock Warrants**

A summary of warrant activity for the nine months ended September 30, 2017 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2016	370,370	\$ 2.70	
Issued	—	_	
Exercised	_		
Expired			
Warrants outstanding at September 30, 2017	370,370	\$ 2.70	4.71
Warrants exercisable at December 31, 2016	370,370	\$ 2.70	
Warrants exercisable at September 30, 2017	370,370	\$ 2.70	4.71

The intrinsic value of exercisable but unexercised in-the-money common stock warrants at September 30, 2017 was approximately \$1,593,000, based on a fair value of \$7.00 per share on September 30, 2017, which is the midpoint of the range of the Company's current estimate of the selling price of its common stock (\$6.00 to \$8.00 per share) in its planned initial public offering in 2017.

There was no warrant activity during the nine months ended September 30, 2016.

# 8. Related Party Transactions

During the nine months ended September 30, 2016, the Company incurred expenses of \$60,000 for patentrelated services provided by MDB, which is included in general and administrative expenses in the condensed statement of operations. During the nine months ended September 30, 2017, the Company did not incur any expense for such patent-related services provided by MDB. At September 30, 2017 and December 31, 2016, \$1,447 and \$26,152, respectively, of amounts payable to MDB relating to reimbursable expenses and patentrelated services were included in accounts payable.

The interim Chief Financial Officer of the Company, who is also the Chief Financial Officer of MDB, has been compensated at a rate of \$6,000 per month, reflecting an aggregate charge to operations for the nine months ended September 30, 2017 and 2016 of \$54,000 and \$54,000, respectively.

Information with respect to payments under the Einstein License and the Service Agreement is described in Note 4.

#### 9. Commitments and Contingencies

### Einstein License and Service Agreement

The Company's commitments with respect to the Einstein License and the Service Agreement are summarized in Note 4.

#### Leased Facilities

On July 29, 2015, the Company entered into an operating lease agreement for its laboratory space for the period from August 1, 2015 through April 30, 2018. The lease contains escalating payments during the lease period. The Company records monthly rent expense on the 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 November 14, 2016, the Company entered into an amended lease agreement that provided the Company with additional laboratory space. This amendment was effective beginning December 1, 2016 and continues through the expiration of the lease on April 30, 2018.

On July 30, 2015, the Company entered into an operating lease agreement, as amended, for dedicated vivarium space for the period from August 1, 2015 through March 31, 2018. The operating lease agreement contains an option to increase the amount of space leased for an additional cost.

As of September 30, 2017, future minimum rental payments required under the operating leases for the years ended December 31 are presented below. Amounts reflected for 2017 represent amounts due at September 30, 2017 for the remainder of the 2017 fiscal year ending December 31, 2017.

Years Ending December 31,	
2017	\$ 676,500
2018	854,000
Total	\$1,530,500

Total lease expense, excluding the dedicated vivarium space, for the nine months ended September 30, 2017 and 2016 was included in the condensed statement of operations as follows:

		Nine Months Ended September 30,	
	2017	2016	
General and administrative	\$ 172,773	\$ 63,818	
Research and development	1,297,909	574,364	
Total	\$1,470,682	\$638,182	

# Legal Contingencies

The Company may be subject to various legal proceedings from time to time as part of its business. As of September 30, 2017, 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.

#### **Registration Statement Filing Obligations**

In conjunction with the sale of common stock on June 15, 2015, including placement agent warrants issued to MDB, the Company granted the investors and MDB certain piggy-back registration rights commencing 180 days after the date that the Company becomes a reporting company under the Exchange Act, and for a period of five years thereafter, and a one-time demand registration right commencing 180 days after the date that the Company under the Exchange Act, which shall terminate on the earliest of when all the underlying securities either (i) have been sold pursuant to a registration statement, (ii) have been covered by an effective registration statement which has been effective for an aggregate period of 16 months, or (iii) sold by the holder pursuant to Rule 144 of the Securities Act of 1933, as amended.

In conjunction with the sale of common stock on December 22, 2016 (see Note 7), the Company granted the investors certain piggy-back and demand registration rights with respect to the common stock commencing six months after an initial public offering by the Company, by joinder to the registration rights agreement entered into by the Company and investors in connection with the Company's June 15, 2015 private placement of common stock.

Upon the completion of an initial public offering, the Company is required to use its best efforts to file a registration statement covering the resale of the shares of common stock issued to Einstein (see Note 4) as soon as practicable, but no later than 180 calendar days from the date of the initial public offering, and to cause such registration statement to be declared effective by the United States Securities and Exchange Commission within 120 calendar days from the shares.

#### Agreement with MDB

Effective April 13, 2015, the Company entered into an agreement with MDB to engage such firm as its exclusive placement agent in connection with one or more offerings of the Company's securities. As consideration for the services to be provided under the agreement, MDB was entitled to a cash fee equal to 10% of the gross proceeds raised in a financing, and warrants for up to 10% of the aggregate securities sold in an offering, exercisable for seven years at 100% of the offering price per share in a private offering and at not less than 120% of the offering price per share in a public offering, each for a cash consideration of \$1,000. The agreement provided for the reimbursement of legal expenses incurred by MDB in conjunction with a securities offering.

Effective December 22, 2016, the Company amended the agreement with MDB to modify the consideration that MDB is entitled to receive for its placement agent services, to provide for a cash fee equal to 10% of the initial \$10,000,000 of gross proceeds raised in a financing and 5% of the amount in excess of \$10,000,000 in gross proceeds raised in a financing, and that MDB shall receive no placement agent warrants.

#### **Employment Agreements**

On August 29, 2016, the Company entered into an employment agreement with its President and Chief Executive Officer for an initial term ending on December 31, 2018 and continuing on a year-to-year basis thereafter, unless earlier terminated. Compensation under the agreement includes an annual salary of \$325,000, with annual review and adjustment at the discretion of the Board of Directors, a signing bonus of \$25,000 which was payable within 30 days of the effective date of the agreement, and an annual incentive bonus that may equal up to 30% of the annual salary based on performance standards established by the Compensation Committee of the Board of Directors. The agreement also provided for the grant of stock options to purchase shares of the Company's common stock (see Note 6). The agreement may be

terminated by the Company without cause, as defined in the agreement, in which case, subject to certain requirements of the agreement, a severance payment would be due in a lump sum amount equal to (a) the target annual bonus prorated for the year of termination, plus (b) 12 months of base salary.

On May 31, 2017, the Company entered into an employment agreement with its Vice President of Translational Medicine for an initial term ending on December 31, 2018 and continuing on a year-to-year basis thereafter, unless earlier terminated. Compensation under the agreement includes an annual salary of \$250,000, with annual review and adjustment at the discretion of the Board of Directors, and an annual incentive bonus that may equal up to 30% of the annual salary based on performance standards established by the Compensation Committee of the Board of Directors. The agreement also provided for the grant of stock options to purchase shares of the Company's common stock (see Note 6). The agreement may be terminated by the Company without cause, as defined in the agreement, in which case, subject to certain requirements of the agreement, a severance payment would be due in a lump sum amount equal to (a) the target annual bonus prorated for the year of termination, plus (b) 6 months of base salary.

### Agreements with Catalent

Catalent is a global provider of drug delivery technology and development solutions for drugs, biologics and consumer health products.

On March 7, 2017, the Company entered into an agreement with Catalent for Catalent to provide services on a sequential milestone basis with respect to the development and manufacture of the Company's lead drug candidate, CUE-101. The services under the agreement are designed to support the preparation and filing of an Investigational New Drug Application with the United States Food and Drug Administration to allow for the commencement of a Phase 1 clinical trial of CUE-101 in the United States. The Company currently estimates that it will incur total direct costs under this agreement aggregating approximately \$5,875,000, most of which the Company estimates will be incurred during the years ending December 31, 2017 and 2018. The Company expects that certain of these payments will consist of nonrefundable advance payments for which the Company anticipates receiving the contracted services within 12 months from the date of payment. Management periodically reviews and updates the project's estimated budget and timeline.

On July 5, 2017, the Company entered into a separate Master Services Agreement with Catalent that outlines the terms and conditions under which Catalent will provide contract services with respect to the Company's research and development activities for a period of five years. The Company may terminate this agreement without cause upon 90 days prior written notice. Unless and until terminated, this agreement will automatically be extended for successive one-year periods.

# 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 six months ended September 30, 2017.

#### 10. Subsequent Events

#### **Collaboration Agreement with Merck**

On November 14, 2017, we entered into an Exclusive Patent License and Research Collaboration Agreement (the "Collaboration Agreement") with Merck Sharp & Dohme Corp. ("Merck") for a partnership to research and develop certain of our proprietary biologics that target certain autoimmune disease indications (the "Initial Indications"). 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. The research program outlined in the Collaboration Agreement entails (1) our research, discovery and development of certain CUE Biologics<sup>™</sup> 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 CUE Biologics<sup>™</sup> 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, we have granted to Merck under the Collaboration 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 CUE Biologics<sup>™</sup> that are elected to be developed by Merck. From the effective date of the Collaboration Agreement until the earlier of (i) the first achievement of Proof of Mechanism for a Cue Biologic<sup>™</sup> drug candidate or (ii) 18 months after we notify the joint steering committee that the first Product Candidate has been synthesized under the research program, we are required to forebear from researching, developing or licensing to a third party rights related to any CUE Biologics<sup>™</sup> drug candidate for the treatment of autoimmune diseases other than pursuant to the Collaboration Agreement. 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 Collaboration Agreement. The Company is not required to forbear at any time, however, from developing other Cue Biologics<sup>™</sup> for use in therapeutic areas other than autoimmune diseases, e.g., for use in treating cancer or infectious diseases.

In exchange for the licenses and other rights granted to Merck under the Collaboration Agreement, we will receive 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 Collaboration 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.

The term of the Collaboration 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 Collaboration 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 Collaboration Agreement at any time upon 30 days' notice to the Company. The Collaboration 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.

#### **Employment Agreement with Senior Vice President and General Counsel**

On November 15, 2017, the Company entered into an employment agreement with its Senior Vice President and General Counsel for an initial term ending on December 31, 2018 and continuing on a year-to-year basis thereafter, unless earlier terminated. Compensation under the agreement includes an annual salary of \$275,000, with annual review and adjustment at the discretion of the Board of Directors, and an annual incentive bonus that may equal up to 20% of the annual salary based on performance standards established by the Compensation Committee of the Board of Directors. The agreement also provided for the grant of stock options to purchase shares of the Company's common stock. The agreement may be terminated by the Company without cause, as defined in the agreement, in which case, subject to certain requirements of the agreement, a severance payment would be due in a lump sum amount equal to (a) the highest annual bonus payable for the year of termination prorated for the year of termination, plus (b) 6 months of base salary.

# Anti-Dilution Rights

Our number of outstanding shares of common stock could change in the future due to the anti-dilution rights of holders of 3,282,980 shares of our outstanding common stock, who have anti-dilution protection that could result in additional dilution to our stockholders generally. These investors acquired their shares in our December 2016 private placement at a price of \$5.00 per share. The anti-dilution protection provides that, if at any time on or prior to December 31, 2019, we issue additional shares of common stock without consideration, or for a consideration per share less than the Effective Per Share Purchase Price (as described below) deemed to be in effect immediately prior to such issuance, then concurrently with such issuance, we shall issue to each of these investors, for no additional consideration, a number of additional shares of common stock to replicate the issuance of shares to such investors at such lower price (subject to a minimum per share price of \$2.50). Notwithstanding the foregoing, no shares will be issued to these investors as the result of an issuance or deemed issuance of additional shares of common stock if we receive written notice from a number of these investors who purchased at least a majority of shares sold in the December 2016 private placement (the "Majority Investors") agreeing that no such issuance will be made as the result of such issuance or deemed issuance of such additional shares. Initially, the "Effective Per Share Purchase Price" is \$5.00. Following any issuance as a result of the foregoing anti-dilution rights, the Effective Per Share Purchase Price will be adjusted to equal the per share price associated with such issuance.

Pursuant to an Irrevocable Waiver and Amendment to Securities Purchase Agreements entered into on December 4, 2017, the Majority Investors agreed that no shares shall be issuable pursuant to these anti-dilution rights in connection with any issuance of common stock occurring after the Company's initial public offering.

Up to 8,000,000 Shares of Common Stock



# Cue Biopharma, Inc.

# **PROSPECTUS**

**MDB** Capital Group, LLC

Feltl and Company

Until , 2017, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus.

# PART II

# INFORMATION NOT REQUIRED IN PROSPECTUS

# ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the various expenses to be incurred in connection with the sale and distribution of our common stock being registered hereby, all of which will be borne by us (except any underwriting commissions and expenses incurred for brokerage, accounting, tax or legal services or any other expenses incurred in disposing of the shares). All amounts shown are estimates except the SEC registration fee.

SEC Filing Fee	\$ 8,404
FINRA Fee	\$ 10,625
Underwriter's Legal Fees and Expenses	\$150,000
Nasdaq Fee	\$ 50,000
Printing Expenses	\$ 40,000
Accounting Fees and Expenses	\$100,000
Legal Fees and Expenses	\$250,000
Transfer Agent and Registrar Expenses	\$ 15,000
Miscellaneous	\$125,971
Total	\$750,000

# ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

The following summary is qualified in its entirety by reference to the complete text of any statutes referred to below and the certificate of incorporation of Cue Biopharma, Inc., a Delaware corporation.

Section 145 of the General Corporation Law of the State of Delaware (the "DGCL") permits a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful.

In the case of an action by or in the right of the corporation, Section 145 of the DGCL permits a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses that the Court of Chancery or such other court shall deem proper.

Section 145 of the DGCL also permits a Delaware corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation,



partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under Section 145 of the DGCL.

Article NINTH of our Amended and Restated Certificate of Incorporation states that our directors shall not be personally liable to us or to our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability. Under Section 102(b)(7) of the DGCL, the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty can be limited or eliminated except (i) for any breach of the director's duty of loyalty to the corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) under Section 174 of the DGCL (relating to unlawful payment of dividend or unlawful stock purchase or redemption); or (iv) for any transaction from which the director derived an improper personal benefit.

Article EIGHTH of our Amended and Restated Certificate of Incorporation provides that we shall indemnify (and advance expenses to) our officers and directors to the full extent permitted by the DGCL.

Effective upon the closing of this offering, we will have directors' and officers' liability insurance insuring our directors and officers against liability for acts or omissions in their capacities as directors or officers, subject to certain exclusions. Such insurance will also insure us against losses which we may incur in indemnifying our officers and directors. As permitted by the DGCL, we have entered into indemnification agreements with each of our directors and executive officers that require us to indemnify such persons against various actions including, but not limited to, third-party actions where such director or executive officer, by reason of his or her corporate status, is a party or is threatened to be made a party to an action, or by reason of anything done or not done by such director in any such capacity. We intend to indemnify directors and executive officers against all costs, judgments, penalties, fines, liabilities, amounts paid in settlement by or on behalf such directors or executive officers and for any expenses actually and reasonably incurred by such directors or executive officers in connection with such action, if such directors or executive officers acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the Company, and with respect to any criminal proceeding, had no reasonable cause to believe their conduct was unlawful. We also intend to advance to our directors and executive officers expenses (including attorney's fees) incurred by such directors and executive officers in advance of the final disposition of any action after the receipt by the Company of a statement or statements from directors or executive officers requesting such payment or payments from time to time, provided that such statement or statements are accompanied by an undertaking, by or on behalf of such directors or executive officers, to repay such amount if it shall ultimately be determined that they are not entitled to be indemnified against such expenses by the Company.

The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification or advancement of expenses, including, among others, provisions about providing notice to the Company of any action in connection with which a director or executive officer seeks indemnification or advancement of expenses from the Company and provisions concerning the determination of entitlement to indemnification or advancement of expenses.

Prior to the closing of this offering we plan to enter into an underwriting agreement, which will provide that the underwriters are obligated, under some circumstances, to indemnify our directors, officers and controlling persons against specified liabilities.

# ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

During the past three years, we issued the following securities without registration under the Securities Act of 1933, as amended (the "Securities Act").

# Stock and Warrants

On January 1, 2015, we sold 3,649,000 shares of common stock to MDB Capital Group, LLC ("MDB"), certain of its affiliates and certain of the founders of our Company for proceeds of \$3,649. We relied on the exemption provided by Section 4(a)(2) of the Securities Act to make the offering in as much as the investors were accredited and there was no form of general solicitation or general advertising relating to the offer.

On June 15, 2015, we sold an aggregate of 3,703,704 shares of common stock to certain investors at an aggregate offering price of \$10,000,000. We relied on the exemption provided by Section 4(a)(2) of the Securities Act to make the offering inasmuch as the investors were accredited and there was no form of general solicitation or general advertising relating to the offer. As consideration for its services as placement agent, MDB received a cash commission of \$1,000,000.

On June 15, 2015, in connection with the consummation of the placement of our common stock on that date, we issued to MDB a warrant to purchase 370,370 shares of our common stock as consideration for its service as placement agent. MDB later assigned one-half of the warrant among eight MDB employees, three of whom are officers or directors of the Company. The warrant has a term of seven years and an exercise price of \$2.70 per share. We relied on the exemption provided by Section 4(a)(2) of the Securities Act of to make the offering inasmuch as the investors were accredited and there was no form of general solicitation or general advertising relating to the offer.

On December 22, 2016, we sold an aggregate of 3,282,980 shares of common stock to certain investors at an aggregate offering price of approximately \$16.4 million. We relied on the exemption provided by Rule 506 of Regulation D promulgated under the Securities Act to make the offering. As consideration for its services as placement agent, MDB received a cash commission of \$1,320,745.

We have agreed to issue to Albert Einstein College of Medicine ("Einstein"), in connection with this offering and pursuant to license agreement between the Company and Einstein, 671,572 shares of common stock. We will rely on the exemption provided by Section 4(a)(2) of the Securities Act to make the offering inasmuch as the investor is accredited and there is no form of general solicitation or general advertising relating to the offer.

# Stock Options

Effective on March 23, 2016, we granted to certain members of our Scientific and Clinical Advisory Board, as consideration for their service on our Scientific and Clinical Advisory Board, options to purchase an aggregate of 240,729 shares of our common stock at an exercise price of \$2.86 per share. Each option has a term of five years and vests over three years in twelve equal quarterly installments.

Effective on March 23, 2016, we granted each of Peter Kiener, Steven McKnight and Barry Simon, our independent directors, an option to purchase 125,920 shares of our common stock at an exercise price of \$2.86 per share. Each option has a term of seven years and vests over five years in equal annual installments.

Effective on August 29, 2016, we granted Daniel Passeri, our President and Chief Executive Officer, an option to purchase 544,732 shares of our common stock at an exercise price of \$2.86 per share. The option has a term of seven years and vests over four years in eight equal semi-annual installments.

Effective on September 7, 2016, we granted to certain employees, including two of our executive officers, as consideration for their service to the Company, options to purchase an aggregate of 440,000 shares of our common stock at an exercise price of \$2.86 per share. Each option has a term of seven years and vests over four years in eight equal semi-annual installments.

Effective on November 16, 2016, we granted to certain members of our Scientific and Clinical Advisory Board, as consideration for their service on our Scientific and Clinical Advisory Board, options to purchase an aggregate of 60,000 shares of our common stock at an exercise price of \$2.86 per share. Each option has a term of seven years and vests in full on the one-year anniversary of the grant date.

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Effective on March 15, 2017, we granted to certain employees, as consideration for their service to the Company, options to purchase an aggregate of 173,000 shares of our common stock at an exercise price of \$5.00 per share. Each option has a term of seven years and vests over four years in eight equal semi-annual installments.

Effective on April 17, 2017, we granted to Ken Pienta, our Chief Medical Officer, an option to purchase 150,000 shares of our common stock at an exercise price of \$5.00 per share. The option has a term of seven years and vests in annual installments over a four year period.

Effective on June 14, 2017, we granted to certain employees, as consideration for their service to the Company, options to purchase an aggregate of 220,000 shares of our common stock at an exercise price of \$5.00 per share. Each option has a term of seven years and vests over four years in eight equal semi-annual installments.

Effective on June 14, 2017, we granted to Peter Kiener, our Chairman, as consideration for his service to our board of directors, an option to purchase 60,000 shares of our common stock at an exercise price of \$5.00 per share. The option has a term of seven years and vests over five years in equal annual installments.

Effective on June 14, 2017, we granted to Ulrich Weidle, a senior scientific advisor, an option to purchase 100,000 shares of our common stock at an exercise price of \$5.00 per share. The option has a term of seven years and vests over four years in equal annual installments.

All of the stock options described above were granted in reliance upon an available exemption from the registration requirements of the Securities Act, including those contained in Rule 701 promulgated under Section 3(b) of the Securities Act. Among other things, we relied on the fact that, under Rule 701, companies that are not subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act are exempt from registration under the Securities Act with respect to certain offers and sales of securities pursuant to "compensatory benefit plans" as defined under that rule. We believe that all of the options described above were issued pursuant qualifying "compensatory benefit plans".

# **ITEM 16. EXHIBITS**

Exhibit No.	Description of Document
<u>1.1</u>	Form of Underwriting Agreement*
<u>3.1</u>	Certificate of Incorporation of the Registrant, as currently in effect*
<u>3.2</u>	Certificate of Amendment to Certificate of Incorporation of the Registrant, as currently in effect*
<u>3.3</u>	Bylaws of the Registrant, as currently in effect*
<u>3.4</u>	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon completion of the offering*
<u>3.5</u>	Form of Amended and Restated Bylaws of the Registrant, to be in effect upon completion of the offering*
<u>4.1</u>	Specimen Certificate representing shares of common stock of the Registrant*
<u>4.2</u>	Form of Underwriters' Warrant*
<u>4.3</u>	<u>Warrant to Purchase Common Stock issued to the placement agent in the Registrant's 2015 private</u> <u>placement offering*</u>
<u>5.1</u>	Opinion of K&L Gates LLP*
<u>10.1</u>	<u>Engagement Agreement dated April 13, 2015 between the Registrant and MDB Capital Group,</u> <u>LLC*</u>
<u>10.2</u>	Form of Lock-Up Agreement*
<u>10.3</u>	Form of Securities Purchase Agreement between the Registrant and investors for an offering completed on June 15, 2015*
<u>10.4</u>	Form of Registration Rights Agreement between the Registrant and investors for an offering completed on June 15, 2015*
<u>10.5</u>	Form of Securities Purchase Agreement between the Registrant and investors for an offering completed on December 22, 2016*

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Exhibit No.	Description of Document		
<u>10.6</u>	Form of Joinder and Amendment to Registration Rights Agreement between the Registrant and		
	investors for an offering completed on December 22, 2016*		
<u>10.7</u>	Executive Employment Agreement between the Registrant and Rodolfo J. Chaparro dated effective		
	<u>June 15, 2015†*</u>		
<u>10.8</u>	Executive Employment Agreement between the Registrant and Ronald D. Seidel dated effective June 15, 2015 <sup>+*</sup>		
10.9	Employment Agreement between the Registrant and Daniel R. Passeri dated August 29, 2016†*		
10.10	Form of Indemnification Agreement*		
10.11	Amended and Restated License Agreement by and between the Registrant and Albert Einstein		
	College of Medicine dated July 31, 2017 <sup>±</sup>		
<u>10.12</u>	Cue Biopharma, Inc. 2016 Omnibus Incentive Plan, as amended and restated <sup>+*</sup>		
<u>10.13</u>	Form of stock option award under 2016 Omnibus Incentive Plan <sup>+*</sup>		
<u>10.14</u>	<u>Cue Biopharma, Inc. 2016 Non-Employee Equity Incentive Plan<sup>+*</sup></u>		
<u>10.15</u>	Form of stock option award under 2016 Non-Employee Equity Incentive Plan <sup>+*</sup>		
<u>10.16</u>	Real Estate License Agreement by and between the Registrant and Mass Innovation Labs, LLC		
	<u>dated July 29, 2015*</u>		
<u>10.17</u>	Amendment to Real Estate License Agreement by and between the Registrant and Mass Innovation Labs, LLC dated November 14, 2016*		
10.10			
<u>10.18</u>	Second Amendment to Real Estate License Agreement by and between the Registrant and Mass Innovation Labs, LLC dated June 28, 2017*		
<u>10.19</u>	Escrow Agreement for the offering by and between the Registrant, MDB Capital Group, LLC and		
	Continental Stock Transfer & Trust Company dated November 24, 2017*		
<u>10.20</u>	Form of Subscription Agreement for the offering*		
<u>10.21</u>	Exclusive Patent License and Research Collaboration Agreement between the Registrant and Merck		
	<u>Sharp &amp; Dohme Corp. dated November 14, 2017</u>		
<u>10.22</u>	Executive Employment Agreement between the Registrant and Colin G. Sandercock dated as of		
	November 15, 2017†*		
<u>10.23</u>	Form of Irrevocable Waiver and Amendment to Securities Purchase Agreements between the		
	Registrant and investors for offerings completed June 15, 2015 and December 22, 2016*		
<u>14.1</u>	Code of Business Conduct and Ethics*		
<u>23.1</u>	Consent of Gumbiner Savett Inc., Independent Registered Public Accounting Firm		
<u>23.2</u>	Consent of K&L Gates LLP (included in Exhibit 5.1)*		
<u>24.1</u>	Power of Attorney*		

\* Previously filed.

