Filed pursuant to Rule 424(b)(1) Registration No. 333-220550 Registration No. 333-222211



### Up to 9,333,333 Shares of Common Stock

# **CUE BIOPHARMA, INC.**

We are offering up to 9,333,333 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 approximately \$70,000,000 of common stock.

This is an initial public offering of our common stock. The public offering price is \$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 16 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 January 13, 2018 (the "Initial Offering Termination Date"), which date may be extended to a date up to and including March 14, 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	\$70,000,000
Underwriting commissions <sup>(1)(2)</sup>	\$0.36	\$ 1,920,000	\$ 3,360,000
Proceeds, before expenses, to us <sup>(3)</sup>	\$7.14	\$ 38,080,000	\$66,640,000

- (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 Feltl 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 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, Feltl 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, Feltl 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

Total Minimum

Total Maximum

The date of this prospectus is December 14, 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 and trade names. We do not intend our use or display of other companies' trademarks, service marks or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

### 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<sup>TM</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>TM</sup>, a growing portfolio of precision immuno-modulatory drug candidates, and two supporting technologies we call MOD<sup>TM</sup> and viraTope<sup>TM</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

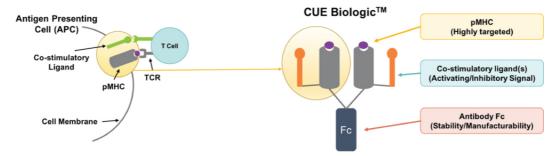
these interactions directs the quality and magnitude of the T cell response. Specific costimulatory signals (activating receptors), as well as coinhibitory signals (inhibitory receptors), may be delivered by the APC to the T cell through specific signaling molecules (ligands) at the interface of these 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 $^{\text{TM}}$  for the Conditional and Unique Engagement $^{\text{TM}}$  (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.

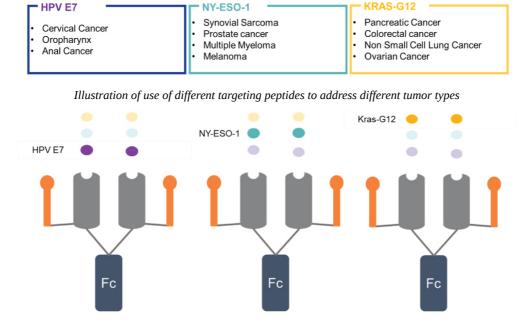


Illustration of use of different targeting peptides to address different indications

Using our CUE Biologics™ 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 — Immunotherapy" and "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™ 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 $^{\text{TM}}$  frameworks. We continue to evaluate additional constructs from which we will launch further framework series in both oncology and autoimmunity.

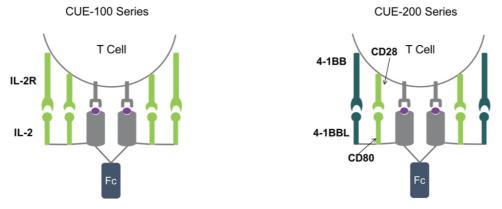
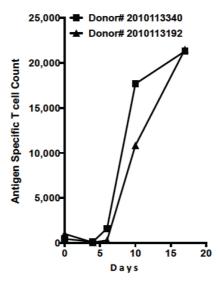
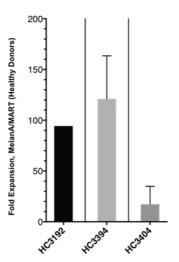


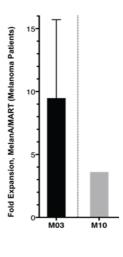
Illustration of CUE-100 and CUE-200 frameworks

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 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™ 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>TM</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>TM</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>TM</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>TM</sup> frameworks in autoimmunity will therefore be intended to treat autoimmune diseases 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™ and viraTope™ Technology Platforms

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

# Selective T cell Stimulation + + + Cue<sup>TM</sup> Biologic TCR Targeted Our viraTope platform enables the discovery of disease associated peptides H Stimulatory Signaling Ligand(s) Fc

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

We believe that the  $\mathsf{MOD^{TM}}$  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  $\mathsf{MOD^{TM}}$  platform represents a high throughput method for determining specific cell surface protein-protein interactions (*e.g.*, signaling receptor:ligand pair(s)). In brief,  $\mathsf{MOD^{TM}}$  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  $\mathsf{MOD^{TM}}$  can provide powerful tools to first define novel protein-protein interactions associated with T cell activation. Secondly,  $\mathsf{MOD^{TM}}$  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  $viraTope^{TM}$  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<sup>TM</sup> 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™ 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™ 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™ 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™, 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™ 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 costeffective 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 9,333,333

> shares of common stock (maximum), or a minimum of approximately \$40,000,000 of common stock and a maximum of

approximately \$70,000,000 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

**Initial Public Offering Price** 

**Common Stock Outstanding After** 

This Offering

10,635,684 shares of common stock. (1)

\$7.50 per share.