† Indicates management compensatory plan, contract or arrangement.

‡ Confidential Treatment requested for certain portions of this Agreement.

# **ITEM 17. UNDERTAKINGS**

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total)

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dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered that remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: (i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424; (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant; (iii) the portion of any other free writing prospectus relating material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (5) To provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.
- (6) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus as filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (7) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (8) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.



# SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 4 to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts, on this 11th day of December, 2017.

/s/T	Daniel	R	Passeri

	Daniel R. Passeri Chief Executive Officer and Director (Principal Executive Officer)		
Pursuant to the requirements of the Securities <i>A</i> following persons in the capacities and on the dates	Act of 1933, this registration statement has been signed by the indicated.		
Dated: December 11, 2017	/s/ Daniel R. Passeri		
	Daniel R. Passeri Chief Executive Officer and Director (Principal Executive Officer)		
Dated: December 11, 2017	/s/ Gary Schuman		
	Gary Schuman Interim Chief Financial Officer (Principal Financial and Accounting Officer)		
Dated: December 11, 2017	/s/ ***		
	Anthony DiGiandomenico, Director		
Dated: December 11, 2017	/s/ ***		
	Cameron Gray, Director		
Dated: December 11, 2017	/s/ ***		
	Peter A. Kiener, Director		
Dated: December 11, 2017	/s/ ***		
	Steven McKnight, Director		
Dated: December 11, 2017	/s/ ***		
	Christopher Marlett, Director		
Dated: December 11, 2017	/S/ ***		
	Barry Simon, Director		
*** By: /s/ Daniel R. Passeri	_		

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Daniel R. Passeri Attorney-in-fact

# CONFIDENTIAL PORTIONS OF THIS AGREEMENT HAVE BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR SUCH PORTIONS. ASTERISKS DENOTE OMISSIONS.

# AMENDED AND RESTATED LICENSE AGREEMENT

This Amended and Restated License Agreement ("**Agreement**") is entered into as of July 31, 2017 ("**Restated Agreement Effective Date**"), by and between Albert Einstein College of Medicine, Inc., a corporation organized and existing under the laws of the State of New York, having an office and place of business at 1300 Morris Park Avenue, Bronx, New York 10461 as successor-in-interest to Albert Einstein College of Medicine of Yeshiva University, a Division of Yeshiva University, ("**Licensor**") and Cue Biopharma Inc., formerly known as Imagen Biopharma, Inc., a corporation organized and existing under the laws of the State of Delaware, having an office and place of business at do MDB Capital Group LLC, 401 Wilshire Blvd, Suite 1020, Santa Monica, California 90401 ("**Licensee**").

# Statement

Licensor is the owner of certain patent rights naming Steven C. Almo, Ronald D. Seidel, Brandan S. Hillerich, Rodolfo J. Chaparro, Sarah C. Garrett-Thomson, Scott J. Garfoth and James D. Love ("**the Investigators**") as inventors, which relate to methods for high throughput receptor-ligand identification, a cellular platform for rapid and comprehensive T-cell immunomonitoring and SYNTAC Fc fusion constructs and uses thereof.

Licensor is also the owner of certain know-how relating to synapse for targeted T-cell activation (synTac) molecules, receptor ligand identification, and platforms for T-cell immunomonitoring. Licensee wishes to acquire an exclusive license in the Field (as defined below) from Licensor with respect to the aforementioned patent rights and know-how.

Licensee and Licensor are parties to a License Agreement effective January 14, 2015, as amended pursuant to Amendment No. 1 to the License Agreement, effective June 2, 2015 and pursuant to a Second Amendment Agreement effective April 19, 2016 (collectively, the "**Original License**"). Licensee and Licensor now desire to amend and restate the Original License to modify certain terms, including adding a license to sell Know-How Products and MHC Class II Products, as hereinafter defined

**NOW, THEREFORE**, in consideration of the promises and mutual covenants, conditions and limitations herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Licensor and Licensee agree as follows:



# 1. <u>Definitions</u>

- 1.01 "Field" means any and all uses under the Agreement Patents and Know-How.
- 1.02 **"Agreement Patents**" means the patent applications listed on Appendix A, together with any and all patents and patent applications which issue from or are based on such patent applications and from any and all divisionals, continuations, continuations-in-part (but only to the extent the claims thereof are enabled by disclosure of the parent application) and foreign counterparts of such patent applications, and any and all reissues, renewals and extensions or the like of such patent applications and any and all U.S. and foreign patents which are based on such patent applications. Appendix A shall be updated from time-to-time by the parties.
- 1.03 **"Original Effective Date**" shall mean January 14, 2015.
- 1.04 **Licensed Product**" means any product, process or service in the Field, the development, manufacture, use, provision, sale or import of which is covered by a Valid Claim in an Agreement Patent in the country of manufacture and/or sale.
- 1.05 **"Know-How**" means technology received by Licensee from Licensor relating to synapse for targeted T-cell activation (synTac) molecules, receptor ligand identification, or platforms for T-cell immunomonitoring.
- 1.06 **"Know-How Product**" means any product or service (or component thereof), other than a Licensed Product or an MHC Class II Product, the discovery, development, manufacture, use, sale, offering for sale, importation, exportation, distribution, rental or lease of which involves the use of or incorporation, in whole or in part, of Know-How. For clarity, a product or service (or component thereof) that includes polypeptides of the major histocompatibility complex Class II grouping but is not a MHC Class II Product, will be considered a Know-How Product if the discovery, development, manufacture, use, sale, offering for sale, importation, exportation, distribution, rental or lease of which involves the use of or incorporation, in whole or in part, of Know-How.
- 1.07 "MHC Class II Products" means any Licensed Product that includes polypeptides of the major histocompatibility complex Class II grouping.
- 1.08 "Net Sales" means the total consideration, in any form, received as consideration for the sale, lease, provision or other disposition of Licensed Products, Know-How Products and/or MHC Class II Products by Licensee and/or Affiliates to an independent third party ("Total Consideration"), less:

- (a) customary trade and quantity discounts actually allowed, refunds, returns and recalls; and,
- (b) when included in gross sales, customary freight, insurance, storage, shipping, duties, and sales, V.A.T. and/or use taxes based on sales prices, but not including taxes when assessed on incomes derived from such sales.

With respect to consideration received by Licensee and Affiliates, the total deductions referenced in Sub-sections (a) and (b) of this Section 1.04 shall not exceed [\*\*\*] of the Total Consideration for Licensed Products, Know-How Products and MHC Class II Products in any calendar quarter.

If Licensee and/or Affiliates intend to accept from independent third parties any non-cash consideration as Net Sales or intend to provide Licensed Product, Know-How Products and/or MHC Class II Products at no charge, Licensee must first notify Licensor in writing in reasonable detail. If the parties can not agree on the present day value of such non-cash consideration, then the parties will appoint an independent third party to determine the present day value of such consideration and that value shall be added to Net Sales in place of the non-cash consideration. The cost of the independent third party will be paid by Licensee.

In the event that, during a particular calendar quarter, a Licensed Product, Know-How Product or MHC Class II Product is sold in combination with one or more other products, whether or not such other products are packaged or otherwise physically combined with such Licensed Product, Know-How Product or MHC Class II Product for a single price (a "**Combination Product**"), Net Sales from sales of a Combination Product, for purposes of calculating royalties due under this Agreement, shall be calculated by multiplying the Net Sales of the Combination Product by the fraction AI(A+B), where A is the average per unit sales price for such calendar quarter of the Licensed Product, Know-How Product or MHC Class it Product sold separately in the country of sale and B is the average per unit sales price for such calendar quarter of the Licensed Product, Know-How Product or MHC Class II Product on the one hand, and/or the other product(s) in the country of sale on the other hand, separate sale prices in commensurate countries may be used instead. In the event that no separate sales are made of the Licensed Product or MHC Class II Product on the one hand, and/or the other, Net Sales from sales of a Combination Product, Know-How Product on the one hand, and/or the other product(s) on the other. Net Sales from sales of a Combination Product, for purposes of determining royalty payments on such Combination Products, shall be calculated using the entire Net Sales of such Combination Products.

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- 1.09 "**Net Proceeds**" shall mean, subject to the exception discussed in sub-section (a) below, the total consideration in any form received by Licensee from a Sublicensee or optionee in connection with the grant to said Sublicensee or optionee of rights under Agreements Patents and/or Know-How. Net Proceeds includes, without limitation, license signing fees, maintenance fees, milestone and minimum payments (whether or not such fees and payments are creditable against future royalties to be paid to Licensee), and just that portion of the funds received for equity purchases of Licensee which exceeds the fair market value of the equity based on the most recent sales price of Licensee's equity securities (or if Licensee is a public company at such time, the average closing price of the immediately preceding 5 trading days) exclusive of transactions covered by Licensee's equity incentive plans.
  - (a) Net Proceeds does not include royalties based on Sublicensee Net Sales, and Contract Research.

If Licensee intends to accept from a Sublicensee or optionee any non-cash consideration as Net Proceeds, Licensee must first notify Licensor in writing in reasonable detail. Licensor shall be deemed to have accepted the transaction unless Licensor notifies Licensee in writing of Licensor's objection in reasonable detail within 5 business days of receipt of Licensee's written notice. if the parties can not agree on the present day value of such non-cash consideration, then the parties will appoint an independent third party to determine the present day value of such consideration and that value shall be added to Net Proceeds in place of the non-cash consideration. The cost of the independent third party will be paid by Licensee.

1.10 **"Contract Research**" shall mean those funds received by Licensee from a Sublicensee in connection with the grant to said Sublicensee of rights under Agreement Patents and/or Know-How, which funds are actually used to pay for research and/or development by Licensee relating directly to Licensed Products, Know-How Products and/or MHC Class II Products, which work is to be performed by or for Licensee after the date of the sublicense agreement and with results to be reported to Licensor and licensed to Sublicensee and which is to be performed at a total cost that does not exceed Licensee's direct costs. Notwithstanding the foregoing, Contract Research funds received from a Sublicensee which are in excess of [\*\*\*] of the total consideration received by Licensee from that Sublicensee in connection with the grant to said Sublicensee of rights under Agreement Patents and/or Know-How in any twelve month period beginning [\*\*\*] after the Restated Agreement Effective Date shall be excluded from the definition of Contract Research and included in the definition of Net Proceeds, unless otherwise approved at the time of execution of the relevant sublicense by Licensor.

- 1.11 "Sublicensee Net Sales" means the total consideration, in any form, received as consideration for the sale, lease, provision or other disposition of Licensed Products, Know-How Products and/or MHC Class II Products by a Sublicensee to an independent third party ("Sublicensee Total Consideration"), less:
  - (a) customary trade and quantity discounts actually allowed, refunds, returns and recalls; and,
  - (b) when included in gross sales, customary freight, insurance, storage, shipping, duties, and sales, V.A.T. and/or use taxes based on sales prices, but not including taxes when assessed on incomes derived from such sales.

With respect to consideration received by Sublicensee, the total deductions referenced in Sub-sections (a) and (b) of this Section 1.11 shall not exceed [\*\*\*] of the Sublicensee Total Consideration for Licensed Products, Know-How Products and MHC Class II Products in any calendar quarter.

If a Sublicensee intends to accept from independent third parties any non-cash consideration as Sublicensee Net Sales or intends to provide Licensed Product, Know-How Products and/or MHC Class II Products at no charge, Licensee must first notify Licensor in writing in reasonable detail. If Licensee and Licensor can not agree on the present day value of such non-cash consideration, then Licensee and Licensor will appoint an independent third party to determine the present day value of such consideration and that value shall be added to Sublicensee Net Sales in place of the non-cash consideration. The cost of the independent third party will be paid by Licensee.

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In the event that, during a particular calendar quarter, a Licensed Product, Know-How Product or MHC Class II Product is sold in combination with one or more other products, whether or not such other products are packaged or otherwise physically combined with such Licensed Product, Know-How Product or MHC Class II Product for a single price (a "**Sublicensee Combination Product**"), Sublicensee Net Sales from sales of a Sublicensee Combination Product, Know-How Product, for purposes of calculating royalties due under this Agreement, shall be calculated by multiplying the Sublicensee Net Sales of the Sublicensee Combination Product by the fraction A/(A+B), where A is the average per unit sales price for such calendar quarter of the Licensed Product, Know-How Product or MHC Class II Product sold separately in the country of sale and B is the average per unit sales price for such calendar quarter of the other product(s) sold separately in the country of sale. In the event that no separate sales are made of the Licensed Product, Know-How Product or MHC Class II Product on the one hand, and/or the other product(s) in the country of sale on the other hand, separate sale prices in commensurate countries may be used instead. In the event that no separate sales are made of the Licensed Product, Know-How Product or the other product(s) on the other, Sublicensee Net Sales from sales of a Sublicensee Combination Product, for purposes of determining royalty payments on such Sublicensee Combination Products, shall be calculated using the entire Sublicensee Net Sales of such Sublicensee Combination Products.

- 1.12 **"Affiliate**" means any entity that, directly or indirectly, through one or more intermediates, controls, is controlled by, or is under common control with Licensee. For the purposes of this definition, control shall mean the direct or indirect ownership of at least Fifty Percent (50%) of (*i*) the stock shares entitled to vote for the election of directors or (ii) ownership interest.
- 1.13 "Sublicensee" shall mean any non Affiliate third party to whom Licensee has granted the right to make and sell (or otherwise dispose of) Licensed Products and/or Know-How Products and/or MHC Class II Products.
- 1.14 **"Confidential Information**" means any information designated as such in writing by the disclosing party, whether by letter or by the use of an appropriate proprietary stamp or legend, prior to or at the time any such confidential or proprietary materials or information are disclosed by the disclosing party to the recipient. Notwithstanding the foregoing, information or materials which are orally or visually disclosed to the recipient by the disclosing party, or are disclosed in a writing or other tangible form without an appropriate letter, proprietary stamp or legend, shall constitute Confidential Information if the disclosing party, within ten (10) days after such disclosure, delivers to the recipient a written or electronic document or documents describing such information or materials and referencing the place and date of such oral, visual, written or other tangible disclosure.

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- 1.15 **"Valid Claim**" means (i) a claim of a pending patent application included within the Agreement Patents that continues to be prosecuted in good faith for a period of not more than [\*\*\*] from the date of filing of the national application including such claim and/or (ii) a claim of an issued and unexpired patent included within the Agreement Patents which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, or which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.
- 1.16 **"Fully-Diluted, as Converted Basis**" shall mean the total number of shares of Licensee's capital stock calculated to include (1) all issued and outstanding shares of Common Stock, excluding treasury shares, (2) all shares of Common Stock issuable upon the conversion or exchange of Licensee's debt or equity securities directly or indirectly convertible into or exchangeable for Common Stock ("Convertible Securities"), (3) all shares of Common Stock issuable upon the exercise of all then outstanding rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities, whether or not then exercisable or convertible, and (4) to the extent the number of securities reserved for future issuance (the "Share Reserve") pursuant to any Licensee equity incentive plan, stock option or similar plan in effect at the time of calculation exceeds [\*\*\*] of the issued and outstanding shares of Common Stock, the amount of such excess shall be assumed issued and granted and included in such calculation.
- 1.17 **"Funding Threshold**" shall mean that Licensee has received total net proceeds of an aggregate of [\*\*\*] in cash in consideration for the sale of shares of Licensee's capital stock or Convertible Securities pursuant to bona fide financing(s) in a transaction or series of related transactions.
- 1.18 "Liquidity Event" shall mean the first to occur of either (i) a public offering registered under Section 5 of the Securities Act of 1933, as amended (the "Securities Act"), or any other transaction or series of transactions in which Licensee or an entity into which Licensee merges, or an Affiliate thereof, becomes or is a public reporting company, or the wholly-owned subsidiary of a public reporting company, pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act), or becomes a listed company on a non-U.S. exchange, or the wholly-owned subsidiary of a listed company on a non-U.S. exchange (a "Going Public Event"), or (ii) any of the following in a single transaction or series of related transactions: (a) a merger, consolidation, reorganization, transfer of Licensee securities, or similar transaction, in which the stockholders of Licensee immediately prior to such transaction possess less than a majority of the voting power of Licensee or any successor entity's issued and outstanding capital stock immediately after such transaction; or (b) a disposition to one or more persons who are not Affiliates of Licensee of all or substantially all of (y) Licensee's assets determined on a consolidated basis or (z) Licensee's business to which the License Agreement relates.

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- 1.19 **"Competing Product**" shall mean a product that (i) is sold in a country where there is a Valid Claim, but is not covered by a Valid Claim, (ii) is a molecule that couples an antigen for targeted T-cell activation or attenuation, and at least one co-stimulatory ligand for activating or attenuating a T-cell response, (iii) binds to the same molecular target(s) as a Licensed Product, and (iv) has been approved by the applicable regulatory authority and is being sold in such country by a third party for use at least one of the same indications as a Licensed Product.
- 1.20 "Sublicensee Product" shall mean a Licensed Product, Know-How Product and/or MHC Class II Product sold by a Sublicensee.

# 2. Licensor's Agreements With U.S. Government

- 2.01 Licensor, through its Investigators, has and will perform research sponsored in part by the United States Government and related to the Field. As a result of this government sponsorship of the aforementioned research, the United States Government retains certain rights in such research as set forth in 35 U.S.C. §200 et. seq. and applicable regulations.
- 2.02 The continuance of such government sponsored research by Licensor and its Investigators during the term of this Agreement will not constitute a breach of this Agreement. All rights reserved to the U.S. Government under 35 U.S.C. §200 et. seq. and applicable regulations shall remain so reserved and shall in no way be affected by this Agreement. Licensor and its Investigators are not obligated under this Agreement to take any action which would conflict in any respect with their past, current or future obligations to the U.S. Government as to work already performed and to be performed in the future.

# 3. <u>Agreement Patents</u>

3.01 Licensor confirms that on the Original Effective Date, Licensee reimbursed Licensor for all costs incurred prior to the Original Effective Date in connection with the preparation, filing, prosecution and maintenance of the Agreement Patents, which totaled [\*\*\*]. Amounts paid by Licensee pursuant to this paragraph are non-refundable and not creditable against any other payment due to Licensor.



- 3.02 Licensee and Licensor executed a joint representation engagement letter ("**Engagement Letter**") dated March 5, 2015 with Amster, Rothstein & Ebenstein LLP, copy attached as Appendix B.
- 3.03 As of and after the Original Effective Date, Licensee will pay the cost of preparing, filing, prosecuting, maintaining and resisting challenges to the validity of the Agreement Patents (as well as the cost of preparing, filing, prosecuting, maintaining and resisting challenges to the validity of corresponding applications in at least the United States, Europe (an EPO filing designating all member countries), Canada, Japan and Australia). As part of this obligation, Licensee will pay the cost of applying for an extension of the term of any patent included within Agreement Patents, if appropriate, under the Drug Price Competition and Patent Term Restoration Act of 1984 and/or European, Japanese and other foreign counterparts. Licensee will pay the cost of defending and/or prosecuting any interference, reexamination, reissue, opposition, cancellation and nullity proceedings involving Agreement Patents. In the event that Licensee elects not to pay to maintain, defend or prosecute any patent or patent applications so elected shall at the end of the notice period cease to be considered Agreement Patents, and Licensor shall then be free, at its election, to abandon or maintain the prosecution of such patent application or issued patent or grant rights to such patent application or issued patent to third parties. For purposes of this Agreement, "**Developing Countries**" shall mean low and lower middle income countries as defined by the World Bank from time to time during the term of this Agreement. Licensee agrees that any pharmaceutical product sold by Licensee and/or its Sublicensees in Developing Countries, other than India, China and Brazil, shall be sold at a price equal to its cost to manufacture, distribute and/or sell the pharmaceutical product, excluding research and development costs associated with developing the pharmaceutical product and obtaining regulatory approvals, plus [\*\*\*].
- 3.04 Amounts paid by Licensee pursuant to Sections 3.01 and 3.03 will be non-refundable and not creditable against any other payment due to Licensor.

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# 4. <u>License Grant</u>

- 4.01 Subject to Section 2, Licensor hereby grants to Licensee and Affiliates a worldwide, exclusive license, with the right by Licensee only to grant sublicenses to unaffiliated third parties, under Licensor's rights in the Agreement Patents and Know-How to import, make, have made, use, provide, offer to sell, and sell products, processes and services in the Field, namely, Licensed Products, Know-How Products and MHC Class II Products. The terms of any sublicense agreement shall not contradict the terms of this Agreement and shall include (at least) the following provisions: prohibiting any use of Licensor's name (consistent with Section 9.01), requiring indemnification of Licensor (consistent with Section 12.04), and requiring appropriate insurance (consistent with Section 12.10), and disclaiming any warranties or representations by Licensor (consistent with Sections 12.05 and 12.06). Licensee shall provide Licensor with a full, unredacted and complete copy of any executed sublicense or amendment within thirty (30) days of execution thereof by Licensee. Licensee may designate any such sublicense or amendment, in whole or in part, as Confidential Information.
- 4.02 Notwithstanding the exclusive rights granted to Licensee pursuant to Section 4.01, Licensor shall retain the right to make, use and practice, but not the right to license to third parties, Agreement Patents and Know-How in its own laboratories for research purposes. Licensor shall also retain the right to make, use, and practice the inventions described in [\*\*\*]. Further, Licensor shall have the right to make available to not-for-profit scientific institutions and non-commercial researchers materials covered under Agreement Patents and Know-How, solely for non-commercial scientific and research purposes.
- 4.03 Nothing contained in this Agreement shall be construed or interpreted as a grant, by implication or otherwise, of any license except as expressly specified in Section 4.01 hereof. The license granted herein shall apply to the Licensee and Affiliates except that Affiliates shall not have the right to grant sublicenses. If any Affiliate exercises rights under this Agreement, Licensee will promptly notify Licensor in writing, and such Affiliate shall be bound by all terms and conditions of this Agreement, including but not limited to indemnity and insurance provisions, which shall apply to the exercise of the rights, to the same extent as would apply had this Agreement been directly between Licensor and the Affiliate. In addition, Licensee shall remain fully liable to Licensor for all acts and obligations of Affiliates such that acts of Affiliates shall be considered the acts of Licensee.

# 5. <u>Confidentiality</u>

5.01 Nothing herein contained shall preclude Licensor from making required reports or disclosures to the NIH or to any other philanthropic or governmental funding organization, provided, however, that no Confidential Information of Licensee is disclosed in the process.

- 5.02 Licensee will retain in confidence Confidential Information of Licensor and Licensee will not disclose any such Confidential Information to any third party without the prior written consent of Licensor, except that Licensee shall have the right to disclose such information to any third party for commercial or research and development purposes under written terms of confidentiality and non-disclosure which are commercially reasonable. These obligations of confidentiality are for a period ending five (5) years after termination or expiration of this Agreement, provided, however, that such obligations shall not apply to any such information which:
  - (a) was known to Licensee or generally known to the public prior to its disclosure hereunder as evidenced by written record; or
  - (b) subsequently becomes known to the public by some means other than a breach of this Agreement; or
  - (c) is subsequently disclosed to Licensee by a third party having a lawful right to make such disclosure; or
  - (d) is required to be disclosed by regulation, law or court order to the most limited extent necessary to comply therewith, provided Licensor is given a fair opportunity to defend against such disclosure, and if disclosure is required, only discloses that portion of the Confidential Information as is required; or
  - (e) is independently developed by Licensee as evidenced by Licensee's written records without reference to Licensor's Confidential Information.
- 5.03 Licensor will retain in confidence Confidential Information of Licensee and Licensor will not disclose any such Licensee Confidential Information to any third party without the prior written consent of Licensee for a period ending five (5) years after termination or expiration of this Agreement, provided however, that such obligations shall not apply to any such information which:
  - (a) was known to Licensor or generally known to the public prior to its disclosure hereunder as evidenced by written record; or
  - (b) subsequently becomes known to the public by some means other than a breach of this Agreement; or
  - (c) is subsequently disclosed to Licensor by a third party having a lawful right to make such disclosure; or

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- (d) is required to be disclosed by regulation, law or court order to the most limited extent necessary to comply therewith, provided Licensee is given a fair opportunity to defend against such disclosure, and if disclosure is required, only discloses that portion of the Confidential Information as is required; or
- (e) is independently developed by Licensor as evidenced by Licensors written records without reference to Licensee's Confidential Information.