16,640,590 shares of common stock (if the minimum amount of common stock is sold) or 20,640,589 shares of common stock (if the

maximum amount of common stock is sold). (1)(2)

**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.

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 \$70,000,000 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 January 13, 2018 (the "Initial Offering Termination Date"), which date may be extended to a date up to and including March 14, 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.

Escrow

Prior to January 13, 2018, 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,				
	2	016	2015		2015		2016	
				(Unaudited)		nudited)	(Unaudited)	
Revenue	\$	<u> </u>	\$		\$	<u> </u>	\$	_
Operating expenses:								
General and administrative	1,9	70,488		425,081	2,	914,452	1	,193,527
Research and development	5,6	87,847	1,	503,649	9,	880,529	3	,622,409
Total operating expenses	7,6	558,335	1,	928,730	12,	794,981	4	,815,936
Loss from operations	(7,6	558,335)	(1,	928,730)	(12,	794,981)	(4	,815,936)
Interest income		52		_		_		52
Net loss	\$(7,6	558,283)	\$(1,	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	7,4	133,433	5,	658,282	10,	635,684	7	,352,704

### **Balance Sheet Data:**

	Decemb	December 31,		
	2016	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, contract research organizations ("CROs"), consultants and collaborators. Relying on third-party clinical investigators, CROs or collaborators may result in delays that are outside of our control.

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

- negative or inconclusive results from our IND-enabling studies, clinical trials or the clinical trials of
  others for product candidates similar to ours, leading to a decision or requirement to conduct additional
  preclinical testing or clinical trials or abandon a program;
- delays in submitting INDs or comparable foreign applications or delays or failure in obtaining the
  necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a
  clinical trial once commenced;
- conditions imposed by the FDA or a foreign regulatory authority regarding the number, scope or design
  of our clinical trials;
- · delays in enrolling patients in clinical trials;
- high drop-out rates of patients;
- inadequate supply or quality of clinical trial materials or other supplies necessary to conduct our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness or unacceptable side effects of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- 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>TM</sup> targeting certain autoimmune diseases. Pursuant to the collaboration agreement, Merck will acquire rights to develop, commercialize and sell CUE Biologics<sup>TM</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>TM</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>TM</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>TM</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™ 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™, MOD™, and viraTope™, 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 34 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 January 13, 2018 . 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 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 15.2% 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 16.1% of our common stock if the maximum amount of 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 \$4.13 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 \$66,640,000 if we sell all \$70,000,000 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 \$48 million to \$52 million, if we sell the maximum of \$70,000,000 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 \$70,000,000 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™, 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 \$70,000,000 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	\$ 68,744,608	
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 20,640,589 shares				
issued and outstanding, pro forma (maximum)	10,636	16,641	20,640	
Additional paid-in capital	26,752,048	68,657,838	97,078,832	
Accumulated deficit	(22,381,994)	(27,418,784)	(27,418,784)	
Total stockholders' equity	4,380,690	41,255,695	69,680,688	
Total capitalization	\$ 4,380,690	\$ 41,255,695	\$ 69,680,688	

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 \$70,000,000 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 \$3.37 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 \$3.00 per share to our existing stockholders and immediate dilution of \$4.13 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
F	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	3.00
	Pro forma tangible book value per share after this offering	2.47	3.37
	Dilution per share to new investors in this offering	\$ 5.03	\$ 4.13

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**

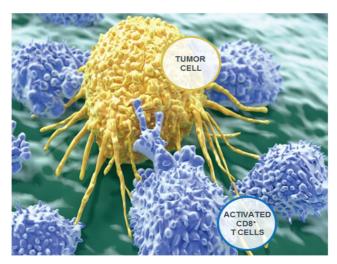
#### Overview

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™ 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>TM</sup> and viraTope<sup>TM</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.).