# 6. <u>Royalties and Payments</u>

- 6.01 Licensee shall make the following payments to Licensor:
  - (a) Licensee will pay to Licensor:
    - (i) [\*\*\*] of Net Sales on Licensed Products, provided, however, that this rate shall be reduced by [\*\*\*] on a country-by-country basis, if a Competing Product exists in such country.
    - (ii) [\*\*\*] of Net Sales on MHC Class II Products, provided, however, that this rate shall be reduced to [\*\*\*] on a country-by-country basis, if a Competing Product exists in such country.
    - (iii) [\*\*\*] of Net Sales on Know-How Products.
  - (b) Licensee will pay to Licensor a percentage of Net Proceeds as follows:
    - (i) [\*\*\*] of Net Proceeds derived from agreements entered into before an Investigational New Drug application (IND) or foreign equivalent is filed;
    - (ii) [\*\*\*] of Net Proceeds derived from agreements entered into after an IND or foreign equivalent is filed but prior to the initiation of a Phase II clinical trial or it foreign equivalent; and
    - (iii) [\*\*\*] of Net Proceeds derived from agreements entered into after initiation of a Phase II clinical trial or its foreign equivalent.
  - (c) Licensee will pay to Licensor a percentage of Sublicensee Net Sales as follows:
    - (i) The greater of [\*\*\*] of the royalty received by Licensee from a Sublicensee based on the sale of a Sublicensee Product or [\*\*\*] of Sublicensee Net Sales for such Sublicensee Product, derived from agreements entered into before an IND is filed;

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- (ii) The greater of [\*\*\*] of the royalty received by Licensee from a Sublicensee based on the sale of a Sublicensee Product or [\*\*\*] of Sublicensee Net Sales for such Sublicensee Product, derived from agreements entered into after an IND but prior to Phase II; and
- (iii) The greater of [\*\*\*] of the royalty received by Licensee from a Sublicensee based on the sale of a Sublicensee Product or [\*\*\*] of Sublicensee Net Sales for such Sublicensee Product, derived from agreements entered into after initiation of a Phase II clinical trial.
- 6.02 Licensee has made or shall make the following license signing and license maintenance payments to Licensor:
  - (a) Licensee has paid Licensor a total of [\*\*\*] as a license signing fee which payment is non-refundable and not creditable against any other payment due to Licensor pursuant to this Agreement.
  - (b) On the second anniversary of the Original Effective Date, Licensee paid to Licensor Twenty-Five Thousand Dollars (US\$25,000) as a license maintenance fee. This fee is non-refundable but is creditable against actual payments due to Licensor pursuant to Section 6.01 during the twelve (12) month period following this anniversary.
  - (c) On the third and fourth anniversaries of the Original Effective Date, Licensee will pay to Licensor Fifty Thousand Dollars (US\$50,000) as a license maintenance fee. Each such fee is non-refundable but is creditable against actual payments due to Licensor pursuant to Section 6.01 during the twelve (12) month period following each such anniversary.
  - (d) On the fifth and sixth anniversary of the Original Effective Date, Licensee will pay to Licensor Seventy-Five Thousand Dollars (US\$75,000) as a license maintenance fee. Each such fee is non-refundable but is creditable against actual payments due to Licensor pursuant to Section 6.01 during the twelve (12) month period following each such anniversary.
  - (e) On the seventh anniversary of the Original Effective Date and every anniversary of the Original Effective Date thereafter, Licensee will pay to Licensor One Hundred Thousand Dollars (US\$100,000) as a license maintenance fee. Each such fee is non-refundable but is creditable against actual payments due to Licensor pursuant to Section 6.01 during the twelve (12) month period following each such anniversary.

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- 6.03 Licensee shall make the following milestone payments to Licensor for Licensed Products:
  - (a) Upon approval of the first Investigational New Drug (IND) application (or its foreign equivalent) by, on behalf of or for the benefit of Licensee or an Affiliate, for a Licensed Product anywhere in the world, Licensee shall pay to Licensor a fee of [\*\*\*];
  - (b) Upon approval of the first Investigational New Drug (IND) application (or its foreign equivalent) by, on behalf of or for the benefit of Licensee or an Affiliate, for a new indication for a Licensed Product anywhere in the world, Licensee shall pay to Licensor a fee of [\*\*\*];
  - (c) Upon the initiation by, on behalf of or for the benefit of Licensee or an Affiliate, of the first Phase II clinical trial (or its foreign equivalent) for a Licensed Product anywhere in the world, Licensee shall pay to Licensor a fee of [\*\*\*];
  - (d) Upon the initiation by, on behalf of or for the benefit of Licensee or an Affiliate, of the first Phase II clinical trial (or its foreign equivalent) for a new indication for a Licensed Product anywhere in the world, Licensee shall pay to Licensor a fee of [\*\*\*];
  - (e) Upon the initiation by, on behalf of or for the benefit of Licensee or an Affiliate, of the first Phase Ill clinical trial (or its foreign equivalent) for a Licensed Product anywhere in the world, Licensee shall pay to Licensor a fee of [\*\*\*]; and
  - (f) Upon the initiation by, on behalf of or for the benefit of Licensee or an Affiliate, of the first Phase III clinical trial (or its foreign equivalent) for a new indication for a Licensed Product anywhere in the world, Licensee shall pay to Licensor a fee of [\*\*\*];
  - (g) Upon first commercial sale by, on behalf of or for the benefit of Licensee or an Affiliate of a Licensed Product anywhere in the world, Licensee shall pay to Licensor [\*\*\*].
  - (h) Upon first commercial sale by, on behalf of or for the benefit of Licensee or an Affiliate of a Licensed Product having a new indication anywhere in the world, Licensee shall pay to Licensor [\*\*\*].

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- (i) When the cumulative sales of Licensed Products from a sublicensing agreement reach [\*\*\*], Licensee shall pay to Licensor Five Million Dollars (US\$5,000,000).
- (j) Licensee shall pay to Licensor a one-time success-based milestone of (i) [\*\*\*] when the cumulative sales of Licensed Products and/or MHC Class II Products developed in whole or in part with Contract Research received prior to the [\*\*\*] of the Restated Agreement Effective Date, reach [\*\*\*] ("the LP/MHC Milestone") or (ii) [\*\*\*] when the cumulative sales of Know-How Products developed in whole or in part with Contract Research received prior to the [\*\*\*] of the Restated Agreement Effective Date, reach [\*\*\*] ("the KH Milestone"), whichever occurs first. If Licensee pays the KH Milestone first, and then the LP/MHC Milestone is achieved thereafter, then Licensee shall pay Licensor an additional [\*\*\*].

Payments made pursuant to Sections (a) through (j) are non-refundable and not creditable against any other payment due to Licensor.

- 6.04 Only one royalty will be payable on Net Sales by Licensee and Affiliates on a Licensed Product or MHC Class II Product under Section 6.01, regardless of the number of Valid Claims in Agreement Patents which cover such Licensed Product or MHC Class II Product. If Licensee or any Affiliate is required, because of the patent rights of any third party or parties, to pay royalties to a third party or parties in order to make, use or sell a specific Licensed Product or MHC Class II Product, then Licensee may deduct [\*\*\*] of all such royalties paid to such third party or parties from up to [\*\*\*] of the royalty due to Licensor on such specific Licensed Product or MHC Class II Product pursuant to Section 6.01. In no event will the royalty payable to Licensor on any Licensed Product or MHC Class II Product be reduced below [\*\*\*] pursuant to this Section 6.04 and/or Section 6.01. The royalty stacking provision of this Section 6.04 does not apply to Know-How Products.
- 6.05 Immediately prior to the consummation of a Liquidity Event, Licensee shall issue to Licensor shares of Licensee's Common Stock (the "Shares") such that, following the issuance of the Shares, Licensor will own:
  - (a) if the Liquidity Event is consummated before achievement of the Funding Threshold, a number of shares of Licensee's Common Stock equal to [\*\*\*] of Licensee's capital stock following such issuance calculated on a Fully Diluted, as Converted Basis, and
  - (b) if the Liquidity Event is consummated after achievement of the Funding Threshold, a number of shares of Licensee's Common Stock equal to [\*\*\*] of Licensee's capital stock following such issuance calculated on a Fully Diluted, as Converted Basis as of the date and time such Funding Threshold was met (subject to adjustment for any stock dividends, stock splits, reverse splits or similar recapitalizations occurring thereafter).

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If the Liquidity Event is a Going Public Event, Licensee will use its best efforts to (i) file a registration statement covering the resale of the Shares as soon as practicable but no later than one hundred eighty (180) calendar days from the date of the Liquidity Event and (ii) cause such registration statement to be declared effective within 120 calendar days from the date of issuance.

6.06 Licensor hereby agrees that, (a) to the extent requested by Licensee and any managing underwriter retained by Licensee, Licensor will not directly or indirectly sell, offer to sell, contract to sell (including without limitation, any short sale), grant any option to purchase, pledge or otherwise transfer or dispose of (other than to donees who agree to be similarly bound), during the period of duration (not to exceed twelve (12) months) specified by Licensee and Licensee's managing underwriter following the effective date of the registration statement of Licensee filed under the Securities Act with respect to Licensee's initial public offering, any securities of Licensee held by Licensor at any time during such period except Common Stock included in such registration and (b) if requested by such underwriter, Licensor agrees to execute a lock-up agreement in such form as the managing underwriter may reasonably propose; provided that, in each case Licensor's obligations under this subsection are conditioned upon all of Licensee's other founders being subject to identical obligations. Furthermore, in the event that the Shares are registered under Section 5 of the Securities Act, or become eligible for sale without registration under SEC Rule 144, Licensee's managing underwriter agrees otherwise. Notwithstanding the foregoing, the registration rights provided for in this Section 6.05 shall terminate on the date that the Shares may be sold without registration under SEC Rule 144.Licensee's failure to pay full royalties or make complete payments under Sections 6.01, 6.02 or 6.03 or to comply with its obligations under Section 6.05 shall be a breach of this Agreement if not cured within forty-five (45) days of Licensee's receipt of written notice of such failure.

### 7. <u>Payment Reports and Records</u>

7.01 All payments required to be made by Licensee to Licensor pursuant to this Agreement shall be made to Licensor in U.S. Dollars by wire transfer or by check payable to Licensor and sent to Licensor's address set out in Section 13.01.



- 7.02 All payments required to be made by Licensee to Licensor pursuant to this Agreement shall be subject to a charge of One and One-Half Percent (1.5%) per month or Two Hundred and Fifty Dollars (US\$250), whichever is greater, if more than 30 days late. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate quoted by the Wall Street Journal, averaged on the last business day of each of the three (3) consecutive calendar months constituting the calendar quarter in which the payment was earned. Licensee will bear any loss of exchange or value and pay any expenses incurred in the transfer or conversion to U.S. dollars.
- 7.03 Payments due from Licensee to Licensor pursuant to Section 6.01 will be paid within thirty (30) days after the end of each calendar year quarter during which the payment accrued. If no payments pursuant to Section 6.01 are due for any quarter, Licensee shall send to Licensor a statement to that effect signed by an officer of Licensee. Payment shall be accompanied by a statement of the number of Licensed Products, Know-How Products, MHC Class II Products and Combination Products sold by Licensee, Affiliates and Sublicensees in each country, total billings for such Licensed Products, Know-How Products, deductions applicable to determine the Net Sales and Sublicensee Net Sales of Combination Products, deductions applicable to determine the Net Sales and Sublicensee Net Sales realized by Licensee and Affiliates and Sublicensees, the amount of Net Proceeds realized by Licensee, the amount of any deduction and a detailed listing thereof, and the total payment due from Licensee to Licensor (the "**Royalty Report**"). Such Royalty Report shall be signed by an officer of Licensee.
- 7.04 Licensee and Affiliates shall maintain complete and accurate books of account and records showing Net Sales, Sublicensee Net Sales and Net Proceeds. Such books and records of Licensee and Affiliates shall be open to inspection, in confidence, during usual business hours, upon at least ten (10) business days prior notice to Licensee, by an independent certified public accountant appointed by Licensor on behalf of Licensor, who has entered into a written agreement of confidentiality with Licensor which is no less protective of Licensee's Confidential Information than the provisions of Section 5.03 hereof and to whom Licensee has no reasonable objection, for five (5) years after the calendar year to which they pertain, for the purpose of verifying the accuracy of the payments made to Licensor by Licensee pursuant to this Agreement. Licensee will use commercially reasonable efforts to require any Sublicensees hereunder to maintain such books and allow such inspection by licensee and shall, on request, disclose such information, if available to Licensee's payment obligations under this Agreement and shall take place not more than once per calendar year. Any underpayment revealed by any inspection, plus interest on the underpayment amount at the rate of One and One-Half Percent (1.5%) per month or Two Hundred Fifty Dollars (US\$250), whichever is greater, shall be promptly paid by Licensee to Licensor. Further, if any inspection reveals an underpayment to Licensor of Ten Percent (10%) or greater, then the cost of the inspection shall be paid by Licensee.

### 8. <u>Infringement</u>

- 8.01 Licensee shall have the right, in its sole discretion and its expense, to initiate legal proceedings on its behalf or in Licenser's name, if necessary, against any infringer, or potential infringer, of an Agreement Patent who imports, makes, uses, sells or offers to sell products in the Field. Licensee shall notify Licensor of its intention to initiate such proceedings at least thirty (30) days prior to commencement thereof. Any settlement or recovery received from any such proceeding shall be divided [\*\*\*] to Licensee and [\*\*\*] to Licensor after Licensee deducts from any such settlement or recovery its actual counsel fees and out-of-pocket expenses relating to any such legal proceeding. If Licensor shall have the right to initiate such legal proceedings. Any settlement or recovery received from any such proceeding initiated by Licensor shall be divided [\*\*\*] to Licensor and [\*\*\*] to Licensee after Licensor deducts from any such settlement or recovery its actual counsel fees and out-of-pocket from any such proceeding initiated by Licensor shall be divided [\*\*\*] to Licensor and [\*\*\*] to Licensee after Licensor deducts from any such settlement or recovery its actual counsel fees and out-of-pocket expenses relating to any such proceeding initiated by Licensor shall be divided [\*\*\*] to Licensor and [\*\*\*] to Licensee after Licensor deducts from any such settlement or recovery its actual counsel fees and out-of-pocket expenses relating to any such legal proceeding.
- 8.02 In the event that either party initiates or carries on legal proceedings to enforce any Agreement Patent against an alleged infringer, the other party shall fully cooperate with and supply all assistance reasonably requested at the expense of the party requesting such assistance. Further, the other party, at its expense, shall have the right to be represented by counsel of its choice in any such proceeding, However, if Licensor initiates legal proceedings in Licensor's name, Licensee shall reimburse Licensor for any reasonable out of pocket counsel fees of Licensor associated with the legal proceedings. The party who initiates or carries on the legal proceedings shall have the sole right to conduct such proceedings provided, however, that such party shall consult with the other party to this Agreement prior to entering into any settlement thereof.

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### 9. <u>Prohibition on Use of Names: No Publicity</u>

9.01 Neither party to this Agreement shall use the name of the other party without the other party's prior written consent, except if the use of such name is required by law, regulation, federal securities law, or judicial order, in which event the party intending to make such announcement will promptly inform the other party, prior to any such required use. Neither party to this Agreement will make any public announcement regarding the existence of this Agreement and/or the collaboration hereunder without obtaining the prior written consent of the other party, except if such announcement is required by law, regulation, federal securities law or judicial order, in which event the party intending to make such announcement will promptly inform the other party prior to any such required announcement.

### 10. <u>Term and Termination</u>

- 10.01 Unless terminated earlier under other provisions hereof, this Agreement will expire upon the expiration of Licensee's last obligation to pay royalties on Net Sales and/or Net Proceeds and/or Sublicensee Net Sales to Licensor pursuant to Section 6.01. Royalties on Net Sales for Know-How Products shall be due for the longer of fifteen (15) years from first sale of such product in each country or for the duration of any market exclusivity period granted by a regulatory agency for such product. Royalties on Sublicensee Net Sales for Know-How Products shall be due for the longer of ten (10) years from first sale of such product in each country or for so long as the Sublicensee agrees to pay such royalties. Upon termination or expiration of this Agreement for any reason, Section 1, 5, 6.05, 7, 8, 9, 10.07 through 10.09, 11, 12.01 through 12.10, 12.13, 12.16 and 13 shall survive and all payment obligations under Sections 3 and 6.01-6.04 hereof accrued as of the termination date shall be paid by Licensee within thirty (30) days of such termination or expiration.
- 10.02 Licensee may terminate this Agreement and the licenses granted hereunder by giving notice to Licensor sixty (60) days prior to such termination. Upon such termination, Licensee shall not use Agreement Patents or Know-How for any purpose and all of Licensee's rights in Agreement Patents and Know-How shall be terminated.



10.03 If either Licensor or Licensee defaults on or breaches any condition of this Agreement, the aggrieved party may serve notice upon the other party of the alleged default or breach, which notice shall state with particularity the alleged breach. If such default or breach is not remedied within sixty (60) days from the date of such notice and the alleged breaching party has not requested the alternative dispute resolution procedure set forth below, then the aggrieved party may at its election terminate this Agreement by providing fifteen (15) days written notice. Any failure to terminate hereunder shall not be construed as a waiver by the aggrieved party of its right to terminate for future defaults or breaches. Licensee's damages for any breach of this Agreement by Licensor will be limited to the amount paid by Licensee to Licensor under this Agreement and a reduction or suspension of the payment obligations of Licensee hereunder Upon termination of this Agreement by Licensor pursuant to this Section 10.03, the licensee spanted by Licensor to Licensee shall terminate and Licensee shall not use Agreement Patents or Know-How for any purpose and all of Licensee's rights in Agreement Patents and Know-How shall be terminated.

In the event that, within thirty (30) days from the date of a notice of breach, the alleged breaching party (1) disputes in good faith the alleged breach, (ii) provides a detailed explanation of why it believes the alleged breach has not occurred, and (iii) requests alternative dispute resolution, then the party representatives, e.g., CEO of Cue and Director, Office of Biotechnology, with authority to settle the dispute shall meet within thirty (30) days at a mutually agreeable time and place and attempt in good faith to amicably resolve the dispute. If the parties fail to resolve the dispute through such meeting, then the aggrieved party may at its election terminate this Agreement by providing fifteen (15) days written notice.

- 10.04 This Agreement sets forth a license to intellectual property rights. To the extent permitted by applicable law (including, but not limited to, 11 U.S.C. Section 365) either party may terminate this Agreement immediately by written notice to the other upon (i) the institution by such party of insolvency, receivership or bankruptcy proceedings or any other act of bankruptcy or proceedings for the settlement of its debts; (ii) the institution of such proceedings against such party, which is not dismissed or otherwise resolved in its favor within ninety (90) days thereafter; or (iii) such party making a general assignment for the benefit of creditors.
- 10.05 If Licensee is convicted of a felony under the Federal Food, Drug and Cosmetic Act, as amended from time to time, relating to the manufacture, use or sale of Licensed Products, Know-How Products and/or MHC Class II Products or a felony involving moral turpitude relating to the manufacture, use or sale of Licensed Products, Know-How Products and/or MHC Class II Products, Licensor may, at its election, terminate this Agreement by notice to Licensee. Upon termination of this Agreement by Licensor pursuant to this Section 10.05, the licenses granted by Licensor to Licensee shall terminate and Licensee shall not use Agreement Patents or Know-How for any purpose and all of Licensee's rights in Agreement Patents shall be terminated, provided that Licensee shall have the right to sell off existing inventory of Licensed Products, Know-How Products and MHC Class II Products for up to sixty (60) days following such termination.

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- 10.06 Notwithstanding the provisions of Section 10.03 hereof, should Licensee fail to pay Licensor any sum due and payable under this Agreement on thirty (30) days written notice, Licensor may, at its election, terminate this Agreement, unless Licensee pays Licensor within forty-five (45) days of notice of non-payment all delinquent sums together with interest due and unpaid. Upon termination of this Agreement by Licensor pursuant to this Section 10.06, the licenses granted by Licensor to Licensee shall terminate and Licensee shall not use Agreement Patents or Know-How for any purpose and all of Licensee's rights in Agreement Patents and Know-How shall be terminated.
- 10.07 Termination of this Agreement by Licensee or Licensor shall not prejudice the rights of either party accruing herein. Notwithstanding any provision herein to the contrary, no termination of this Agreement shall be construed as a termination of any valid sublicense of any Sublicensee hereunder, and thereafter each such Sublicensee shall be considered a direct licensee of Licensor, provided that (i) such Sublicensee is not in material breach of its sublicense agreement with Licensee, and (ii) such Sublicensee agrees in writing to assume all applicable obligations of Licensee under this Agreement.



- 10.08 If Licensee terminates this Agreement pursuant to Section 10.02, or if Licensor terminates this Agreement pursuant to Sections 10.03, 10.04, 10.05 or 10.06 of this Agreement, and if no sublicenses granted pursuant to Section 4.01 are in effect at the time of such termination, then Licensee shall, upon such termination, grant a royalty-free, non-exclusive license to Licensor in and to any Dependent Patents and Dependent Know-How (as defined below) developed by or for Licensee or Affiliates during the term of this Agreement for no additional consideration, and shall, within thirty (30) days of termination, provide copies of all documents and other materials embodying Dependent Know-How to Licensor. As used in this Section 10.08, the term "Dependent Patents" means any U.S. or foreign patent application or patent which claims an invention the practice of which would infringe a claim of a patent or patent application of the Agreement Patents or the practice of which results in a product covered by a claim of a patent or patent application of Agreement Patents. "Dependent Know-How" means confidential information, including clinical trial information, the practical application of which would infringe a claim of a patent or patent application of Agreement Patents, or which results in a product covered by a claim of a patent or patent application of Agreement Patents. Licensee agrees to take all actions and execute any and all documents reasonably requested by Licensor to effectuate the terms of this Section 10.08. During the time period between notice of termination and the effective date of termination, Licensee will take whatever actions are necessary to prevent any Dependent Patent from becoming abandoned or canceled. If Licensee terminates this Agreement pursuant to Section 10.02, or if Licensor terminates this Agreement pursuant to Sections 10.03, 10.04, 10.05 or 10.06 of this Agreement, and if no sublicenses granted pursuant to Section 4.01 are in effect at the time of such termination, then Licensee shall also grant Licensor (and/or Licensor's designee) a right of reference with respect to any investigation performed by or on behalf of Licensee in connection with the Agreement - i.e., the authority to rely upon and otherwise use said investigation for the purpose of obtaining FDA approval of an application for marketing clearance and/or approval, including without limitation, the ability to make available the underlying raw data from the investigation for FDA audit, if necessary. In the event that one or more sublicenses granted pursuant to Section 4,01 are in effect at the time of such termination, then Licensor shall receive no rights in and to any such Dependent Patents and Dependent Know-How, right of reference, or any other property of Licensee for as long as any direct license(s) between Licensor and such sublicensee(s) provided in Section 10.07 remain in effect. If Licensee terminates this Agreement pursuant to Section 10.02, or if Licensor terminates this Agreement pursuant to Sections 10.03, 10.04, 10.05 or 10.06 of this Agreement, and sublicenses granted pursuant to Section 4.01 are in effect at the time of such termination, then the provisions of this paragraph shall be stayed for the duration of the sublicenses, provided however, that such sublicenses have licenses under Dependent Patents and Dependent Know-How from Licensee.
- 10.09 If Licensee terminates this Agreement pursuant to Section 10.02 or 10.03, or if Licensor terminates this Agreement pursuant to Sections 10.03, 10.04, 10.05 or 10.06 of this Agreement, Licensee shall submit a final Royalty Report to Licensor and any payments and patent costs due to Licensor hereunder as of the date of termination shall be payable within thirty (30) days of the date of termination. In addition, within ten (10) days of notice of such termination, Licensee shall provide Licensor with a report showing the status of all Dependent Patents, including, without limitation, a list of all countries where Dependent Patents have been filed and a list of all actions which must be taken with respect to the Dependent Patents and relevant due dates.

### 11. <u>Amendment and Assignment</u>

- 11.01 This Agreement sets forth the entire understanding between the parties pertaining to the subject matter hereof and supersedes and replaces all prior agreements between the parties, including, without limitation, the Original License.
- 11.02 Except as otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified, except by an instrument in writing signed by all parties.
- 11.03 Without the prior written approval of the other party, which approval shall not be unreasonably withheld, no party may assign this Agreement except that this Agreement may be assigned to an entity acquiring substantially all of such party's business to which this Agreement relates, or in the event of a merger, consolidation, change in control or similar transaction of such party. Any attempted assignment in contravention of this Section 11.03 shall be null and void.

### 12. <u>Miscellaneous Provisions</u>

- 12.01 This Agreement shall be construed and the rights of the parties governed in accordance with the laws of the State of New York, excluding its law of conflict of laws. Any dispute or issue arising hereunder, including any alleged breach by any party, shall be heard, determined and resolved by an action commenced first in federal courts in New York, New York, which the parties hereby agree shall have proper jurisdiction and venue over the issues and the parties or in the state courts in New York, New York, only if the federal courts do not have subject matter jurisdiction. Licensor and Licensee hereby agree to submit to the jurisdiction of the state or federal courts in New York and waive the right to make any objection based on jurisdiction or venue. The New York courts shall have the right to grant all relief to which Licensor and Licensee are or shall be entitled hereunder, including all equitable relief as the Court may deem appropriate.
- 12.02 This Agreement has been prepared jointly.
- 12.03 If any term or provision of this Agreement or the application thereof to any person or circumstance shall to any extent be invalid or unenforceable, the remainder of this Agreement or the application of such term or provision to persons or circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby and each term and provision of this Agreement shall be valid and enforced to the fullest extent permitted by law.

- 12.04 Licensee agrees to indemnify Licensor and its current or former directors, governing board members, trustees, officers, faculty, medical and professional staff, employees, students and agents and their respective successors, heirs and assigns (Licensor and each such person being the "**Indemnified Parties**") for the cost of defense and for damages awarded and losses and liabilities incurred, if any, as a result of any third party claims, liabilities, suits or judgments based on or arising out of the research, development, marketing, manufacture, sale and/or provision of Licensed Products, Know-How Products and/or MHC Class II Products by Licensee, Affiliates and Sublicensees, and/or the licenses granted under this Agreement, or otherwise related to the conduct of Licensee's, Affiliates' or Sublicensees' business, so long as such claims, liabilities, suits, or judgments are not solely attributable to grossly negligent or intentionally wrongful acts or omissions by the Indemnified Parties. This indemnity is conditioned upon Licensor's obligation to: (i) advise Licensee of any claim or lawsuit, in writing promptly after Licensor or the Indemnified Party has received notice of said claim or lawsuit, (ii) assist Licensee and its representatives, at Licensee's expense, in the investigation and defense of any lawsuit and/or claim for which indemnification is provided, and (iii) permit Licensee to control the defense of such claim or lawsuit for which indemnification is provided.
- 12.05 Nothing in this Agreement is or shall be construed as:
  - (a) A warranty or representation by Licensor that anything made or used by Licensee under any license granted in this Agreement is or will be free from infringement of patents, copyrights, and other rights of third parties; or
  - (b) Granting by implication, estoppel, or otherwise any license, right or interest other than as expressly set forth herein.
- 12.06 Except as expressly set forth in this Agreement, the parties MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTE OR OTHERWISE, AND THE PARTIES SPECIFICALLY DISCLAIM ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT. IN ADDITION, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

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- 12.07 Licensor and Licensee represent and warrant that, to the best of their knowledge, as of the Original Effective Date:
  - (a) they have the legal right and authority to enter into this Agreement and to perform all of their obligations hereunder;
  - (b) when executed by all parties, this Agreement will constitute a valid and legally binding obligation and shall be enforceable in accordance with its terms; and
  - (c) there are no existing or threatened actions, suits or claims pending or threatened against it that may affect the performance of its obligations under the Agreement.
- 12.08 Licensor represents and warrants that:
  - (a) Licensor owns all right, title and interest in, to and under the Agreement Patents by virtue of assignment from the Investigators;
  - (b) Licensor has the legal power and authority to extend the rights granted to Licensee in this Agreement;
  - (c) Subject to the rights, if any, of the U.S. government, Licensor has not conveyed or transferred any intellectual property rights under the Agreement Patents to any person other than Licensee.
  - (d) to the best of Licensor's knowledge, as of the Original Effective Date, subject to any rights of the government as discussed in Section 2.01, the Agreement Patents are free and clear of all liens and encumbrances; and
  - (e) other than U.S. Patent Application No. 13/085,081, as of the Original Effective Date, Licensor's Investigator, Steven C. Almo is not listed as an inventor on any patents or patent applications or "invention disclosures" by Mr. Almo made to Licensor relevant to the subject matter disclosed and claimed in the Agreement Patents.
- 12.09 Licensee represents and warrants that it has not relied on any information provided by Licensor, Licensor's current or former employees or the Investigators and has conducted its own due diligence investigation to its satisfaction prior to entering into this Agreement.

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- 12.10 Licensee represents and warrants that before Licensee, or an Affiliate or a Sublicensee makes any sales of Licensed Products, Know-How Products and/or MHC Class II Products or performs or causes any third party to perform any clinical trials or tests in human subjects involving Licensed Products, Know-How Products and/or MHC Class II Products, Licensee or Affiliates or Sublicensees will acquire and maintain in each country in which Licensee or Affiliates or Sublicensees shall test or sell Licensed Products, Know-How Products and/or MHC Class II Products, appropriate insurance coverage reasonably acceptable to Licensor, but providing coverage in respect of Licensed Products, Know-How Products and MHC Class II Products in an amount no less than [\*\*\*] per claim and [\*\*\*] in the aggregate for all claims. Licensee or Affiliates will not perform, or cause any third party to perform, any clinical trials or any tests in human subjects involving Licensed Products, Know-How Products and/or MHC Class II Products unless and until it obtains all required regulatory approvals with respect to Licensed Products, Know-How Products and/or MHC Class II Products in the applicable countries. Prior to instituting any clinical trials or any tests in human subjects, or sale of any Licensed Product, Know-How Product and/or WIC Class II Product, Licensee shall provide evidence of such insurance to Licensor. If Licensor determines that such insurance is not reasonably appropriate, it shall so advise Licensee and Licensee shall delay such trials, tests or sales until the parties mutually agree that reasonably appropriate coverage is in place. Licensor shall be listed as an additional insured in Licensee's insurance policies. If such insurance is underwritten on a 'claims made' basis, Licensee agrees that any change in underwriters during the term of this Agreement will require the purchase of 'prior acts' coverage to ensure that coverage will be continuous throughout the term of this Agreement.
  - (a) The minimum amounts of insurance coverage required under this Section shall not be construed to create a limit of Licensee's liability with respect to its indemnification under Section 12.04 of this Agreement.
  - (b) Licensee shall provide Licensor with written evidence of such insurance upon request of Licensor. Licensee shall provide Licensor with written notice at least sixty (60) days prior to the cancellation, non-renewal or material change in such insurance; if Licensee does not obtain replacement insurance providing comparable coverage within such sixty (60) day period, Licensor shall have the right to terminate this Agreement effective at the end of such sixty (60) day period without notice or any additional waiting periods.
  - (c) Licensee shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (I) the period that any product, process or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold or tested in clinical trials by Licensee or by a Sublicensee, Affiliate, optionee or agent of Licensee and (ii) a reasonable period after the period referred to in (i) above which in no event shall be less than fifteen (15) years.

- 12.11 Licensee shall exercise its rights and perform its obligations hereunder in compliance with all applicable laws and regulations. In particular, it is understood and acknowledged that the transfer of certain commodities and technical data is subject to United States laws and regulations controlling the export of such commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. These laws and regulations, among other things, prohibit or require a license for the export of certain types of technical data to certain specified countries. Licensee hereby agrees and gives written assurance that it will comply with all United States laws and regulations controlling the export of commodities and technical data, that it will be solely responsible for any violation of such by Licensee or Affiliates or Sublicensees, and that it will defend and hold Licensor harmless in the event of any legal action of any nature occasioned by such violation.
- 12.12 Licensee agrees (i) to obtain all regulatory approvals required for the manufacture and sale of Licensed Products, Know-How Products and MHC Class II Products prior to marketing or selling any such Licensed Products, Know-How Products and/or MHC Class II Products and (ii) to utilize legally appropriate patent marking on such Licensed Products. Licensee agrees to register or record this Agreement as is required by law or regulation in any country where the license is in effect.
- 12.13 Licensee agrees that any Licensed Products for use or sale in the United States will be manufactured substantially in the United States.
- 12.14 Any tax required to be withheld under the laws of any jurisdiction on royalties payable to Licensor by Licensee under this Agreement will be promptly paid by Licensee for and on behalf of Licensor to the appropriate governmental authority, and Licensee will furnish Licensor with proof of payment of the tax together with official or other appropriate evidence issued by the competent governmental authority sufficient to enable Licensor to support a claim for tax credit with respect to any sum so withheld. Any tax required to be withheld on payments by Licensee to Licensor will be an expense of and be borne solely by Licensor, and Licensee's royalty payment(s) to Licensor following the withholding of the tax will be decreased by the amount of such tax withholding. Licensee will cooperate with Licensor in the event Licensor elects to assert, at its own expense, exemption from any tax.

- 12.15 Licensee, by itself or through an Affiliate or Sublicensee, will meet all of the following due diligence requirements:
  - Provide a research and development plan within forty-five (45) days of signing and update the research and development plan annually.
     Each update shall include not only a research and development plan for the upcoming twelve (12) months, but also, a summary of the activity for the past twelve months, including (i) all research and development; (ii) all fundraising efforts and the results of those efforts; and (iii) all diligence requirements and milestones achieved; and;
  - (b) Submit an investigational new drug application to the FDA for a Licensed Product within [\*\*\*] of the Original Effective Date; and
  - (c) Initiate an FDA approved Phase I clinical trial for a Licensed Product within [\*\*\*] of the Original Effective Date; and
  - (d) Initiate an FDA approved Phase II clinical trial for a Licensed Product within [\*\*\*] of the Original Effective Date; and
  - (e) Initiate an FDA approved Phase Ill clinical trial for a Licensed Product within [\*\*\*] of the Original Effective Date.
  - (f) Submit an application for FDA approval to market and sell a Licensed Product within [\*\*\*] of the Original Effective Date;
  - (g) Have a first commercial sale of a Licensed Product within [\*\*\*] of the Original Effective Date.
  - (h) Spend a minimum of Two Hundred and Fifty Thousand Dollars (US\$250,000) per year on product development until the first commercial sale of the first Licensed Product.
- 12.16 Licensee shall have raised the following aggregate amounts in cash from the sale of its capital stock and Convertible Securities on or before the dates set forth below.
  - (a) [\*\*\*] by the first anniversary of the Original Effective Date;
  - (b) [\*\*\*] by the third anniversary of the Original Effective Date; and
  - (c) [\*\*\*] by the fifth anniversary of the Original Effective Date.

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- 12.17 If any one of the due diligence requirements in Section 12.15 and/or 12.16 is not met, Licensor shall have the right to terminate pursuant to Section 10.03 and all rights will revert to Licensor, after providing Licensee with written notice of failure to meet such requirements and thirty (30) days from the date of such written notice to cure such failure. Notwithstanding the foregoing, in the event that Licensee provides Licensor with prior written notice that Licensee, despite its best efforts, is unable to fulfill the due diligence requirement for Section 12.16(d), (e), (f), (g) and/or (h), the deadline for fulfilling such requirement shall be extended by [\*\*\*]. No further extensions shall be granted for such diligence requirement without Einstein's prior written consent. In the event Licensee is unable to fulfill a due diligence requirement for Section 12.16(d), (e), (f), (g) or (h) after an extension has been granted, Licensor shall have the right to terminate pursuant to Section 10.03 and all rights will revert to Licensor, after providing Licensee with written notice of failure to meet such requirements and thirty (30) days from the date of such written notice to cure such failure.
- 12.18 In the event Licensee (or any entity acting under Licensee's control or on its behalf) initiates any proceeding or otherwise asserts any claim challenging the validity or enforceability of a claim of an Agreement Patent in any court, administrative agency or other forum other than as a defense to an action initiated by the Licensor ("**Challenge**"), the royalty rates set forth in Section 6.01 and the license maintenance fees set forth in Section 6.02 shall increase by [\*\*\*] during the pendency of such Challenge. Should the outcome of such Challenge determine that any challenged claim of an Agreement Patent is valid, Licensee (i) shall thereafter, and for the remaining term of this Agreement, continue to pay the royalty rate set forth in Section 6.01 and the license maintenance fees set forth in Section 6.02 increased by [\*\*\*]; and (ii) agrees to pay all costs and expenses (including actual outside attorneys' fees) incurred by Licensor in connection with defending the Challenge. Should the outcome of such Challenge determine that the challenged claim or claims of an Agreement Patent are invalid, Licensor shall be responsible for paying its own costs and expenses in connection with defending the Challenge and this Agreement shall not be construed otherwise to create a Valid Claim by contract.
- 12.19 Licensee will promptly notify Licensor in writing if Licensee or any Sublicensees ceases to be a small entity (as defined by the United States Patent and Trademark Office)
- 12.20 This Agreement may be signed in one or more counterparts, each of which shall be deemed an original and all of which shall be deemed one and the same document. Counterparts may be signed and delivered by facsimile or PDF file, each of which shall be binding when received by the applicable party.

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12.21 Neither party shall be liable for any failure of or delay in the performance of this Agreement for the period that such failure or delay is due to causes beyond its reasonable control, including but not limited to acts of god, war, strikes or labor disputes, embargoes, action or inaction of a government agency or any other force majeure event.

### 13. <u>Notices</u>

13.01 Any correspondence, document, notice or report required or permitted hereunder shall be given in writing, and shall be deemed to have been properly given and effective upon delivery, by registered or certified mail, return receipt requested, or by facsimile with proof of receipt and a confirmation copy sent by overnight courier, or by email with proof of receipt and a confirmation copy sent by overnight courier, or by email with proof of receipt and a confirmation copy sent by overnight courier, or by email with proof of receipt and a confirmation copy sent by overnight courier, or by overnight courier to the following addresses or to such other address that a party may give by written notice to all parties:

### To Licensee:

Cue Biopharma Inc. c/o MDB Capital Group LLC 401 Wilshire Blvd, Suite 1020 Santa Monica, CA 90401

with copies to:

Scott E. Bartel, Esq. Locke Lord LLP 500 Capitol Mall, Suite 1800 Sacramento, CA 95814 sbartel@lockelord.com

### To Licensor:

Albert Einstein College of Medicine, Inc.

1300 Morris Park Avenue Bronx, New York 10461 Attention: Office of Biotechnology John.Harb@einstein.yu.edu

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with copies to:

Kenneth P. George, Esq. Amster, Rothstein & Ebenstein LLP 90 Park Avenue New York, NY 10016 kgeorge@arelaw.com IN WITNESS WHEREOF, the parties have entered into this Agreement effective as of the day and year first above written.

	ALBERT EINSTEIN COLLEGE OF MEDICINE, INC.
WITNESS	/s/ John L. Harb Name: John L. Harb
	Title Assistant Dean
Date:	Date: July 31, 2017
WITNESS	CUE BIOPHARMA INC.
	/s/ Daniel R. Passeri
	Name Daniel R. Passeri Title President & CEO
Date:	Date: July 31, 2017
AGREED TO AND ACCEPTED BY:	
/s/ Steven C. Almo	
Date: July 31, 2017	
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### **APPENDIX A - Agreement Patents**

(1) "Methods for high throughput receptor-ligand identification," Application No. PCT/US13/73275 (Einstein Invention Disclosure No. D-972; ARE Client Matter No. 96700/2061; Inventors: Steven C. Almo, Ronald D. Seidel, Brandan S. Hillerich, Sarah C. Garrett-Thomson and James D. Love) (Assignee: Einstein) filed nationally in the United States, Australia, Brazil, Canada, China, EPO, Hong Kong, Israel, India, Japan, South Korea and Singapore;

(2) "Cellular platform for rapid and comprehensive T-cell immunomonitoring," Application No. 61/929,651 (Einstein Invention Disclosure No. D-1046; ARE Client Matter No. 96700/2095; Inventors: Steven C. Almo, Ronald D. Seidel, Brandan S. Hillerich and Rodolfo J. Chaparro) (Assignee: Einstein);

(3) "SYNTAC Fc fusion constructs and uses thereof," Application No. 62/013,715 (Einstein Invention Disclosure No. D-1073; ARE Client Matter No. 96700/2138; Inventors: Steven C. Alma, Ronald D. Seidel, Rodolfo J. Chaparro, Brandan S. Hillerich and Scott J. Garforth) (Assignee: Einstein); and

(4) "VARIANT PD-L1 POLYPEPTIDES, T-CELL MODULATORY MULTIMERIC POLYPEPTIDES, AND METHODS OF USE THEREOF" (Application No. 62/338,128); (Case No. C-00001209; ARE Client Matter No. 96700/2347; Inventors: Steven C. Almo, Sarah C. Garrett-Thomson and Ronald D. Seidel (Assignee: Einstein).

(5) "Methods for high throughput receptor-ligand identification," Application No. 61/735,791, (Einstein Invention Disclosure No. D-972; ARE Client Matter No. 96700/1928; Inventors: Steven C. Almo, Ronald D. Seidel, Brandan S. Hillerich, Sarah C. Garrett-Thomson and James D. Love) (Assignee: Einstein);

(6) "Methods for high throughput receptor-ligand identification," Application No. 61/833,588, (Einstein Invention Disclosure No. D-972; ARE Client Matter No. 96700/1961; Inventors: Steven C. Almo, Ronald D. Seidel, Brandan S. Hillerich, Sarah C. Garrett-Thomson and James D. Love) (Assignee: Einstein);

(7) "Cellular platform for rapid and comprehensive T-cell immunomonitoring," Application No. PCT/US15/012160 (Einstein Invention Disclosure No. D-1046; ARE Client Matter No. 96700/2199; Inventors: Steven C. Almo, Ronald D. Seidel, Brandan S. Hillerich and Rodolfo J. Chaparro) (Assignee: Einstein) filed nationally in the United States, Australia, Brazil, Canada, China, EPO, Israel, India, Japan, South Korea and Singapore;

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(8) "SYNTAC Fc fusion constructs and uses thereof," Application No. PCT/US15/035777 (Einstein Invention Disclosure No. D-1073; ARE Client Matter No. 96700/2236; Inventors: Steven C. Almo, Ronald D. Seidel, Rodolfo J. Chaparro, Brandan S. Hillerich and Scott J. Garforth) (Assignee: Einstein) filed nationally in the United States, Australia, Brazil, Canada, China, EPO, Taiwan, Israel, India, Japan, South Korea and Singapore;

(9) "VARIANT PD-LI POLYPEPTIDES, T-CELL MODULATORY MULTIMERIC POLYPEPTIDES, AND METHODS OF USE THEREOF," Application No. PCT/US2017/33042; (Einstein Invention Disclosure No. unknown; ARE Client Matter No. 96700/2508; Inventors: Steven C. Almo, Sarah C. Garrett-Thomson and Ronald D. Seidel) (Assignee: Einstein). CONFIDENTIAL PORTIONS OF THIS AGREEMENT HAVE BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR SUCH PORTIONS. ASTERISKS DENOTE OMISSIONS.

# EXCLUSIVE PATENT LICENSE AND RESEARCH COLLABORATION AGREEMENT

# by and between

# CUE BIOPHARMA, INC.

### and

# **MERCK SHARP & DOHME CORP.**

### EXCLUSIVE PATENT LICENSE AND RESEARCH COLLABORATION AGREEMENT

This Agreement ( **"Agreement"**) is effective as of November 14, 2017, (the **"Effective Date"**) and is entered into by and between CUE BIOPHARMA, INC., a corporation organized and existing under the laws of Delaware (**"Company"**) and MERCK SHARP & DOHME CORP., a corporation organized and existing under the laws of New Jersey (**"Merck"**).

### **RECITALS:**

WHEREAS, Company has developed Company Know-How (as hereinafter defined) and has rights to Company Patent Rights (as hereinafter defined) related to antigen-specific T cell-targeted biologics, including an exclusive license to certain intellectual property rights pursuant to an Amended and Restated License Agreement dated July 31, 2017 between Company and Albert Einstein College of Medicine, Inc. ("Albert Einstein"), a corporation organized and existing under the laws of the State of New York, having an office and place of business at 1300 Morris Park Avenue, Bronx, New York 10461 as successor-in-interest to Albert Einstein College of Medicine of Yeshiva University, a Division of Yeshiva University (the "Amended and Restated Einstein License Agreement");

**WHEREAS**, such antigen-specific T cell-targeted biologics have multiple potential uses, including but not limited to the treatment of Autoimmune Disease (as hereinafter defined), cancer, and infectious diseases;

**WHEREAS**, Merck and Company desire to enter into a research collaboration to research and develop certain antigen-specific T cell-targeted biologics and in particular Cue Biologics, Compounds and Products of potential utility for treating Initial Indications in Autoimmune Disease (as those terms are hereinafter defined) upon the terms and conditions set forth herein, with the goal of identifying and/or optimizing novel biologics to be developed and commercialized by Merck;

**WHEREAS,** Merck desires to obtain a license under the Company Patent Rights and Company Know-How upon the terms and conditions set forth herein, and Company desires to grant such a license;

**NOW, THEREFORE,** in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, Company and Merck hereby agree as follows:

#### ARTICLE 1 DEFINITIONS.

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below.

- 1.1 "AAALAC" shall mean the Association for Assessment and Accreditation of Laboratory Animal Care International.
- **1.2** "Act" shall mean, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and/or the Public Health Service Act, 42 U.S.C. §§ 262 et seq., as amended from time to time.

- **1.3 "Affiliate"** shall mean: (i) any corporation or business entity of which, now or hereafter, fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by Merck or Company; or (ii) any corporation or business entity which, now or hereafter, directly or indirectly, owns, controls or holds fifty percent (50%) (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of Merck or Company; or (iii) any corporation or business entity of which, now or hereafter, fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of Merck or Company; or (iii) any corporation or business entity of which, now or hereafter, fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interests representing the equity, the voting stock or general partnership interests representing the equity, the voting stock or general partnership interests representing the equity, the voting stock or general partnership interests representing the equity, the voting stock or general partnership interests representing the equity, the voting stock or general partnership interests are owned, controlled or held, directly or indirectly, by a corporation or business entity described in (i) or (ii).
- **1.4 "Agreement"** shall have the meaning given such term in the preamble to this document.
- **1.5 "Antigen"** as used herein shall mean any protein or Peptide that, when bound or presented by a Disease-Associated Allele, binds to T cells or evokes an immune response.
- **1.6 "Applicable Laws"** means any and all applicable laws of any jurisdiction which are applicable to any of the Parties or their respective Affiliates in carrying out activities hereunder or to which any of the Parties or their respective Affiliates in carrying out the activities hereunder is subject, and shall include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, policies, directions, directives and orders of any statutory authority, tribunal, board, or court or any central or state government or local authority or other governmental entity in such jurisdictions, including the Act, GLPs, GCPs and GMPs.
- **1.7 "Autoimmune Disease"** means a disease or inflammatory disorder in which the body's immune system produces antibodies and/or proinflammatory chemical agents that attack its own tissues, leading to the deterioration and in some cases to the destruction of such tissue.
- **1.8** "Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
- **1.9 "Calendar Year"** shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- **1.10 "Change of Control"** shall mean with respect to a Party: (1) the sale of all or substantially all of such Party's assets or business relating to this Agreement; (2) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (3) a person or entity, or group of persons or entities, acting in concert acquire at least fifty percent (50%) of the voting equity securities or management control of such Party.
- 1.11 "Clinical Trial" shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, and/or Post-Approval Clinical Trial.
- **1.12 "Combination Product"** shall mean a Product that includes one or more active pharmaceutical ingredients other than Compound in combination with Compound. All references to Product in this Agreement shall be deemed to include Combination Product.

- 1.13 "Commercially Reasonable Efforts" shall mean, with respect to the efforts to be expended by a Party with respect to any objective, such reasonable and diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances. It is understood and agreed that with respect to the Research, Development and Commercialization of Product by either Party, such efforts shall be substantially equivalent to those efforts and resources commonly used by such Party for biological products owned by it or to which it has rights, which product is at a similar stage in its Development or product life and is of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the Regulatory Authority involved, the profitability of the product including the amounts payable to licensors of patent or other intellectual property rights, alternative products, other risks associated with the Development or Commercialization of the product and other relevant factors. Commercially Reasonable Efforts shall be determined on a market-by-market and Indication-by-Indication basis for a particular Product, and it is anticipated that the level of effort will be different for different markets, and will change over time, reflecting among other things changes in the status of the Product and the market(s) involved.
- **1.14 "Commercialization"** shall mean any and all activities related to the import, export, transportation, storage, marketing, detailing, promotion, distribution, sale or other disposition and/or other approved use of a Product in a country or region in the Territory, including: (a) strategic marketing, sales force detailing, advertising, medical affairs, reimbursement and market access activities and market and product support; and (b) all customer support, distribution matters, invoicing and sales activities. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization, and "Commercialized" has a corresponding meaning. For clarity, Commercialization excludes any Research, Development or Manufacturing activities.
- **1.15 "Company"** shall have the meaning given such term in the preamble to this Agreement.
- **1.16** "Company Information and Inventions" shall mean all protocols, formulas, data, Inventions, know-how and trade secrets, patentable or otherwise, resulting from the Research Program developed or invented solely by employee(s) of Company and/or its Affiliates, and/or a Third Party acting on behalf of Company and/or its Affiliates, and not employed by Merck and/or its Affiliates.
- **1.17 "Company Know-How"** shall mean all information and materials, including but not limited to discoveries, improvements, processes, methods, protocols, formulas, data, inventions (including without limitation Company Information and Inventions and Company's rights in Joint Information and Inventions), know-how and trade secrets, patentable or otherwise, which during the term of this Agreement: (i) are Controlled by Company or its Affiliates; (ii) are not generally known; and (iii) are necessary or useful to Merck in the Field, or necessary or useful to Merck in connection with the Research Program and the Research, Development, Manufacture, Commercialization or use of Compound or Product in the Territory; excluding, however, any Merck Know-How. Company Know-How includes Einstein Know-How and Cue Know-How.
- **1.18 "Company Patent Rights"** shall mean Patent Rights that during the term of this Agreement are Controlled by Company or any of its Affiliates, including, but not limited to, those listed on <u>Schedule 1.1</u>, which: (i) claim or cover a Cue Biologic, Compound and/or Product, or a method of use or process of Manufacture thereof, including without limitation any improvements; or (ii) claim or cover Company Information and Inventions. Company Patent Rights include Einstein Patent Rights and Cue Patent Rights.

- **1.19 "Competing Pharma"** shall mean a company or group of companies acting in concert (a) for which the collective worldwide sales of ethical pharmaceutical products in the preceding Calendar Year were one billion United States dollars (US\$1,000,000,000) or more, or (b) which has a research, development or commercialization program for any preparation or product that may be used for the treatment of an Initial Indication, or any other preparation or product that is reasonably considered to be competitive with any Cue Biologic, Compound or Product.
- **1.20 "Competing Pharma Change of Control"** shall mean a Change of Control in which a company or group of companies acting in concert (a) for which the collective worldwide sales of ethical pharmaceutical products in the Calendar Year that preceded the Change of Control were one billion United States dollars (US\$1,000,000,000) or more, or (b) which has a research, development or commercialization program for any preparation or product that may be used for the treatment of an Initial Indication, or any other preparation or product that is reasonably considered to be competitive with any Cue Biologic, Compound or Product, is the acquirer (by asset purchase, merger, consolidation, reorganization or otherwise) as part of such Change of Control.
- **1.21 "Compound"** shall mean a Product Candidate; or a derivative thereof [\*\*\*].
- **1.22 "Control"**, **"Controls"** or **"Controlled by"** shall mean with respect to any item of or right under Company Patent Rights, Company Know-How, Merck Patent Rights, Merck Know-How, or Joint Patent Rights, or other intellectual property assets or rights, as applicable, the possession of (whether by ownership or license, other than pursuant to this Agreement) or the ability of a Party to grant access to, or a license or sublicense of, such items or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time or in effect during the time such Party would be required hereunder to grant the other Party such access or license or sublicense.
- **1.23** "Cue Biologic" shall mean [\*\*\*].
- **1.24 "Cue Biologics Patent Rights"** shall be as defined in <u>Section 7.1.1</u>.
- **1.25 "Cue Biologics-Specific Information and Inventions"** shall be as defined in <u>Section 7.1.1</u>.
- **1.26 "Cue Know-How"** shall man all Company Know-How other than Einstein Know-How.
- **1.27 "Cue Patent Rights"** shall mean all Company Patent Rights other than Einstein Patent Rights.
- **1.28** "Cue Platform" shall mean Company's proprietary Antigen-specific T cell-targeted biologic platform that produces biologics designed and engineered to selectively modulate function of T cell subsets.
- **1.29** "Cue Platform Biologic" shall mean [\*\*\*].
- **1.30 "Development"** means any and all clinical drug development activities, Clinical Trials, statistical analysis and report writing, the preparation and submission of regulatory filings, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a regulatory approval for a Cue Biologic, Compound or Product, and "Develop", "Developed" and "Developing" will have corresponding meanings. For clarity, Development excludes any Research, Commercialization or Manufacturing activities.

- **1.31 "Disease-Associated Allele"** shall mean any allele from any species which is associated with [\*\*\*].
- 1.32 "Einstein Know-How" shall mean all know-how licensed to Company under the Amended and Restated Einstein License Agreement.
- **1.33 "Einstein Patent Rights"** shall mean all patent rights licensed to Company under the Amended and Restated Einstein License Agreement.
- **1.34 "Exclusions Lists"** shall be as defined in <u>Section 1.90</u> Violation.
- **1.35** "Field" shall mean [\*\*\*].
- **1.36 "First Collaborative Cue Biologic"** shall mean the first Cue Biologic synthesized under the Research Program [\*\*\*].
- **1.37 "First Commercial Sale"** shall mean, with respect to any Product, the first sale for end use or consumption of such Product in a country, excluding, however, any sale or other distribution for use in a Clinical Trial.
- **1.38 "Good Clinical Practices"** or **"GCPs"** shall mean the applicable then-current Good Clinical Practices as such term or its equivalent is defined from time to time by the United States Food and Drug Administration or other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or Commercialization of Product in the Territory pursuant to its regulations, guidelines or otherwise, as applicable.
- **1.39 "Good Laboratory Practices"** or **"GLPs"** shall mean the applicable then-current standards for laboratory activities for pharmaceuticals or biologicals, as set forth in the Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with any similar standards of good laboratory practice as are required by any Regulatory Authority in the Territory.
- **1.40 "Good Manufacturing Practices"** or **"GMPs"** shall mean the applicable then-current Good Manufacturing Practices as such term or its equivalent is defined from time to time by the United States Food and Drug Administration or other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or Commercialization of Product in the Territory pursuant to its regulations, guidelines or otherwise, as applicable.
- 1.41 "Human Leukocyte Antigen" or "HLA" shall mean a protein or protein complex involved in the presentation of Peptide antigens to T cells.
- 1.42 [\*\*\*\*]
- **1.43 "IND"** shall mean an investigational new drug application, clinical study application, clinical trial exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

- **1.44 "IND Enabling Studies"** shall mean the genotoxicity, acute toxicology, safety, pharmacology, and/or sub-chronic toxicology studies in species using applicable GLPs that in Merck's sole discretion satisfy applicable regulatory requirements and meet the standard necessary for submission as part of an IND filing with a Regulatory Authority.
- **1.45 "Indication"** shall mean a separate and distinct disease or medical condition in humans which a Product that is in Clinical Trials is intended to treat, prevent and/or diagnose and/or for which a Product has received Marketing Authorization.
- **1.46 "Indication Specific Peptide"** shall mean a Peptide Researched or Developed pursuant to the Research Program which is [\*\*\*].
- **1.47 "Initial Indication"** shall mean [**\*\*\***] and **"Initial Indications"** shall mean [**\*\*\***], collectively.
- **1.48 "Information"** shall mean any and all information and data, including without limitation all Merck Know-How, all Company Know-How, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by one Party to the other Party in connection with this Agreement.
- **1.49 "Invention"** shall mean any process, method, composition of matter, article of manufacture, discovery or finding that is conceived and/or reduced to practice as a result of the Research Program.
- **1.50 "Joint Information and Inventions"** shall mean all protocols, formulas, data, Inventions, know-how and trade secrets, patentable or otherwise, resulting from the Research Program and developed or invented jointly by employee(s) of Merck and/or its Affiliates, and/or a Third Party acting on behalf of Merck and/or its Affiliates, on the one hand, and by employee(s) of Company and/or its Affiliates, and/or a Third Party acting on behalf of Company and/or its Affiliates, on the other hand.
- **1.51 "Joint Patent Rights"** shall mean Patent Rights that claim or cover Joint Information and Inventions.
- **1.52 "Joint Steering Committee"** shall mean the joint steering committee established to facilitate the Research Program as more fully described in <u>Section 2.4</u>.
- **1.53 "Maintained Initial Indication**" shall mean an Initial Indication in which Merck has not discontinued Research, Development and Commercialization efforts with respect to any Compound or Product pursuant to <u>Section 2.11.5</u>.
- **1.54** "Major Market" shall mean [\*\*\*].
- **1.55 "Manufacturing"** means the production, manufacture, synthesis, processing, filling, formulating, finishing, packaging, labeling, shipping and holding of Cue Biologic, Compound or Product or any intermediate thereof, including sequencing, process development, process qualification and validation, scale-up, commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control. "Manufacturing" refers to both pre-clinical and clinical Manufacturing for Research and Development, and Manufacturing for Commercialization. "Manufacture" and "Manufactured" will have corresponding meanings. For clarity, "Manufacturing" excludes Research, Development or Commercialization activities.

- **1.56 "Marketing Authorization"** shall mean all approvals from the relevant Regulatory Authority necessary to market and sell a Product in the applicable country (including without limitation, in countries outside of the United States, all applicable pricing and governmental reimbursement approvals only if required to market and sell Product in a country).
- **1.57 "Merck"** shall have the meaning given such term in the preamble to this Agreement.
- **1.58 "Merck Information and Inventions"** shall mean all protocols, formulas, data, Inventions, know-how and trade secrets, patentable or otherwise, resulting from the Research Program developed or invented solely by employee(s) of Merck and/or its Affiliates, and/or a Third Party acting on behalf of Merck and/or its Affiliates, and not employed by Company and/or its Affiliates.
- **1.59 "Merck Know-How"** shall mean all information and materials, including but not limited to discoveries, improvements, processes, methods, protocols, formulas, data, inventions (including without limitation Merck Information and Inventions and Merck's rights in Joint Information and Inventions), know-how and trade secrets, patentable or otherwise, which during the term of this Agreement: (i) are Controlled by Merck; (ii) are not generally known; and (iii) are in Merck's opinion necessary to Company in the performance of its obligations under the Research Program.
- **1.60** "Merck Patent Rights" shall mean Patent Rights that during the term of this Agreement are Controlled by Merck or any of its Affiliates, or to which Merck or any of its Affiliates, through license or otherwise, acquires rights, which: (i) claim or cover Compound and/or Product; or (ii) claim or cover Merck Information and Inventions.
- **1.61 "NDA"** shall mean a new drug application, biologics license application, Marketing Authorization application, filing pursuant to Section 510(k) of the Act, or similar application or submission for Marketing Authorization of a Product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.
- **1.62 "Net Sales"** shall mean the gross invoice price (not including value added taxes, sales taxes, or similar taxes) of Product sold by Merck or its Related Parties to the first Third Party after deducting, if not previously deducted, from the amount invoiced or received:
  - **1.62.1** trade and quantity discounts, other than early payment cash discounts;
  - 1.62.2 returns, rebates, chargebacks and other allowances;
  - **1.62.3** retroactive price reductions that are actually allowed or granted;
  - **1.62.4** deductions for Health Care Reform fees and similar deductions to gross invoice price of Product imposed by Regulatory Authorities or other governmental entities;

- **1.62.5** a fixed amount equal to [\*\*\*] of the amount invoiced to cover bad debt, early payment cash discounts, transportation and insurance and custom duties; and
- **1.62.6** the standard inventory cost of devices or delivery systems used for dispensing or administering Product.

[\*\*\*]

With respect to sales of Combination Products, Net Sales shall be calculated on the basis of the gross invoice price of Product(s) containing the same strength of Compound sold without other active ingredients. In the event that Product is sold only as a Combination Product, Net Sales shall be calculated on the basis of the gross invoice price of the Combination Product multiplied by a fraction, the numerator of which shall be the inventory cost of Compound in the Product and the denominator of which shall be the inventory cost of all of the active ingredients in the Combination Product. Inventory cost shall be determined in accordance with Merck's regular accounting methods, consistently applied. The deductions set forth in <u>Section 1.62.6</u> will be applied in calculating Net Sales for a Combination Product. In the event that Product is sold only as a Combination Product and either Party reasonably believes that the calculation set forth in this Paragraph does not fairly reflect the value of Compound relative to the other active ingredients in the Combination Product, the Parties shall reasonably negotiate, in good faith, other means of calculating Net Sales with respect to Combination Products.

- **1.63 "Party"** shall mean Merck or Company, individually, and "Parties" shall mean Merck and Company, collectively.
- **1.64 "Patent Rights"** shall mean any and all patents and patent applications in the Territory (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, pediatric exclusivity periods and the like of any such patents and patent applications, and foreign equivalents of the foregoing.
- **1.65 "Peptide**" shall mean a series of two or more amino acids connected by peptide bonds.
- **1.66 "Person"** means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.
- 1.67 "Phase I Clinical Trial" shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).
- **1.68** "Phase II Clinical Trial" shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).
- **1.69 "Phase III Clinical Trial"** shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).
- **1.70 "Platform Information and Inventions"** shall be as defined in <u>Section 7.1.2</u>.
- **1.71 "Platform Patent Rights"** shall be as defined in <u>Section 7.1.2</u>.

- 1.72 "Post-Approval Clinical Trial" shall mean any clinical trial conducted in an Indication after the Regulatory Approval of such Indication.
- **1.73 "Product(s)"** shall mean any pharmaceutical or biological preparation in final form containing a Compound: (i) for sale by prescription, over-thecounter or any other method; or (ii) for administration to human patients in a Clinical Trial, for any and all uses in the Field, including without limitation any Combination Product.
- **1.74 "Product Candidate"** shall mean a Cue Biologic which: (i) meets or exceed Proof of Concept, as determined by Merck in accordance with its usual procedures for the development of new biological entities; and (ii) is designated in writing pursuant to <u>Section 2.2.4</u> as a Product Candidate by Merck to Company.
- **1.75 "Proof of Concept"** shall mean the demonstration of all or substantially all of the properties outlined in the Product Candidate Profile as defined in <u>Schedule 2.1</u> Research Program, as determined by Merck in its sole discretion.
- **1.76 "Proof of Mechanism"** shall mean the demonstration of biologically significant effect of a Cue Biologic [\*\*\*], as determined by the Joint Steering Committee pursuant to <u>Section 2.2.2</u>.
- **1.77** "**Proposed Product Candidate**" shall be a Cue Biologic which has achieved Proof of Mechanism as determined by the Joint Steering Committee, as reflected in meeting minutes of the Joint Steering Committee.
- **1.78 "Qualifying Phase II Clinical Trial"** shall mean a human clinical trial, in any country, the principal purpose of which is a confirmation of efficacy and safety, consistent with that observed in previous Clinical Trial(s) of the relevant Product, in the target population, at the intended clinical dose or doses or range of doses, on a sufficient number of subjects and for a sufficient period of time to determine the optimal manner of use of the Product (dose and dose regimen) prior to the Initiation of a Phase III Clinical Trial of such Product. For clarity, the Parties' expectation is that a Qualifying Phase II Clinical Trial will be a phase IIb Clinical Trial which is intended to confirm the efficacy demonstrated in a prior phase IIa Clinical Trial or phase Ib Clinical Trial.
- **1.79 "Regulatory Authority"** shall mean any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a Product in the Territory, including, in the United States, the United States Food and Drug Administration and any successor governmental authority having substantially the same function.
- **1.80 "Regulatory T cells" or "T-regs"** also known as suppressor T cells, are a subpopulation of T cells which modulate the immune system, maintain tolerance to self-antigens, and prevent autoimmune disease.
- **1.81** "Related Party" shall mean each of Merck, its Affiliates, and their respective sublicensees (which term does not include distributors), as applicable.
- **1.82 "Research"** means activities related to the design, discovery, identification, synthesis, research, pre-clinical development, preclinical toxicology studies, profiling, characterization, improvement or optimization of a Cue Biologic, Compound or Product. For clarity, "Research" excludes Development, Commercialization or Manufacturing activities.

- **1.83 "Research Program"** shall mean the Research activities undertaken by the Parties as set forth in <u>Article 2</u> and <u>Schedule 2.1</u>, as may be revised from time to time pursuant to <u>Section 2.1</u>, Section 2.2, or <u>Section 2.10</u>.
- **1.84 "Research Program Term"** shall mean the duration of the Research Program as it may be extended or terminated as described more fully in <u>Section 2.10</u> and <u>Article 8</u>.
- **1.85 "Royalty Period"** shall be as defined in <u>Section 5.4.1(c)</u>.
- **1.86 "Term"** is defined in <u>Section 8.1</u>.
- **1.87 "Territory"** shall mean all of the countries in the world, and their territories and possessions.
- **1.88 "Third Party"** shall mean an entity other than Merck and its Related Parties, and Company and its Affiliates.
- **1.89 "Valid Patent Claim"** shall mean a claim of an issued, unexpired and in-force patent included within the Company Patent Rights or Joint Patent Rights that claims a Compound as a composition of matter, which claim has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction (which decision is not appealable or has not been appealed within the time allowed for appeal), and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination, supplemental examination or disclaimer or otherwise.
- 1.90 "Violation" shall mean that either Company, or any of its officers or directors has been: (a) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (<u>https://oig.hhs.gov/exclusions/index.asp</u>); and/or (b) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (<u>https://oig.hhs.gov/exclusions/exclusions list.asp</u>) or the U.S. General Services Administration's list of Parties Excluded from Federal Programs (<u>https://www.sam.gov/portal/public/SAM/</u>) (each of (a) and (b), singly and collectively, the "Exclusions Lists").

### ARTICLE 2 RESEARCH PROGRAM, GOVERNANCE, EXCLUSIVE EFFORTS

- **2.1 General.** Company and Merck shall engage in the Research Program upon the terms and conditions set forth in this Agreement. The activities to be undertaken in the course of the Research Program are set forth in <u>Schedule 2.1</u> as may be revised from time to time upon mutual written agreement by authorized representative(s) of the Parties.
- 2.2 Conduct of Research. The Research Program is directed to: (i) the Research by Company of Cue Biologics up to Proof of Mechanism for each of the Initial Indications; and, subject to Section 2.2.2; (ii) the further Research and/or Development by Merck of Proposed Product Candidates. Subject to Section 2.2.4, Merck may, in its sole discretion, elect [\*\*\*\*] Product Candidates for use by Merck and its Related Parties in efforts to Research, Develop, Manufacture and Commercialize Compounds and Products.
  - **2.2.1** Until the expiration of the Research Program Term, Company and Merck each shall proceed diligently with the work set out in the Research Program by using their respective reasonable good faith efforts to allocate sufficient time, effort, equipment and facilities to the Research Program and to use personnel with sufficient skills and experience as are required to accomplish the Research Program in accordance with the terms of this Agreement and <u>Schedule 2.1</u> as may be revised from time to time pursuant to <u>Section 2.1</u>.
  - **2.2.2** Upon the generation of data supporting achievement of Proof of Mechanism for each Cue Biologic, Company shall present such information along with the identity of the Cue Biologic to the Joint Steering Committee. Following a determination by the Joint Steering Committee that such Cue Biologic has achieved Proof of Mechanism as reflected in the meeting minutes of the Joint Steering Committee, such Cue Biologic shall constitute a Proposed Product Candidate. Merck shall thereafter perform the Research and/or Development activities assigned under the Research Program for the Proposed Product Candidate. Company shall have responsibility for supply of such Proposed Product Candidate.
  - **2.2.3** Upon achievement of Proof of Concept for one or more Proposed Product Candidates, Merck shall provide written notice to Company that such one or more Proposed Product Candidates have achieved Proof of Concept.
  - **2.2.4** Following written notice to Company of the achievement of Proof of Concept for a Proposed Product Candidate, Merck shall conduct an internal review to determine in its sole discretion whether it wishes to elect the Proposed Product Candidate as a Product Candidate. Merck shall then request through the Joint Steering Committee a meeting with Company to discuss and mutually agree upon a technology transfer strategy to provide for the continued supply and Manufacturing of Product Candidates for IND Enabling Studies. Following Merck's request for a meeting pursuant to this <u>Section 2.2.4</u> and mutual agreement on the technology transfer strategy, Merck may elect in its sole discretion to designate a Proposed Product Candidate as a Product Candidate and provide written notice to Company informing them of such election. Parties shall thereafter work to execute on the mutually-agreed upon technology transfer strategy.

Merck shall be entitled to utilize the services of its Affiliates and Third Parties to perform its Research Program activities, provided that all such Affiliates and Third Parties are bound or agree to be bound by confidentiality and non-use obligations no less stringent than that contained in this Agreement. Company shall be entitled to utilize the service of Third Parties to perform its Research Program activities only upon Merck's prior written consent or as specifically set forth in <u>Schedule 2.1</u>. Notwithstanding the foregoing, each Party shall remain at all times fully liable for its respective responsibilities under the Research Program.

- **2.3 Use of Research Funding**. Company shall apply any Research funding it receives from Merck under this Agreement solely to carry out its Research Program activities in accordance with <u>Schedule 2.1</u>, as may be revised from time to time pursuant to <u>Section 2.1</u>, and the terms and conditions of this Agreement. Apart from the foregoing, each Party shall be responsible for its own cost and expense in carrying out its activities under the Research Program.
- **2.4 Joint Steering Committee.** The Parties hereby establish a committee to facilitate the Research Program as follows:
  - 2.4.1 Composition of the Joint Steering Committee. The Research Program shall be conducted under the direction of a joint steering committee (the "Joint Steering Committee") comprised of two (2) Merck representatives (who shall be employees of Merck or its Affiliate, as applicable) and two (2) Company representatives (who shall be employees of Company or its Affiliate, as applicable). Each Party may change its representatives on the Joint Steering Committee from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Research Program. Additional representative(s) or consultant(s) may from time to time, by mutual consent of the Parties, be invited to attend Joint Steering Committee meetings, subject to such representative's or consultant's written agreement to comply with the requirements of Section 4.1. The Joint Steering Committee shall be chaired by a representative of Merck. The role of the chairperson shall be to preside in person or telephonically at meetings of the Joint Steering Committee, to prepare and circulate agendas and to ensure the preparation of minutes. The chairperson of the Joint Steering Committee will be responsible for preparing reasonably detailed written minutes of all Joint Steering Committee meetings that reflect, without limitation, material decisions made at such meetings. The chairperson shall send draft meeting minutes to each member of the Joint Steering Committee for review and approval reasonably promptly after each meeting. Such minutes will be deemed approved unless one or more of the members of the Joint Steering Committee objects to the accuracy of such minutes within ten (10) business days of receipt. Decisions of the Joint Steering Committee shall be made unanimously by the representatives. In the event that the Joint Steering Committee cannot or does not, after reasonable good faith efforts, reach agreement on an issue, the resolution and/or course of conduct shall be determined by Merck, in its sole discretion.

- 2.4.2 Scope of Joint Steering Committee Oversight. The Joint Steering Committee shall be responsible for overseeing the Research Program, including to: (i) review and amend the Research Program activities set forth in <u>Schedule 2.1</u> as may be revised from time to time pursuant to Section 2.1; (ii) review and coordinate the Parties' activities under the Research Program; (iii) confer regarding the status of the Research Program and the progress under the Research Program and to make determinations and decisions in connection with the activities under the Research Program (including issues of priority); (iv) review relevant data under the Research Program; (v) consider and advise on any technical issues that arise under the Research Program; (vi) review and advise on any budgetary and economic matters relating to the Research Program which may be referred to the Joint Steering Committee; and (vii) to determine such other matters as allocated to the Joint Steering Committee hereunder. The Joint Steering Committee shall not have the authority to: (w) modify or amend the terms and conditions of this Agreement; (x) waive either Party's compliance with the terms and conditions of this Agreement; (y) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (z) amend the Research Program activities in a manner that would increase the financial or other resource obligations imposed on the Company beyond the scope of those required under the then current planned activities, and if such amendment would increase such financial or other resource obligations, then such amendment must be mutually agreed to by the Parties in writing; provided that, for the avoidance of doubt if the work proposed in the amendment to the Research Program activities could be performed with the financial or other resource obligations then currently being funded by Merck and such work would not impose additional financial obligations on Company beyond the then current Research Program activities, Company shall perform such work at no additional charge and the Research Program activities shall automatically be deemed to be amended to include such work as proposed by the Joint Steering Committee.
- **2.4.3 Meetings.** During the Research Program Term, the Joint Steering Committee shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than once per Calendar Quarter, with the location for such meetings alternating between Company and Merck facilities (or such other location may be determined by the Joint Steering Committee). Alternatively, the Joint Steering Committee may meet by means of teleconference, videoconference or other similar communications equipment. Each Party shall bear its own expenses related to the attendance of such meetings by its representatives.
- **2.4.4 Disbandment of Joint Steering Committee.** Upon completion (or earlier termination) of the Research Program, the Joint Steering Committee shall be disbanded and shall have no further authority with respect to the activities hereunder.

### 2.5 Alliance Managers.

- **2.5.1 Appointment**. Each Party shall have the right to appoint an employee who shall oversee interactions between the Parties for all matters related to this Agreement (each an **"Alliance Manager"**). Such persons shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information, and may serve as a single point of contact for any matters arising under this Agreement. The Alliance Managers shall have the right to attend all Joint Steering Committee meetings as non-voting participants and may bring to the attention of the Joint Steering Committee any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as the Parties may mutually agree in writing. Each Party may designate different Alliance Managers by notice in writing to the other Party.
- **2.5.2 <u>Responsibilities of the Alliance Managers</u>.** The Alliance Managers, if appointed, shall have the responsibility of creating and maintaining a constructive work environment between the Parties. Without limiting the generality of the foregoing, each Alliance Manager shall:
  - (a) identify and bring disputes and issues that may result in disputes (including without limitation any asserted occurrence of a material breach by a Party) to the attention of the Joint Steering Committee in a timely manner, and function as the point of first referral in all matters of conflict resolution;

- (b) provide a single point of communication for seeking consensus both internally within the Parties' respective organizations and between the Parties;
- (c) plan and coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement; and
- (d) take responsibility for ensuring that meetings and the production of meeting agendas and minutes occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.
- **2.6 Patent Committee.** The Parties hereby establish a committee to facilitate the filing, prosecution and maintenance of Patent Rights as follows:
  - **2.6.1 Establishment.** Within sixty (60) days after the Effective Date, the Parties shall establish a patent committee (the "**Patent Committee**") to discuss, oversee and coordinate the filing, prosecution, maintenance and enforcement of Merck Patent Rights, Company Patent Rights and Joint Patent Rights; and the filing of Patent Rights on Information and Inventions (with the exception of Other Information and Inventions which are not Joint Information and Inventions); and defense against claims of infringement of Third Party patents related to the intellectual property licensed or practiced under this Agreement. The Patent Committee will provide recommendations to the Parties regarding the filing, prosecution, maintenance and enforcement of such Patent Rights and related intellectual property matters.
  - **2.6.2 Membership; Meetings.** The Patent Committee shall be composed of one (1) employee from each of Merck and Company knowledgeable in U.S. patent law and the technology areas that are the subject of this Agreement. The Patent Committee shall meet, in person, by teleconference, or by video-teleconference, at least one (1) time per Calendar Quarter, or more or less often as the Parties shall determine. In-person meetings shall alternate between Company and Merck locations within the United States whenever possible unless otherwise agreed by the Parties. The first such meeting shall be within ninety (90) days after the Effective Date. Any member of the Patent Committee may designate a substitute, who shall be an employee of the applicable Party, to attend with prior written notice to the other Party. Ad hoc guests who are subject to written confidentiality obligations at least as stringent as the provisions in <u>Article 4</u> may be invited to Patent Committee meetings. Each Party may replace its Patent Committee members with other of its employees with the qualifications set forth in this <u>Section 2.6.2</u>, at any time, upon written notice to the other Party.
  - **2.6.3 Recommendations; Limitations on Patent Committee.** Recommendations of the Patent Committee shall be made by consensus, with each Party having collectively one (1) vote in all decisions. The Patent Committee shall have only such powers as are specifically delegated to it in this Agreement and such powers shall be subject to the terms and conditions set forth herein. Without limiting the generality of the foregoing, the Patent Committee shall have no power to amend this Agreement, the Research Program or any written Research plan. Recommendations where the Patent Committee is unable to reach a consensus are determined as follows:

- (a) Merck shall have final decision-making authority with respect to any dispute relating specifically to Cue Biologics-Specific Information and Inventions, Cue Biologics Patent Rights, and Merck Other Information and Inventions;
- (b) Company shall have final decision-making authority with respect to any dispute relating specifically to Platform Information and Inventions, Platform Patent Rights, and Company Other Information and Inventions; and
- (c) The Patent Committee shall seek to resolve disputes concerning recommendations on Joint Other Information and Inventions. If the Patent Committee is unable to reach a consensus recommendation on a matter that relates to the Joint Other Information and Inventions within thirty (30) days after it has met and attempted to reach such recommendation, then either Party may refer such matter for resolution by nominated executives of each Party.

The Patent Committee shall provide status updates to the Joint Steering Committee once per Calendar Quarter as long as the Joint Steering Committee is in existence and, thereafter, to the Parties.

Company shall update Schedule 1.1 and provide such updated schedule to the Patent Committee on a monthly basis.

- **2.6.4 Duration of Patent Committee.** The Patent Committee shall endure for the Term and, by mutual agreement, beyond the Term.
- 2.7 Exchange of Information. Following execution of this Agreement, and during the term of the Research Program, Company shall on a quarterly basis and at least ten (10) days before each Joint Steering Committee meeting disclose to Merck in English and in writing or in an electronic format, any: [\*\*\*]. Notwithstanding the foregoing, the Information exchanged pursuant to this <u>Section 2.7</u> or the subject of a Company representation pursuant to <u>Article 6</u> does not in any way limit the definition of Company Know-How as employed throughout the Agreement.

### 2.8 Records and Reports.

- **2.8.1 Records.** Company shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved in the performance of the Research Program by Company.
- 2.8.2 Copies and Inspection of Records. Merck shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such records of Company referred to in <u>Section 2.8.1</u>. Merck shall maintain such records and the information disclosed therein in confidence in accordance with <u>Section 4.1</u>. Merck shall have the right to arrange for its employee(s) and/or consultant(s) involved in the activities contemplated hereunder to visit the offices and laboratories of Company and any of its Third Party contractors as permitted under <u>Section 2.2</u> during normal business hours and upon reasonable notice, and to discuss the Research Program work and its results in detail with the technical personnel and consultant(s) of Company. Upon request, Company shall provide copies of the records described in <u>Section 2.8.1</u>.

- **2.8.3 Quarterly Reports.** Within thirty (30) calendar days following the end of each Calendar Quarter during the term of this Agreement, Company shall provide to Merck a written progress report in English which shall describe the work performed to date on the Research Program, evaluate the work performed in relation to the goals of the Research Program and provide such other information as may be required by the Research Program or reasonably requested by Merck relating to the progress of the goals or performance of the Research Program. For clarity, all such reports shall be considered the confidential Information of Merck.
- **2.9 Research Information and Inventions.** The entire right, title and interest in:
  - **2.9.1** Company Information and Inventions shall be owned solely by Company;
  - 2.9.2 Merck Information and Inventions shall be owned solely by Merck; and
  - **2.9.3** Joint Information and Inventions shall be owned jointly by Company and Merck.

Company shall promptly disclose to Merck in writing the development, making, conception or reduction to practice of Company Information and Inventions and Joint Information and Inventions. For the purposes of determining ownership under this <u>Section 2.9</u>, inventorship shall be determined in accordance with United States patent laws (regardless of where the applicable activities occurred). Subject to the licenses granted to the other party under this Agreement and the other terms and conditions of this Agreement, each Party shall have the non-exclusive right to exploit its interest in Joint Information and Inventions and Joint Patent Rights, and to grant licenses under its interest in Joint Information and Inventions and Joint Patent Rights, and to grant licenses under its interest in Joint Information and Inventions and Joint Patent Rights, and without accounting to, the other Party; <u>provided</u>, <u>however</u>, that for clarity, the foregoing joint ownership rights shall not be construed as granting, conveying or creating any license or other rights to the other Party's intellectual property, unless otherwise expressly set forth in this Agreement; and <u>further provided</u> that, in the event that any Joint Patent Rights claim or cover a Compound or the Manufacturing process therefor, Company shall not grant any license under its interest in such Joint Patent Rights to any Third Party without Merck's prior written consent.

- **2.10 Research Program Term.** The term of the Research Program shall commence on the Effective Date and continue until the later of: (i) election of [\*\*\*\*] Product Candidates; or (ii) [\*\*\*\*] from the Effective Date, except as provided below in <u>Section 2.10.1</u> or as otherwise stated herein.
  - **2.10.1** Extensions. The term of the Research Program may be extended by Merck at its sole discretion for a total of [\*\*\*\*] additional years on a year-by-year basis. To exercise each of these extensions, Merck shall provide written notice of such request at least ninety (90) days prior to the expiration of the then current Research Program term. For each extension exercised pursuant to this <u>Section 2.10.1</u>, the Parties shall work together to mutually agree on a revised Research Program and <u>Schedule 2.1</u>. Such revised Research Program shall be encompassed within the definition of Research Program for purposes of this Agreement.

### 2.11 Exclusive Efforts.

**2.11.1 Cue Biologics, Compounds, Indication Specific Peptides**. During the Research Program Term, Company shall keep Merck informed of any Indication Specific Peptide or of any Cue Biologic or Compound that is Researched or Developed for use in an Initial Indication. During the Research Program Term, Company shall, and shall cause its Affiliates and Third Parties working on Company's behalf to, work exclusively (even as to Company itself) with Merck in efforts to research, develop, make, have made, use, sell, offer for sale, import or otherwise exploit, or license any rights in intellectual property to any Cue Biologic, Compound, or Indication Specific Peptide for an Initial Indication, other than for performing Company's obligations under the Research Program in accordance with this Agreement.

**2.11.2 Cue Platform Biologics.** Company, its Affiliates and Third Parties working on Company's behalf, may independently engage in research, discovery, development and commercialization of Cue Platform Biologics: (i) for any purpose outside of Autoimmune Disease from the Effective Date until the earlier of a) achievement of Proof of Mechanism for the first Cue Biologic, or b) eighteen (18) months after Company's written notice to the Joint Steering Committee of the First Collaborative Cue Biologic; and (ii) for any purpose other than an Initial Indication, from the first of the (a) or (b) conditions to be achieved in <u>Section Error! Reference source not found. (i)</u> for the remainder of the Term of this Agreement. Company may seek a waiver pursuant to <u>Section Error! Reference source not found</u> should Company wish to engage in the research, discovery and/or development of a Cue Platform Biologic beyond the purposes outlined above.

## 2.11.3 Company Forbearance.

- 2.11.3.1 From the Effective Date until the earlier of a) Achievement of Proof of Mechanism for the first Cue Biologic, or b) eighteen (18) months after Company's written notice to the Joint Steering Committee of the First Collaborative Cue Biologic, Company hereby covenants and agrees that it will not alone or with Third Parties research, develop, make, have made, use, sell, offer for sale, import, or otherwise exploit, or license any rights in intellectual property to, any Peptide or biologic in the treatment of an Autoimmune Disease. Company shall, and shall cause its Affiliates to, furthermore expressly exclude from the scope of any license, assignment, transfer, conveyance, grant, agreement or covenant between Company (and/or an Affiliate) and a Third Party any rights with respect to any Peptide or biologic for the treatment of an Autoimmune Disease. During this period, Company may seek a waiver pursuant to Section Error! Reference source not found. should Company wish to engage in the research, discovery and/or development of a Cue Platform Biologic for the treatment of an Autoimmune Disease.
- 2.11.3.2 From Proof of Mechanism for the first Cue Biologic to the end of the Agreement Term. Company hereby covenants and agrees that it will not alone or with Third Parties research, develop, make, have made, use, sell, offer for sale, import or otherwise exploit, or license any rights in intellectual property to, use of any Peptide or biologic in the treatment of an Initial Indication. Company shall, and shall cause its Affiliates to, furthermore expressly exclude from the scope of any license, assignment, transfer, conveyance, grant, agreement or covenant between Company (and/or an Affiliate) and a Third Party any rights with respect to any Peptide or biologic for the treatment of an Initial Indication.
- **2.11.4 [\*\*\*\*]**. From the Effective Date until **[\*\*\*]**, and subject to the provisions of <u>Section 2.11.6</u> below relating to Company Candidates, Company may.

### 2.11.5 Discontinued Initial Indication.

- 2.11.5.1 Merck Discontinuance. Subject to the provisions of Section Error! Reference source not found. below relating to Company Candidates, following the Research Program Term, should Merck decide through an authorized executive committee to discontinue the Research, Development and/or Commercialization of any Compound or Product for one of the Initial Indications, Merck shall promptly provide written notice ("Merck Discontinuance") to Company of same (such Initial Indication a "Discontinued Initial Indication"), and Company shall have the opportunity upon Company notification to the Joint Steering Committee to engage in the Research and Development of a Peptide or biologic for such Discontinued Initial Indication; [\*\*\*]. Such Company notification shall, subject to the provisions of Section Error! Reference source not found., constitute a waiver with respect to Company's obligations pursuant to any of Section 2.11.5 to determine whether the Research, Development and Commercialization of an Initial Indication should be discontinued if a period of eighteen (18) months has passed since Merck has provided a Progress Report pursuant to <u>Section Error! Reference source not found</u>. Berror! Reference source not found.
- 2.11.5.2 Company Discontinuance. Notwithstanding the foregoing, if the Research Program Term expires and Merck is not continuing to Research, Develop or Commercialize a Product Candidate having as a component thereof an Indication Specific Peptide in any allele which is associated with one of the Initial Indications, such one Initial Indication shall constitute a Discontinued Initial Indication and Company shall have the opportunity upon Company notification to the Joint Steering Committee ("Company Discontinuance") to engage in the Research and Development of a Peptide or biologic for such Discontinued Initial Indication, [\*\*\*]

### 2.11.6 Company Candidate(s).

- 2.11.6.1 Company Candidate(s). Following the earlier of: (i) the first waiver granted pursuant to Section 2.11.4 ; or (ii) the discontinuance of any Research, Development and Commercialization of any Compound or Product for an Initial Indication pursuant to Section 2.11.5, until the date which is [\*\*\*] after the end of the Research Program Term, Company shall provide to Merck by January 1<sup>st</sup> and June 1<sup>st</sup> of each Calendar Year a written summary of Company's activities in researching, developing or commercializing a Cue Platform Biologic pursuant to a waiver granted in Section 2.11.4, or a Peptide or biologic for a Discontinued Indication pursuant to Section 2.11.5. No written summary is required in the event that Company has no such activities. In the event that: (i) Company: (a) researches or develops a Cue Platform Biologic during the Research Program Term pursuant to a waiver granted in <u>Section 2.11.4</u> and said Cue Platform Biologic is researched or developed for an Initial Indication; or (b) researches or develops a Peptide or biologic for a Discontinued Initial Indication pursuant to Section 2.11.5 during the Research Program Term or within the [\*\*\*] period after the end of the Research Program Term; and (ii) such Cue Platform Biologic, Peptide or biologic, as applicable, demonstrates a biologically significant effect in testing consistent with that required to achieve Proof of Mechanism in Table 3 of Schedule 2.1 Research Program ("Company Candidate"), then Company shall so notify Merck and provide Merck with the information in Company's possession relating to such Company Candidate and the testing to establish Proof of Mechanism. Thereafter, Merck shall have ninety (90) days (the "Evaluation Period") in which to inform Company in writing whether it wishes to designate such Company Candidate as a Proposed Product Candidate. During the Evaluation Period, Company shall promptly provide Merck with any additional information relating to the Company Candidate in Company's possession that is requested by Merck, and the Parties shall extend the Evaluation Period as reasonably necessary in order to: (i) perform any additional testing required to establish Proof of Mechanism as set forth in this Agreement; and (ii) provide Merck with a reasonable period of time to consider such additional testing. The obligations of this provision shall apply regardless of whether the Agreement has been previously terminated. Company (and its Affiliates) shall not assign, transfer, convey or otherwise grant to any Person or otherwise encumber (including through lien, charge, security interest, mortgage, encumbrance or otherwise) any rights to a Company Candidate or any Company Know-How, Company Patent Rights or Company's interest in Joint Patent Rights related to said Company Candidate (or any rights to any intellectual property that would otherwise be included in such Company Know-How, Company Patent Rights or Joint Patent Rights), in any manner that is inconsistent with or would interfere with the grant of the rights or licenses to Merck in this Section 2.11.6; and any such assignment, transfer, conveyance or grant of rights or licenses from Company or an Affiliate in violation thereof or inconsistent therewith shall be void *ab initio*.
- 2.11.6.2 Designation of a Company Candidate as a Proposed Product Candidate. In the event that Merck agrees in writing during the Evaluation Period to designate the Company Candidate as a Proposed Product Candidate, then Merck shall commence Commercially Reasonable Efforts to Research, Develop and Commercialize the Proposed Product Candidate under the same financial terms contained in this Agreement, including payment of the [\*\*\*] milestone for Proof of Mechanism set forth in Section 5.2.1 if such milestone has not previously been paid; and the definition of "Cue Biologic", for all purposes in the Agreement including definitions directly and indirectly reliant thereon (e.g., Product Candidate, Compound, Product), shall thereafter be amended to include the Company Candidate. In the event that this Agreement has been terminated prior to such designation, then the Parties shall execute a new agreement for Such Company Candidate which shall contain: (i) the same financial terms; (ii) an exclusive license from Company to Merck for Merck to make, have made, use, import, offer to sell and sell said Company Candidate (and Compound or Product Candidate, Product Candidate, Compound and Product (as if derived from a Company Candidate), including but not limited to the treatment of confidential information and intellectual property resulting from said Company Candidate (and Proposed Product Candidate, Product Candidate, Compound or Product derived therefrom) or the research, development, manufacture and commercialization thereof; together with such other terms as the Parties deem appropriate at that time.
- **2.11.6.3 Non-Designation of a Company Candidate as a Proposed Product Candidate.** In the event that Merck does not agree in writing during the Evaluation Period to designate such Company Candidate as a Proposed Product Candidate, then Company shall have no other obligation to Merck regarding such Company Candidate and Company's further research and development of the Company Candidate shall not violate the exclusive efforts provisions of <u>Section 2.11</u>.
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# 2.12 Compliance with Law and Ethical Business Practices.

- **2.12.1** Company shall conduct the activities of the Research Program in accordance with all relevant applicable laws, rules and regulations including, without limitation, all current governmental regulatory requirements concerning Good Laboratory Practices. Company shall notify Merck in writing of any deviations from applicable regulatory or legal requirements if Company becomes aware of any such deviation. Company hereby certifies that it has not and will not employ or otherwise use in any capacity the services of any person or entity debarred under Section 21 USC 335a in performing any services hereunder. Company shall notify Merck in writing immediately if any such debarment occurs or comes to its attention, and shall promptly remove any person or entity so disbarred from performing any activity or function or capacity related to the Research Program. Merck shall have the right, in its sole discretion, to terminate this Agreement immediately in the event that Company fails to promptly remove any such persons.
- **2.12.2** Company acknowledges that Merck's corporate policy requires that Merck's business must be conducted within the letter and spirit of the law. By signing this Agreement, Company agrees to conduct the services contemplated herein in an ethical, reasonable and lawful manner.
- **2.12.3** Specifically, Company warrants that none of its employees, agents, officers or other members of its management are officials, officers, agents, representatives of any government or international public organization. *–NOTE: FOR A LIST OF "American institutions of research, public international organizations and designations under the International Immunities Act" SEE Section 316.20 at <u>http://www.ecfr.gov/cgi-bin/retrieveECFR?</u>*

<u>gp=&SID=d2739abeb6ca1764c5defa8607248f64&n=8y1.0.1.3.68&r=PART&ty=HTML#8:1.0.1.3.68.0.1.14</u> Company shall not make any payment, either directly or indirectly, of money or other assets, including but not limited to the compensation Company derives from this Agreement (hereinafter collectively referred as a **"Payment"**), to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred as **"Officials"**) where such Payment would constitute violation of any law. In addition regardless of legality, Company shall make no Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of Merck's business.

- **2.12.4** Company acknowledges that no employee of Merck or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by Company or its agents to any Third Party in violation of terms of this or any other provisions of this Agreement.
- 2.12.5 Company certifies to Merck that as of the date of this Agreement that Company has screened itself, and its officers, directors and employees against the Exclusions Lists and that it has informed Merck whether Company, or any of its officers or directors has been in Violation. After the execution of this Agreement, Company shall notify Merck in writing immediately if any such Violation occurs or comes to its attention.
- **2.12.6** Company's failure to abide by the provisions of <u>Section 2.12</u> shall be deemed a material breach of this Agreement. In the event that Company fails to cure such failure within the time specified in <u>Section 8.3.1(a)</u> after being notified by Merck of such failure, Merck may in such case and with immediate effect terminate this Agreement at its sole discretion upon written notice to Company and without prejudice to any other remedies that may be available to Merck.
- **2.12.7** Company shall indemnify and hold Merck and any of its Affiliates harmless from and against any and all liabilities (including all costs and reasonable attorneys' fees associated with defending against such claims) that may arise by reason of the negligent or willful acts or omissions of Company or its agents which would constitute a violation of <u>Section 2.12</u>.
- **2.12.8** Company shall indemnify and hold Merck and any of its Affiliates harmless from and against any and all liabilities (including all costs and reasonable attorneys' fees associated with defending against such claims) that may arise by reason of the careless, negligent or willful acts or omissions of Third Parties acting on Company's behalf which would constitute a violation of <u>Section 2.12</u>. [\*\*\*]
- 2.13 Use of Human Materials. If any human cell lines, tissue, human clinical isolates or similar human-derived materials ("Human Materials") have been or are to be collected and/or used in the Research Program, Company represents and warrants: (i) that it has complied, or shall comply, with all applicable laws, guidelines and regulations relating to the collection and/or use of the Human Materials; and (ii) that it has obtained, or shall obtain, all necessary approvals and appropriate informed consents, in writing, for the collection and/or use of such Human Materials. Company shall provide documentation of such approvals and consents upon Merck's request. Company further represents and warrants that such Human Materials may be used as contemplated in this Agreement without any obligations to the individuals or entities ("Providers") who contributed the Human Materials, including, without limitation, any obligations of compensation to such Providers or any other Third Party for the intellectual property associated with, or commercial use of, the Human Materials for any purpose.

2.14 Animal Research. If animals are used in research hereunder, Company will comply with the Animal Welfare Act or any other applicable local, state, national and international laws and regulations relating to the care and use of laboratory animals. Merck encourages Company to use the highest standards, such as those set forth in the Guide for the Care and Use of Laboratory Animals (NRC, 1996), for the humane handling, care and treatment of such research animals. Company hereby certifies that it has and shall maintain current and valid accreditation from AAALAC during the Term. Any animals which are used in the course of the Research Program, or products derived from those animals, such as eggs or milk, will not be used for food purposes, nor will these animals be used for commercial breeding purposes.

### ARTICLE 3 LICENSE; EXCHANGE OF INFORMATION; DEVELOPMENT AND COMMERCIALIZATION.

#### 3.1 License Grants.

- **3.1.1** Company hereby grants to Merck an exclusive sublicense (even as to Company) in the Field and in the Territory under Company's rights in the Einstein Patent Rights and Einstein Know-How, with the right to grant and authorize sublicenses, for any and all uses, including without limitation: (i) to make, have made or use Cue Biologics; (ii) to make, have made, use, import, offer to sell and sell Compound(s) and/or Product(s); and (iii) to otherwise carry out activities contemplated under this Agreement; all within the Field.
- **3.1.2** Company hereby grants to Merck an exclusive license (even as to Company) in the Field and in the Territory under Cue Patent Rights, Cue Know-How, and Company's interest in Joint Patent Rights, with the right to grant and authorize sublicenses, for any and all uses, including without limitation: (i) to make, have made or use Cue Biologics; (ii) to make, have made, use, import, offer to sell and sell Compound(s) and/or Product(s); and (iii) to otherwise carry out activities contemplated under this Agreement; all within the Field.
- 3.1.3 [\*\*\*]
- **3.1.4** Notwithstanding the scope of the exclusive sublicenses and licenses granted to Merck under <u>Section 3.1.1</u> and <u>Section 3.1.2</u>, Company shall retain the rights under the Company Know-How, Company Patent Rights and Joint Patent Rights during the Research Program Term solely in connection with performing Company's obligations under the Research Program in accordance with this Agreement to: (i) research, develop, make, have made, sell, offer to sell, import and use in the Territory, Cue Biologics, Compounds, Products and any invention claimed in or covered by Company Patent Rights or Joint Patent Rights; and (ii) use Company Know-How.
- 3.1.5 [\*\*\*]
- 3.2 Non-Exclusive License Grant. In the event that either: (i) the making, have made or use by Merck or its Related Parties of any Cue Biologics during the term of this Agreement; or (ii) the making, having made, use, import, offer for sale and/or sale by Merck or its Related Parties of Compound or Product in the Territory would infringe a claim of an issued letters patent that Company (or its Affiliate) Controls and which patents are not covered by the grant in Section 3.1, Company hereby grants to Merck, to the extent Company is legally able to do so, a non-exclusive, sublicensable, royalty-free license in the Territory under such issued letters patent for Merck and its Related Parties to conduct such activities with respect to the Cue Biologics, Compounds and Products for all activities in the Field.

- **3.3 No Implied Licenses.** Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Information disclosed to it under this Agreement or under any patents or patent applications owned or Controlled by the other Party or its Affiliates.
- 3.4 No Grant of Inconsistent Rights by Company. Company (and its Affiliates) shall not assign, transfer, convey or otherwise grant to any Person or otherwise encumber (including through lien, charge, security interest, mortgage, encumbrance or otherwise): (i) any rights to any Company Know-How, Company Patent Rights or Company's interest in Joint Patent Rights (or any rights to any intellectual property that would otherwise be included in the Company Know-How, Company Patent Rights or Joint Patent Rights), in any manner that is inconsistent with or would interfere with the grant of the rights or licenses to Merck hereunder; (ii) any rights to any Cue Biologic prior to the expiration of the Research Program Term (provided that Company shall grant to Merck the rights to the Cue Biologics as set forth herein); or (iii) any rights to any Compounds or Products (provided that Company shall grant to Merck the rights to the Compounds and Products as set forth herein). Without limiting the foregoing, during the Term, (x) Company (and its Affiliates) shall not use (and shall not grant to any Third Party the right to use) any Cue Biologics (prior to the expiration of the Research Program Term) or Compounds or Products for any purposes (including the Research, Development, Manufacturing or Commercialization thereof), except for Company's performance of the activities to be performed by Company under the Research Program in accordance with this Agreement and (y) Company (and its Affiliates) shall not provide or otherwise transfer to any Third Parties any Company Know-How which constitutes Cue Biologics-Specific Information and Inventions, for use in the Field.
- **3.5 Development and Commercialization.** Merck shall use Commercially Reasonable Efforts, at its own expense, to Research, Develop and Commercialize a Compound or Product. Company shall timely supply adequate and sufficient amounts of Product Candidates through IND Enabling Studies for each Product Candidate. Merck shall reimburse Company for its reasonable expenses in supplying such adequate and sufficient amounts. Following the Research Program Term, upon Company's written request which shall be no more frequently than once per year, Merck shall provide a written summary of Merck's activities in Researching, Developing and/or Commercializing a Compound or Product ("**Progress Report**").
- **3.6 Excused Performance.** In addition to the provisions of <u>Article 6</u>, the obligations of Merck with respect to any Product under <u>Section 3.5</u> are expressly conditioned upon the continuing absence of any adverse condition or event relating to the safety or efficacy of the Compound or Product, and the obligation of Merck to Research, Develop or Commercialize any such Compound or Product shall be delayed or suspended so long as in Merck's good faith determination any such condition or event exists. Where such adverse condition or event exists, Merck will provide written notice as soon as practicable of a delay or suspension exercised under this <u>Section 3.6</u>.

- 3.7 **Regulatory Matters.** In the event that Merck determines that any regulatory filings for any Compounds and/or Products are required for any activities hereunder (including any activities under the Research Program), including INDs, NDAs and other Marketing Authorizations (as applicable), then as between the Parties, Merck (or its Affiliate or Related Party) shall have the sole right, in its discretion, to obtain such regulatory filings (in its (or its Affiliate's or its Related Party's) name) and as between the Parties, Merck (or its Affiliate or Related Party) shall be the owner of all such regulatory filings. As between the Parties, Merck (or its Affiliate or Related Party) shall have the sole right to communicate and otherwise interact with Regulatory Authorities with respect to the Compounds and/or Products (including during the Research Program Term). For clarity, Company shall have no right to, and shall not, make any regulatory filings related to any Compounds or Products or otherwise interact with any Regulatory Authorities with respect to the Compounds or Products.
- **3.8 Sublicenses.** Merck shall ensure that all sublicenses of the Cue Patent Rights and Cue Know-How granted by Merck under this Agreement comport with the terms of this Agreement, and that all sublicenses of the Einstein Patent Rights and Einstein Know-How granted by Merck under this Agreement comport with the terms of this Agreement and the Amended and Restated Einstein License Agreement.

## ARTICLE 4 CONFIDENTIALITY AND PUBLICATION.

- **4.1 Nondisclosure Obligation.** All Information disclosed by one Party to the other Party hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, except to the extent that such Information:
  - **4.1.1** is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;
  - **4.1.2** is in the public domain by use and/or publication before its receipt from the disclosing Party, or thereafter enters the public domain through no fault of the receiving Party;
  - **4.1.3** is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party;
  - **4.1.4** is developed by the receiving Party independently of Information received from the disclosing Party, as documented by the receiving Party's business records;
  - **4.1.5** is disclosed to governmental or other regulatory agencies in order to obtain patents on Inventions in accordance with <u>Article 7</u> herein or to gain or maintain approval to conduct clinical trials on Compound or Product or to market Product, but such disclosure may be only to the extent reasonably necessary to obtain such patents or approvals;
  - **4.1.6** is deemed necessary by Merck to be disclosed to Related Parties, agent(s), consultant(s), and/or other Third Parties for any and all purposes Merck and its Affiliates deem necessary or advisable in the ordinary course of business to achieve the objectives of this Agreement on the condition that such Third Parties agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; <u>provided, however</u>, that the term of confidentiality for such Third Parties shall be no less than ten (10) years; or



- **4.1.7** is deemed necessary by counsel to the receiving Party to be disclosed to such Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party, on the condition that such attorneys, independent accountants and financial advisors agree to be bound by the confidentiality and non-use obligations contained in this Agreement; <u>provided</u>, <u>however</u>, that the term of confidentiality for such attorneys, independent accountants and financial advisors shall be no less than ten (10) years.
- **4.1.8** is deemed necessary by the receiving Party to be disclosed to such Party's executives, management and other advisors, including but not limited to members of the Board of Directors and/or Scientific Advisory Board, consultants, bankers, lenders, existing and prospective bona fide investors, and prospective merger and/or acquisition partners ("Representatives") on the following conditions: [\*\*\*].

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

If a Party is required by judicial or administrative process (including a request for discovery received in an arbitration or litigation proceeding), or by a statute, regulation or rule of law (e.g., securities laws, rules and regulations), to disclose information that is subject to the non-disclosure provisions of this <u>Section 4.1</u> or <u>Section 4.2</u>, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this <u>Section 4.1</u> and <u>Section 4.2</u>, and the Party disclosing information pursuant to law or court order shall take all steps reasonably necessary, including without limitation obtaining an order of confidentiality, to ensure the continued confidential treatment of such information. The Parties will consult and cooperate fully with each other on the provisions of this Agreement to be redacted in any filings made by the Parties with the Securities and Exchange Commission or similar governmental agency in the U.S. or abroad, or as otherwise required by law.

**4.2 Company Know-How**. During the period from the Effective Date until achievement of Proof of Mechanism for the first Cue Biologic, Company agrees to keep all Company Know-How specifically related to any Cue Biologic, Compound, Product, Indication Specific Peptide, or any Peptide or biologic which is of utility for [\*\*\*\*] confidential subject to <u>Section 4.1</u>. Upon achievement of Proof of Mechanism for the first Cue Biologic, Company agrees to keep all Company Know-How specifically related to any Cue Biologic, Compound, Product, Indication Specific Peptide or any Peptide or biologic which is of utility for [\*\*\*\*] confidential subject to <u>Section 4.1</u>. In the event that a Company Candidate is not designated as a Proposed Product Candidate pursuant to <u>Section 2.11.6.3</u>, then with respect to such Company Know-How which is specifically related to to such Proposed Product Candidate (and not related to any other molecule which is a subject of the Agreement) Company's obligations of confidentiality shall cease.

- 4.3 Publication. Each Party to this Agreement recognizes that the publication or disclosure of papers, presentations, abstracts or any other written or oral presentations regarding results of and other information regarding the subject matter of this Agreement, including the Research Program, may be beneficial to both Parties. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. Accordingly, except for disclosures permitted pursuant to Section 4.1 each Party shall have the right to review and approve any paper or presentation proposed for disclosure by the other Party which utilizes data related to the Research Program, Cue Biologic, Compound or Product and/or includes confidential Information of the other Party. Before any such paper or presentation is disclosed, the Party proposing disclosure shall deliver a complete copy to the other Party at least sixty (60) days prior to submitting the paper to a publisher or making the presentation to a Third Party. The reviewing Party shall have the right (a) to propose modifications to the publication or presentation for patent reasons, trade secret reasons or business reasons or (b) to request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party requests a delay, the publishing Party shall delay submission or presentation for a period of up to ninety (90) days as necessary to enable patent applications protecting each Party's rights in such information to be filed in accordance with Article 7. Upon expiration of such ninety (90) days, the publishing Party shall be free to proceed with the publication or presentation. Notwithstanding the foregoing, if the reviewing Party requests modifications to the publication or presentation including the deletion of certain proprietary information, the publishing Party shall edit such publication to prevent disclosure of trade secret or proprietary business information (including but not limited to information related to Cue Biologics-Specific Information and Inventions) prior to submission of the publication or presentation. The disclosing Party shall comply with any such requests of the reviewing Party.
- **4.4 Publicity/Use of Names/Press Releases.** No disclosure of the existence, or the terms, of this Agreement may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by law. If a Party is required by a statute, regulation or rule of law (e.g., securities laws, rules and regulations), to disclose the existence, or the terms, of this Agreement or the name, trademark, trade name or logo of the other Party, such Party shall promptly inform the other Party of the disclosure that is being sought and provide for a period of at least ten (10) days, or if the period provided by statute, regulation or rule of law is less than ten (10) days, the maximum period allowable thereunder in order to provide the other Party an opportunity to review the disclosure, provide comments, and challenge or limit the disclosure obligations. Information that is disclosed shall remain otherwise subject to the confidentiality and non-use provisions of <u>Section 4.1</u> and <u>Section 4.2</u>, and the Party disclosing information shall take all steps reasonably necessary, to ensure the continued confidential treatment of such information. The Parties will furthermore consult and cooperate fully with each other on the provisions of this Agreement to be redacted in any filings made by the Parties with the Securities and Exchange Commission or similar governmental agency in the U.S. or abroad, or as otherwise required by law.

#### **ARTICLE 5 PAYMENTS; ROYALTIES AND REPORTS**

5.1 License Fee. In consideration for the licenses and other rights granted to Merck herein under the Company Patent Rights, Company Know-How and Company's interest in Joint Patent Rights, upon the terms and conditions contained herein, Merck shall pay to Company US\$ 2,500,000 (two million five hundred thousand) payable within thirty (30) days after the Effective Date. Company shall use these funds to pay for Contract Research as that term is defined in the Amended and Restated Einstein License Agreement.

**5.2 Milestone Payments.** Subject to the terms and conditions of this Agreement, Merck shall pay to Company the following milestone payments, for which Merck or any Related Party achieves, or Company achieves and Merck confirms, the following milestone events hereunder during the Term:

#### 5.2.1 Research Collaboration Milestones.

	Milestone Event	Payment to Company
1.	[***]	[***]
2.	[***]	[***]

# 5.2.2 Development and Regulatory Milestones.

	Milestone	Event P	ayment to Company
3.	[***]	[***]	
4.	[***]	[***]	
5.	[***]	[***]	
6.	[***]	[***]	
7.	[***]	[***]	
8.	[***]	[***]	
9.	[***]	[***]	

**5.3** Merck shall notify Company in writing within sixty (60) days following the achievement of each milestone set forth in <u>Section 5.2.1</u> and <u>Section 5.2.2</u>. With respect to the achievement of a milestone under <u>Section 5.2.1</u> and milestones 1-9 under <u>Section 5.2.2</u>, Merck shall make the appropriate milestone payment within sixty (60) days after the achievement of such milestone. Unless otherwise agreed, the payments for Milestone Event 1 and at least the first two successful Proofs of Concept for Milestone Event 2 shall be used by Company to pay for "Contract Research" as that term is defined in the Amended and Restated Einstein License Agreement. The milestone payments pursuant to <u>Section 5.2.1</u> and <u>Section 5.2.2</u> shall be payable only upon the initial achievement of such milestone [\*\*\*\*]; but in no event shall such milestone payment be paid [\*\*\*\*]. Such milestones are independent of the royalty payments due under <u>Section 5.4</u> and shall not offset or affect the payment of any royalty payments due under <u>Section 5.4</u>.

#### 5.4 Royalties.

- **5.4.1 Royalties Payable By Merck.** Subject to the terms and conditions of this Agreement, Merck shall pay Company royalties, calculated on a Product-by-Product basis, as set forth in <u>Section 5.4</u>.
  - (a) <u>Patent Royalties</u>. Subject to the provisions of <u>Section 5.4.1(b)</u>, Merck shall pay Company royalties in an amount equal to the following percentage of Net Sales of Products by Merck or its Related Parties where the sale of Product would infringe a Valid Patent Claim in the country of sale:
    - (1) [\*\*\*] of Net Sales in the Territory in each Calendar Year up to and including [\*\*\*];
    - (2) [\*\*\*] of Net Sales in the Territory in each Calendar Year for the portion of Net Sales exceeding [\*\*\*] up to and including [\*\*\*]; and
    - (3) [\*\*\*] of Net Sales in the Territory in each Calendar Year for the portion of Net Sales exceeding [\*\*\*].
  - (b) <u>Know-How Royalty</u>. Notwithstanding the provisions of <u>Section 5.4.1(a)</u>, in countries where the sale of Product by Merck or its Related Parties would not infringe a Valid Patent Claim, Merck shall pay royalty rates that shall be set at [\*\*\*] of the applicable royalty rate determined according to <u>Section 5.4.1(a)</u>. Such royalties shall be calculated after first calculating royalties under <u>Section 5.4.1(a)</u>.
  - (c) Royalty tiers pursuant to <u>Section 5.4.1(a)</u> and <u>Section 5.4.1(b)</u> shall be calculated based on Net Sales of each Product in the Territory, provided that the determination of whether the royalty shall be calculated under <u>Section 5.4.1(a)</u> or <u>Section 5.4.1(b)</u> shall be determined on a country-by-country basis. Royalties on each Product at the rates set forth above shall continue on a country-by-country basis until the expiration of the later of: (i) the last-to-expire Valid Patent Claim claiming the Compound; or (ii) for a period of ten (10) years after First Commercial Sale of such Product in such country (the "**Royalty Period**").
  - (d) All royalties are subject to the following conditions:
    - (i) that only one royalty shall be due with respect to the same unit of Product;
    - (ii) that no royalties shall be due upon the sale or other transfer among Merck or its Related Parties, but in such cases the royalty shall be due and calculated upon Merck's or its Related Party's Net Sales to the first independent Third Party;
    - (iii) no royalties shall accrue on the sale or other disposition of Product by Merck or its Related Parties for use in a Clinical Trial; and
    - (iv) no royalties shall accrue on the disposition of Product in reasonable quantities by Merck or its Related Parties as samples (promotion or otherwise) or as donations (for example, to non-profit institutions or government agencies for a noncommercial purpose).

- **5.4.2 Change in Sales Practices.** The Parties acknowledge that during the term of this Agreement, Merck's sales practices for the marketing and distribution of Product may change to the extent to which the calculation of the payment for royalties on Net Sales may become impractical or even impossible. In such event the Parties agree to meet and reasonably discuss in good faith new ways of compensating Company to the extent currently contemplated under <u>Section 5.4.1</u>.
- **5.4.3 Royalties for [\*\*\*\*].** In those cases in which [\*\*\*\*], the royalty obligations of this <u>Section 5.4</u> shall be applicable to the compensation and/or other amount of consideration received by Merck [\*\*\*\*].
- **5.4.4 Compulsory Licenses.** If a compulsory license is granted to a Third Party with respect to Compound or Product in any country in the Territory with a royalty rate lower than the royalty rate provided by <u>Section 5.4.1</u>, then the royalty rate to be paid by Merck on Net Sales in that country under <u>Section 5.4.1</u> shall be reduced to the rate paid by the compulsory licensee.

5.4.5 [\*\*\*]

- **5.4.6 Royalty Rates.** Notwithstanding any provision in this Agreement, where a royalty payment is due in a particular country, in no event shall Merck pay royalty rates on Net Sales of any Product in such country that are less than [\*\*\*]. Accordingly, [\*\*\*] the royalty rate can under no circumstance go lower than [\*\*\*].
- 5.5 **Reports; Payment of Royalty.** During the term of this Agreement following the First Commercial Sale of a Product, Merck shall furnish to Company a quarterly written report for the Calendar Quarter showing the Net Sales of all Products subject to royalty payments sold by Merck and its Related Parties in the Territory during the reporting period and the royalties payable under this Agreement. Subject to the provisions of <u>Section</u> <u>9.2.2</u>, if applicable, such reports shall be sufficiently detailed so as to permit company to independently determine the accuracy of the amount of royalties paid. Reports shall be due on the sixtieth (60th) day following the close of each Calendar Quarter. Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. Merck shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined.

#### 5.6 Audits.

**5.6.1** Upon the written request of Company and not more than once in each Calendar Year, Merck shall permit an independent certified public accounting firm of nationally recognized standing selected by Company and reasonably acceptable to Merck, at Company's expense, to have access during normal business hours to such of the records of Merck as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any Calendar Year ending not more than twenty-four (24) months prior to the date of such request. The accounting firm shall disclose to Company only whether the royalty reports are correct or incorrect and the amount of any discrepancy. No other information shall be provided to Company. The accounting firm shall be given copies of all documents needed to accurately perform the accounting being unredacted.

- **5.6.2** If such accounting firm correctly identifies an underpayment by Merck during such period, then Merck shall pay to Company the amount of the discrepancy within thirty (30) days of the date Company delivers to Merck such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by Company, except in the situation that the accounting firm determines that Merck has underpaid by the greater of [\*\*\*] or [\*\*\*] the royalties it owed for any Calendar Year reviewed by the accounting firm. If such accounting firm correctly identified an overpayment by Merck during such period, then such overpayment shall be withheld from a next payment due from Merck to Company.
- **5.6.3** Merck shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the sublicensee to make reports to Merck, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by Company's independent accountant to the same extent required of Merck under this Agreement.
- **5.6.4** Upon the expiration of twenty-four (24) months following the end of any Calendar Year, the calculation of royalties payable with respect to such Calendar Year shall be binding and conclusive upon Company, and Merck and its Related Parties shall be released from any liability or accountability with respect to royalties for such Calendar Year.
- **5.6.5** Company shall treat all financial information subject to review under this <u>Section 5.6</u> or under any sublicense agreement in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Merck and/or its Related Parties obligating it to retain all such information in confidence pursuant to such confidentiality agreement.
- 5.7 **Payment Exchange Rate.** All payments to be made by Merck to Company under this Agreement shall be made in United States dollars and may be paid by check made to the order of Company or bank wire transfer in immediately available funds to such bank account in the United States as may be designated in writing by Company from time to time. In the case of sales outside the United States, the rate of exchange to be used in computing the monthly amount of currency equivalent in United States dollars due Company shall be made at the monthly rate of exchange utilized by Merck in its worldwide accounting system.
- **5.8 Income Tax Withholding.** Company shall be liable for all income and other taxes (including interest) ("**Taxes**") imposed upon any payments made by Merck to Company under this <u>Article 5</u> ("**Agreement Payments**"). If applicable laws, rules or regulations require the withholding of Taxes because of Company's tax obligations, Merck shall make such withholding payments and shall subtract the amount thereof from the Agreement Payments. For clarity, Merck shall not deduct from Agreement Payments any Taxes withheld by Merck to satisfy Merck's tax obligations. Merck shall submit to Company appropriate proof of payment of the withheld Taxes as well as the official receipts within a reasonable period of time. Merck shall provide Company reasonable assistance in order to allow Company to obtain the benefit of any present or future treaty against double taxation which may apply to the Agreement Payments.

#### ARTICLE 6 REPRESENTATIONS AND WARRANTIES

- 6.1 **Representations and Warranties of Each Party.** Each Party represents and warrants to the other Party that as of the Effective Date:
  - **6.1.1** such Party is duly organized and validly existing under the laws of the state or jurisdiction of its organization and has full corporate right, power and authority to enter into this Agreement and to perform its obligations hereunder;
  - **6.1.2** the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by the necessary corporate actions of such Party. This Agreement has been duly executed by such Party. This Agreement and any other documents contemplated hereby constitute valid and legally binding obligations of such Party enforceable against it in accordance with their respective terms, except to the extent that enforcement of the rights and remedies created thereby is subject to bankruptcy, insolvency, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors; and
  - **6.1.3** the execution, delivery and performance by such Party of this Agreement and any other agreements and instruments contemplated hereunder will not: (i) in any respect violate any statute, regulation, judgment, order, decree or other restriction of any governmental authority to which such Party is subject; (ii) violate any provision of the corporate charter, by-laws or other organizational documents of such Party; or (iii) constitute a material violation or breach by such Party of any provision of any material contract, agreement or instrument to which such Party is a party or to which such Party may be subject although not a party.
- 6.2 Company Representations and Warranties. Company represents and warrants to Merck that as of the date of this Agreement:
  - **6.2.1** all Patent Rights within the Company Patent Rights are in full force and effect, and, to the best of Company's knowledge, the Company Patent Rights and Company Know-How exist and are not invalid or unenforceable, in whole or in part;
  - **6.2.2** it has the full right, power and authority to enter into this Agreement, to perform the activities hereunder, including the Research Program, and to grant the license and sublicense granted hereunder (including under <u>Article 3</u>);
  - **6.2.3** it (and its Affiliates) has not prior to the Effective Date: (i) assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Company Patent Rights or Company Know-How; or (ii) otherwise granted any rights to any Third Parties that would conflict with the rights granted to Merck hereunder;
  - **6.2.4** it is the sole and exclusive owner or licensee of the Cue Patent Rights and Cue Know-How, all of which are (and shall be, in the case of Company Information and Inventions) free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has or shall have any claim of ownership whatsoever with respect to the Cue Patent Rights and Cue Know-How;

- **6.2.5** to the best of Company's knowledge, it is the sole and exclusive licensee of the Einstein Patent Rights and Einstein Know-How, all of which are free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has or shall have any claim of ownership whatsoever with respect to the Einstein Patent Rights and Einstein Know-How, with the exception that Company is aware that the United States Government has sponsored certain related research of Albert Einstein and may have certain rights in any subject inventions resulting therefrom;
- **6.2.6** to the best of Company's knowledge, the exercise of the license granted to Merck under the Company Patent Rights and Company Know-How, including without limitation the Research, Development, Manufacture, use, sale and import of Cue Biologics, Compounds and Products do not interfere with or infringe any intellectual property rights owned or possessed by any Third Party other than Albert Einstein;
- **6.2.7** there are no claims, judgments or settlements against or owed by Company (or any of its Affiliates) and no pending or threatened claims or litigation relating to the Company Patent Rights and Company Know-How;
- **6.2.8** to the best of Company's knowledge, Company has disclosed to Merck all reasonably relevant information which Company reasonably believes to be necessary for Merck to accomplish the goals of the Research Program and any additional information requested by Merck regarding: (i) the Cue Biologics, Compounds or Products; and/or (ii) the Company Patent Rights and Company Know-How licensed under this Agreement, including: (a) any licenses and material agreements related to the Company Patent Rights, Company Know-How, Cue Biologics, Compounds and/or Products; and (b) and safety or efficacy information related to the Cue Biologics, Compounds and/or Products;
- **6.2.9** Company has disclosed to Merck the existence of any patent opinions related to the Company Patent Rights and Company Know-How licensed under this Agreement;
- **6.2.10** neither it nor any of its Affiliates has received any written notification from a Third Party that the Research, Development, Manufacture, use, sale or import of Cue Biologics, Compounds or Products infringes or misappropriates the Patent Rights or know-how owned or controlled by such Third Party, and Company has no knowledge that a Third Party has any basis for any such claim;
- **6.2.11** Company has complied with all existing country-specific laws and regulations involving inventor remuneration associated with the Company Patent Rights, including <u>Article 6</u> of the Third Amendment of Chinese Patent Law;
- **6.2.12** Schedule 1.1 sets forth a true, correct and complete list of Company Patent Rights existing as of the Effective Date and such schedule contains all application numbers and filing dates, registration numbers and dates, jurisdictions and owners. The Company Patent Rights and Company Know-How constitute all intellectual property owned or otherwise controlled (through license or otherwise) by Company (or any of its Affiliates) as of the Effective Date that are necessary or useful for (or otherwise used by Company or any of its Affiliates in connection with), the Cue Biologics, Compounds and/or Products or the Research, Development, Manufacture, Commercialization and/or use thereof;



- **6.2.13** to the best of Company's knowledge, Company has disclosed to Merck all material information and data which Company reasonably believes to be necessary for Merck to accomplish the goals of the Research Program and any additional information requested by Merck, in each case related to the Research Program and/or any Cue Biologics, Compounds or Products, regardless of whether such data and information would have a positive, negative or neutral impact on the potential commercial, scientific or strategic value or attractiveness of the Research Program, any Cue Biologics, Compounds or Products;
- **6.2.14** Company has obtained all necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by it as of the Effective Date, as applicable, in connection with the execution, delivery and performance of this Agreement;
- **6.2.15** neither Company nor any of its Affiliates has obtained, or filed for, any INDs, NDAs or Marketing Authorizations for any Cue Biologics, Compounds or Products, and, to the best of Company's knowledge, no other Person has obtained, or filed for, any INDs, NDAs or Marketing Authorizations for any Cue Biologics, Compounds or Products;
- **6.2.16** to the best of Company's knowledge, Company (and its Affiliates) has not employed or otherwise used in any capacity, and will not employ or otherwise use in any capacity, the services of any Person debarred under United States law, including under Section 21 USC 335a or any foreign equivalent thereof, with respect to the Cue Biologics, Compounds or Products or otherwise in performing any portion of the Research Program.
- **6.2.17** to the best of Company's knowledge, all research and development (including non-clinical studies) related to the Cue Biologics, Compounds and/or Products prior to the Effective Date has been conducted in accordance with all Applicable Laws;
- **6.2.18** except for the Third Party licenses and agreements resulting from the receipt of certain grants by Albert Einstein from the United States Government, there are no agreements (including any licenses), written or oral, granting any licenses or other rights to (or from) Company (or any of its Affiliates) relating to the Cue Biologics, Compounds or Products or the Company Know-How or Company Patent Rights;
- **6.2.19** with respect to each Third Party license: (i) it is in full force and effect; (ii) neither Company nor any of its Affiliates is in breach thereof; (iii) neither Company nor any of its Affiliates has received any notice of breach or notice of threatened breach thereof; and (iv) neither Company nor any of its Affiliates has received any notice from the counterparty to such Third Party license of intent to reduce the scope of the field thereof or render any of the licenses thereunder non-exclusive, and no event, act or omission has occurred which could give rise to the right of the counterparty to such Third Party license to reduce the scope of the field thereof or render any of the licenses thereunder non-exclusive;
- **6.2.20** to the best of Company's knowledge, all information and data provided by or on behalf of Company to Merck on or before the Effective Date in contemplation of this Agreement was and is true and accurate and complete in all material respects, and Company has not intentionally disclosed, failed to disclose, or cause to be disclosed, any information or data that would reasonably be expected to cause the information and data that has been disclosed to be misleading in any material respect; and

**6.2.21** it has or ensures that it will have the resources and capabilities to do the work contemplated by the Research Program.

For purposes of the above representations, the phrase "to the best of Company's knowledge" means that the employee(s) of the Company with responsibility for the matter have conducted a reasonable inquiry regarding such matter.

6.3 Company Third Party License Agreements Representations, Warranties and Covenants. Company represents and warrants to Merck that it has provided to Merck as of the Effective date a true, correct and complete copy of each relevant Company Third Party license agreements, and each such copy includes any and all amendments, restatements, side letters, and other modifications thereto, as each such Company Third Party license agreement is in effect as of the Effective Date. Company further covenants and agrees that during the Term, (a) it shall satisfy all of its obligations under (including making all payments), and take all steps to maintain in full force and effect, each such relevant Company Third Party license agreements; (b) it will not assign (except an assignment to a party to which this Agreement has been assigned as permitted under Section 9.2), amend, restate, amend and restate, terminate in whole or in part, or otherwise modify any of the Company Third Party license agreements necessary or useful to Merck's exercise of the rights granted in this Agreement without the prior written consent of Merck; (c) it will provide Merck with prompt notice of any claim of a breach under any of the Company Third Party license agreements or notice of termination of any of the Company Third Party license agreements, made by either Company or the counterparty to such Company Third Party license agreement (or any party acting on behalf of such counterparty); and, (d) it will promptly send to Merck copies of all other material correspondence to or from the counterparty to such Company Third Party license agreement related to such Company Third Party license agreement. For the purposes of clarity, Company (and not Merck) shall be responsible for all of the financial and other obligations of Company (and/or any of its Affiliates) under any of the Company Third Party license agreements, including any and all financial obligations thereunder with respect to Net Sales of Merck and its Related Parties. Merck shall have the right, in its sole discretion, to terminate this Agreement immediately upon written notice to Company pursuant to Section 8.3, in the event that Company is in breach of this Section 6.3.

## **ARTICLE 7 PATENT PROVISIONS.**

7.1 [\*\*\*\*]

- (a) Merck shall have the sole right to file, prosecute, maintain and defend patent applications on Merck Information and Inventions ("**Merck Other Information and Inventions"**);
- (b) Company shall have the sole right to file, prosecute, maintain and defend patent applications on Company Information and Inventions ("**Company Other Information and Inventions**"); and
- (c) The Patent Committee will review proposed patent filings pertaining to Joint Other Information and Inventions. A Party that believes that a patent application should be filed regarding any Joint Information and Inventions which constitute Other Information and Inventions ("Joint Other Information and Inventions") shall bring the matter to the attention of the Patent Committee and the Patent Committee shall discuss how to proceed. If Merck takes the lead in filing and prosecuting the application, then the Parties shall follow the general procedure described in Section 7.1.1. If Company takes the lead in filing and prosecuting the application regarding any Joint Information and Inventions should be filed, then the Parties will split the costs evenly or as otherwise agreed. If only one Party believes that a patent application regarding any Joint Information should be filed, then the Parties will split the costs evenly or as otherwise agreed. If only one Party believes that a patent application regarding any Joint Information regarding any Joint Information and Inventions should be filed, then that Party shall bear all costs unless the Parties agree otherwise.
- **7.1.4 Patent Term Extension.** The Parties shall cooperate fully with each other to provide necessary information and assistance, as the other Party may reasonably request, in obtaining patent term extension or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Company Patent Rights and Joint Patent Rights. In the event that elections with respect to obtaining such patent term extension are to be made, Merck shall have the right to make the election and Company agrees to abide by such election.
- 7.1.5 **Other Cooperation.** The Parties agree to cooperate fully and provide any information and assistance that either may reasonably request for the filing, prosecution and maintenance of Company Patent Rights and Joint Patent Rights, including but not limited to the preparation and filing of any terminal disclaimers and other documents required to procure and preserve the protections under Applicable Law for all Company Patent Rights and Joint Patent Rights relevant to a Compound or Product. The Parties further agree to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. 102(c) for U.S. patents and patent applications.
- **7.1.6 Filing, Prosecution and Maintenance Expenses.** Unless stated otherwise herein, with respect to all filing, prosecution and maintenance activities under this <u>Section 7.1</u>, the filing and/or prosecuting Party shall be responsible for payment of all costs and expenses related to such activities.
- **7.1.7 Inventor Remuneration.** Company shall comply with all applicable country-specific inventor remuneration laws and regulations, including <u>Article 6</u> of the Third Amendment of Chinese Patent Law associated with Company Patent Rights and Joint Patent Rights when inventor remuneration obligations are triggered by an employee of Company and/or its Affiliates, or a Third Party acting on behalf of Company and/or its Affiliates.



7.2 Interference, Derivation, Opposition, Reexamination, Reissue, Supplemental Examination, *Inter Partes* Review and Post-Grant Review Proceedings.

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- **7.2.3 Cooperation.** In connection with any administrative proceeding under <u>Section 7.2.1</u> or <u>Section 7.2.2</u>, Merck and Company shall cooperate fully and provide each other with any information or assistance that either may reasonably request. The Parties shall keep each other informed of developments in any such action or proceeding, including the status of any settlement negotiations and the terms of any offer related thereto. For any proceeding not controlled by Merck, Company shall obtain prior approval from Merck of any settlement offer or settlement agreement. For any proceeding specifically related to Platform Information and Inventions which is not controlled by Company, Merck shall obtain prior approval from Company of any settlement offer or settlement agreement.
- **7.2.4 Expenses.** The Party controlling any administrative proceeding pursuant to <u>Section 7.2.1</u> and <u>Section 7.2.2</u> shall bear all expenses related thereto, unless the Parties agree otherwise.

# 7.3 Enforcement and Defense.

- 7.3.1 [\*\*\*\*]
- **7.3.2** The Party having the first right to initiate and prosecute legal action pursuant to <u>Section 7.3.1</u> shall promptly inform the other Party if it elects not to exercise its first right under <u>Section 7.3.1</u> to initiate and prosecute legal action, and the other Party shall thereafter have the right to either initiate and prosecute such action or to control the defense of such declaratory judgment action in its name and, if necessary, the name of the other Party. The costs of any agreed-upon course of action to terminate infringement of Company Patent Rights or Joint Patent Rights or misappropriation or misuse of Company Know-How, including without limitation the costs of any legal action commenced or the defense of any declaratory judgment, shall be paid by the Party initiating and/or prosecuting the action. Each Party shall have the right to be represented by counsel of its own choice.

- **7.3.3** For any action to terminate any infringement of Company Patent Rights or Joint Patent Rights or any misappropriation or misuse of Company Know-How pursuant to <u>Section 7.3.1</u>, in the event that a Party is unable to initiate or prosecute such action solely in its own name, the other Party will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for the Party to initiate litigation to prosecute and maintain such action under this <u>Section 7.3</u>. In connection with any action or potential action, Merck and Company will cooperate fully and will provide each other with any information or assistance that either may reasonably request, including cooperating with regard to any pre-litigation review of the Company Patent Rights and Joint Patent Rights. Each Party shall keep the other informed of developments in any action or proceeding. For any proceeding not controlled by Merck, Company shall obtain prior approval from Merck of any settlement offer or settlement agreement. For any proceeding specifically related to Platform Information and Inventions not controlled by Company, Merck shall obtain prior approval from Company of any settlement offer or settlement agreement.
- **7.3.4** Any recovery obtained by either or both Merck and Company in connection with or as a result of any action contemplated by this <u>Section</u> <u>7.3</u>, whether by settlement or otherwise, shall be shared in order as follows:
  - (a) the Party which initiated and prosecuted the action shall recoup all of its costs and expenses incurred in connection with the action;
  - (b) the other Party shall then, to the extent possible, recover its costs and expenses incurred in connection with the action; and
  - (c) the amount of any recovery remaining shall then be allocated between the Parties on a pro rata basis taking into consideration the relative economic losses suffered by each Party.
- **7.3.5** Company shall inform Merck of any matter of which it becomes aware concerning the submission of an application to the U.S. Food & Drug Administration under Section 351(k) of the U.S. Public Health Services Act (42 USC 262(k)), or to a similar agency under any similar provisions in a country in the Territory, seeking approval of a biosimilar or interchangeable biological product with regard to which Merck is a reference product sponsor involving Company Patent Rights or Joint Patent Rights ("Biosimilar Application"). Company shall provide Merck with the unopened Biosimilar Application within three (3) days of receipt. Notwithstanding the foregoing provisions of <u>Article 7</u>, Merck shall have the sole right, in its discretion, to control any legal action and any activity taken to resolve a dispute with respect to any infringement of Company Patent Rights or Joint Patent Rights with respect to any Biosimilar Application, including selection of any patents for listing under 42 U.S.C. §262(l), and Company shall have no rights in connection therewith. For any action with Merck is unable to initiate or prosecute such action solely in its own name, Company will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for Merck to initiate, prosecute and maintain such action. In connection with any action, Company shall cooperate with Merck and provide Merck with information and assistance that Merck may reasonably request, including as defined in <u>Section 7.3.3</u>.

### **ARTICLE 8 TERM AND TERMINATION**

- **8.1 Term and Expiration.** This Agreement shall be effective as of the Effective Date and unless terminated earlier pursuant to <u>Section 8.2</u> or <u>Section 8.3</u>, this Agreement shall continue in full force and effect until one or more Products has received Marketing Authorization and, thereafter, until expiration of all royalty obligations hereunder. In the event that [\*\*\*].
- 8.2 Termination by Merck. Notwithstanding anything contained herein to the contrary, Merck shall have the right to terminate this Agreement at any time in its sole discretion by giving thirty (30) days' advance written notice to Company. For the avoidance of doubt, termination by Merck under this <u>Section 8.2</u> can be effected only through a written notice specifically referring to this <u>Section 8.2</u>. No later than thirty (30) days after the effective date of such termination, each Party shall return or cause to be returned to the other Party all Information in tangible form received from the other Party and all copies thereof; <u>provided</u>, <u>however</u>, that each Party may retain one copy of Information received from the other Party in its confidential files for record purposes. In the event of termination under this <u>Section 8.2</u>: (i) each Party shall pay all amounts then due and owing as of the termination date; and (ii) except for the surviving provisions set forth in <u>Section 8.4</u>, the rights and obligations of the Parties hereunder shall terminate as of the date of such termination; <u>provided</u>, <u>however</u>, that upon payment of the License Fee pursuant to <u>Section 5.1</u> Merck shall have a fully paid-up non-exclusive license under Company Information and Inventions and Company's interest in Joint Information and Inventions to [\*\*\*]. Upon termination, the Parties shall confer to determine how the Joint Patent Rights will be addressed.

### 8.3 Termination for Cause.

- **8.3.1 <u>Cause for Termination.</u>** This Agreement may be terminated at any time during the term of this Agreement:
  - (a) upon written notice by either Party if the other Party is in breach of its material obligations hereunder by causes and reasons within its control and has not cured such breach within ninety (90) days after notice requesting cure of the breach; <u>provided</u>, <u>however</u>, in the event of a good faith dispute with respect to the existence of a material breach, the ninety (90) day cure period shall be tolled until such time as the dispute is resolved pursuant to <u>Section 9.7</u>; or
  - (b) by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; <u>provided</u>, <u>however</u>, that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

### 8.3.2 Effect of Termination for Cause on License.

(a) If either Merck or Company terminates this Agreement under <u>Section 8.3.1(a)</u> or <u>Section 8.3.1(b)</u>, then Merck's sublicense(s) and license(s) pursuant to <u>Section 3.1</u> and <u>Section 3.2</u> shall terminate as of such termination date and each Party shall, within thirty (30) days after the effective date of such termination, return or cause to be returned to the other Party all Information of the other Party in tangible form and substances or compositions delivered or provided by the other Party, as well as any other material provided by the other Party in any medium; <u>provided</u>, <u>however</u>, that each Party may retain one copy of Information received from the other Party in its confidential files for record purposes.



- (b) If Merck terminates this Agreement under <u>Section 8.3.1(a)</u> for willful conduct of Company resulting in a material breach of [\*\*\*], which material breach cannot be cured within one hundred twenty (120) days of written notice from Merck detailing such alleged breach, and which uncured material breach results in a material adverse effect on Merck's rights under this Agreement, then Merck shall have the option in its sole discretion to either: (i) pursue all remedies available to it at law or in equity; or (ii) have as its sole remedy the reduction of any payments pursuant to <u>Article 5</u> [\*\*\*], such option to be provided in writing by Merck to Company within one hundred fifty (150) days of the written notice from Merck detailing the alleged breach. Notwithstanding the foregoing, if there is a good faith dispute between the Parties regarding whether there has been such an uncured material breach, such question shall be determined in accordance with <u>Section 9.7</u>.
- (c) Upon termination of this Agreement by Merck pursuant to <u>Section 8.2</u>, or by Company pursuant to <u>Section 8.3.1(a)</u>, Merck and its Affiliates, sublicensees and distributors shall be entitled, during the twelve (12) month period immediately following the effective date of termination, to finish any work-in-progress and to sell any Product or Compound remaining in inventory, in accordance with the terms of this Agreement.
- (d) If this Agreement is terminated by Merck pursuant to <u>Section 8.3.1(b)</u> due to the rejection of this Agreement by or on behalf of Company under Section 365 of the United States Bankruptcy Code (the "Code"), all licenses and rights to licenses granted under or pursuant to this Agreement by Company to Merck are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. The Parties agree that Merck, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against Company under the Code, Merck shall be entitled to a complete duplicate of or complete access to (as Merck deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to Merck: (i) upon any such commencement of a bankruptcy proceeding upon written request therefore by Merck, unless Company elects to continue to perform all of its obligations under this Agreement; or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of Company upon written request therefore by Merck.

The foregoing provisions of <u>Section 8.3.2(d)</u> are without prejudice to any rights Merck may have arising under the Code or other applicable law.

- 8.4 **Termination of the Amended and Restated Einstein License Agreement**. Merck may terminate this Agreement under <u>Section 8.3.1(a)</u>. in the event that the Amended and Restated Einstein License Agreement between Albert Einstein and Cue is terminated prior to expiration of the last-to-expire patent rights licensed to Company thereunder. In such event, Merck shall at its option enter directly into a license with Albert Einstein pursuant to <u>Section 10.07</u> of the Amended and Restated Einstein License Agreement dated July 31, 2017, as amended in the Merck Amendment to the Amended and Restated License Agreement dated November 10, 2017, and the Consent and Waiver Agreement dated November 14, 2017 between Merck and Albert Einstein. For clarity, if Merck terminates this Agreement under <u>Section 8.3.1(a)</u> except for termination due to Company's willful conduct as set forth in <u>Section 8.3.1(b)</u>, then Merck's sublicense(s) and license(s) pursuant to <u>Section 3.1</u>, and <u>Section 3.2</u> shall terminate pursuant to <u>Section 8.3.2(a)</u> and Merck shall have no rights under Company Patent Rights and Company Know-How unless provided directly from Albert Einstein.
- **8.5** Effect of Expiration or Termination; Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including without limitation the obligation to pay royalties for Product(s) or Compound sold prior to such expiration or termination. The provisions of <u>Article 4</u> shall survive the expiration or termination of this Agreement and shall continue in effect for ten (10) years. In addition, the provisions of <u>Article 1</u>, <u>Article 3</u>, <u>Article 6</u>, <u>Article 7</u>, <u>Article 8</u>, <u>Article 9</u> and <u>Sections 2.6, 2.8, 2.9, 2.11 and 5.2 5.8</u> shall survive any expiration or termination of this Agreement.

## **ARTICLE 9 MISCELLANEOUS**

- **9.1 Force Majeure**. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including, but not limited to, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.
- **9.2** Assignment/Change of Control. Except as provided in this <u>Section 9.2</u>, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party.
  - **9.2.1** Merck may, without consent of Company, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of Merck or in connection with a Change of Control.
  - **9.2.2** Company may assign this Agreement in its entirety to the successor party in connection with a Change of Control. In the event that there is a Company Change of Control that is a Competing Pharma Change of Control, then Company shall provide written notice to Merck at least thirty (30) days prior to the completion of such Change of Control, i.e., the closing of the transaction that results in Change of Control, and Merck shall have the right, at Merck election at any time after such Change of Control to implement some or all of the following revisions to this Agreement:
    - (a) Merck may limit its obligations to provide Company royalty related reports pursuant to <u>Section 5.5</u> to reporting only Merck's total royalty obligations; <u>provided</u> that, Merck will, if requested by Company, provide royalty reports specified in such <u>Section 5.5</u> to an independent certified public accounting firm for auditing in accordance with <u>Section 5.6</u>.
    - (b) Merck shall have the right to require Company, including the Change of Control party, to adopt reasonable procedures to be agreed upon in writing with Merck to prevent the disclosure of all Information of Merck and other information with respect to the Research, Development, Manufacture and Commercialization of Compounds and Products (collectively "Sensitive Information") beyond Company personnel having access to and knowledge of Sensitive Information prior to the Change of Control and to control the dissemination of Sensitive Information disclosed after the Change of Control. The purposes of such procedures shall be to strictly limit such disclosures to only those personnel having a need to know Sensitive Information in order for Company to perform its obligations under this Agreement and to prohibit the use of Sensitive Information for competitive reasons against Merck and its Related Parties, and for Compounds or Products, including without limitation, the use of Sensitive Information for the research, development or commercialization of competing products.

- **9.2.3** In the event that there is a Company Change of Control: [\*\*\*].
- **9.2.4** Any attempted assignment not in accordance with this <u>Section 9.2</u> shall be void. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.
- **9.3 Use of Affiliates.** Merck shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates.
- **9.4 Severability.** If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

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**9.5 Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Company, to:	Cue Biopharma, Inc. 675 West Street Cambridge, MA 02142 Attention: Daniel Passeri, President and CEO Email: <u>dpasseri@cuebio.com</u>
and:	Mark R. Busch K&L Gates LLP 214 North Tryon Street, 47th Floor Charlotte, NC 28202 Phone: 704.331.7440 Fax: 704.353.3694 <u>mark.busch@klgates.com</u>
if to Merck, to:	Merck Sharp & Dohme Corp. One Merck Drive Whitehouse Station, NJ 08889-0100 Attention: Office of Secretary Facsimile No.: (908) 735-1246
And	Merck Sharp & Dohme Corp. 2000 Galloping Hill Road PO Box 539 Mailstop K-1-4161 Kenilworth, NJ 07033-1310 Attention: Senior Vice President, Business Development

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a business day (or if delivered or sent on a non-business day, then on the next business day); (b) on the business day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) business day following the date of mailing, if sent by mail. The Parties hereby agree that, to the extent permitted by law, any notice provided in accordance with this <u>Section 9.5</u> shall constitute due service of process with respect to any legal proceeding between the Parties arising hereunder and that compliance with the Hague Convention for the Service of Process, if otherwise applicable, shall not be required.

**9.6** Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to any rules of conflict of laws or renvoi.

## 9.7 Dispute Resolution.

- **9.7.1** The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof (a **"Dispute"**). Any Party shall give the other Party written notice of any Dispute not resolved in the normal course of business. Within twenty (20) days from the date of delivery of such notice, the receiving Party shall submit to the other Party a written response. The notice and response shall include (a) a statement of that Party's position and a summary of arguments supporting that position, and (b) the name and title of the executive who will represent that Party and of any other person who will accompany the executive. Within forty-five (45) days from the date of delivery of the initial notice, the executives of both Parties shall meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the Dispute. These executives shall have the authority to settle the Dispute and shall be at a higher level of management than the persons with direct responsibility for administration of this Agreement. All negotiations pursuant to this paragraph are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.
- **9.7.2** If the Parties do not fully settle following the procedure in <u>Section 9.7.1</u>, and a Party wishes to pursue the matter, each dispute, controversy or claim arising from or related to this Agreement or the breach thereof that is not an **"Excluded Claim"** shall be brought in the federal court for the Southern District of New York, if federal jurisdiction is available, or, alternatively, in the state court in the borough of Manhattan, New York City, New York. Each of the Parties hereby submits to the exclusive jurisdiction of such courts for the purpose of any such litigation; provided, that a final judgment in any such litigation shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. **Each party irrevocably and unconditionally agrees not to assert (a) any objection which it may ever have to the laying of venue of any such litigation in such courts, (b) any claim that any such litigation brought in any such court has been brought in an inconvenient forum, and (c) any claim that such court does not have jurisdiction with respect to such litigation. EACH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT TO A TRIAL BY JURY AND AGREES THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY LITIGATION.**
- **9.7.3** As used in this <u>Section 9.7</u>, the term **"Excluded Claim"** shall mean a dispute, controversy or claim that concerns (a) a decision by the Joint Steering Committee, the Patent Committee, or Merck within the proper scope of the Committee's authority pursuant to Section 2.4 or Section 2.5, or an issue concerning the integrity of data submitted to a regulatory agency, neither of which shall be arbitrable or justiciable in any forum; (b) the validity or infringement of a patent, trademark or copyright; or (c) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory. Any action concerning Excluded Claims identified in clauses (b) and (c) of this Paragraph may be brought in any court having jurisdiction.
- **9.8 Limitation of Liability.** Notwithstanding anything to the contrary contained herein, no party shall be liable to another party under any theory for any special, incidental, indirect, consequential or other similar damages, or any punitive damages, whether arising directly or indirectly out of the transactions contemplated by this Agreement. To be clear, neither party shall be entitled to recover for any lost profit or lost sale damages of any kind, whether those claimed damages are direct or indirect.

**9.9** Entire Agreement; Amendments. This Agreement, together with the Schedules and Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter hereof are superseded by the terms of this Agreement. The Schedules and Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

Notwithstanding anything to the contrary in the foregoing, that certain confidentiality agreement between the Parties dated as of May 15, 2017, shall remain in full force and effect with respect to the subject matter thereof and information disclosed thereunder.

- **9.10 Headings.** The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.
- **9.11 Independent Contractors**. It is expressly agreed that Company and Merck shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Company nor Merck shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.
- **9.12 Waiver.** The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.
- **9.13 Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.
- **9.14 Certain Conventions.** Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa.
- **9.15 Business Day Requirements.** In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a business day (excluding notices required under <u>Section 3.6</u>), then such notice or other action or omission shall be deemed to be required to be taken on the next occurring business day.

**Counterparts.** This Agreement may be signed in any number of counterparts (including by facsimile or electronic transmission), each of which shall be deemed an original, but all of which shall constitute one and the same instrument. After facsimile or electronic transmission, the Parties agree to execute and exchange documents with original signatures.

# [Remainder of page intentionally left blank. Signature page follows.]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

# MERCK SHARP & DOHME CORP.

BY: /s/ [\*\*\*] [\*\*\*]

TITLE: Senior Vice President and Global Head of Business Development & Licensing

# CUE BIOPHARMA, INC.

BY: /s/ Daniel Passeri

Daniel Passeri

TITLE: President and CEO

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Schedule 1.1

Schedule 2.1

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# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors Cue Biopharma, Inc.

We hereby consent to the use in the Prospectus constituting a part of this pre-effective amendment number 4 to Form S-1 Registration Statement (registration number 333-220550) of our report dated September 21, 2017, relating to the balance sheets of Cue Biopharma, Inc. (the "Company") as of December 31, 2016 and 2015, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2016, which is contained in the Prospectus. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

We also consent to the reference to us under the caption "Experts" in the Prospectus.

/s/ Gumbiner Savett Inc. December 11, 2017 Santa Monica, California