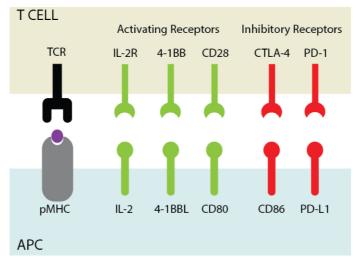


Illustration of the interaction between antigen presenting cells ("APCs") and T cells. Stimulatory signals are shaded green and inhibitory signals are shaded red.

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-PD-1 and 12% 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.

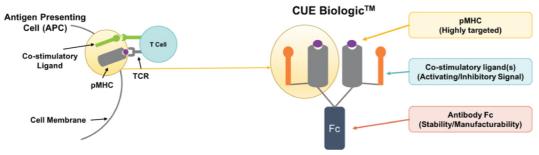
A different approach that has shown some promise in tumor therapy is to remove T cells from patients, activate and stimulate them outside the body (*ex vivo*), which expands them (usually over 7-14 days), and then infuse them back into the patients. These methods are termed cellular therapies, and include 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 $^{\text{TM}}$  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 $^{\text{TM}}$  for the Conditional and Unique Engagement $^{\text{TM}}$  (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.

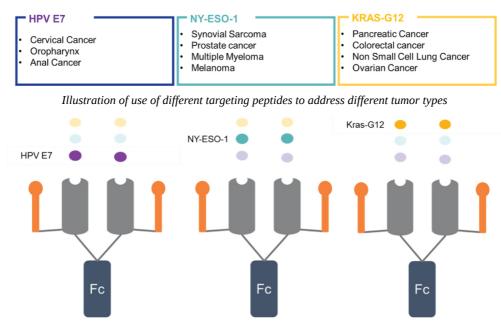


Illustration of use of different targeting peptides to address different indications

Using our CUE Biologics™ 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™." 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<sup>TM</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>TM</sup> frameworks. We continue to evaluate additional constructs from which we will launch further framework series in both oncology and autoimmunity.

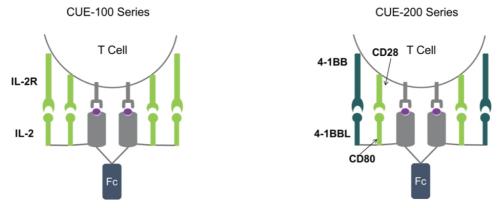
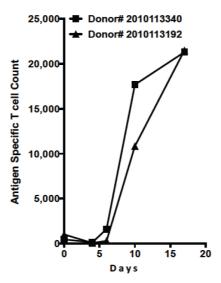
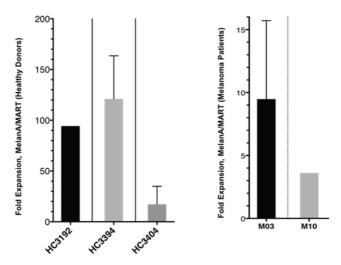


Illustration of CUE-100 and CUE-200 frameworks CUE-101

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>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-101 framework to support the versatility and robustness of our CUE Biologics<sup>TM</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>TM</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>TM</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™ 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™ 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™ frameworks in autoimmunity will therefore be intended to treat autoimmune diseases 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".

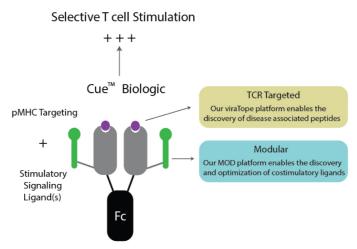
# Manufacturing CUE Biologics<sup>TM</sup>

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). Bi-specifics 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 antibody extremely challenging and disadvantageous. The CUE Biologics™ platform focuses on 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™ and viraTope™ Technology Platforms

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



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

We believe that the  $MOD^{TM}$  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  $MOD^{TM}$  platform represents a high throughput method for determining specific cell surface protein-protein interactions (*e.g.*, signaling receptor:ligand pair(s)). In brief,  $MOD^{TM}$  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  $\mathsf{MOD^{TM}}$  can provide powerful tools to first define novel protein-protein interactions associated with T cell activation. Secondly,  $\mathsf{MOD^{TM}}$  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>TM</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<sup>TM</sup> 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™ 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™ 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™ 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 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™ 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 costeffective 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>TM</sup>, viraTope<sup>TM</sup> and MOD<sup>TM</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>TM</sup> platform or technology, (ii) a cellular platform for rapid and comprehensive T cell immunomonitoring, which we refer to as our ViraTope<sup>TM</sup> platform or technology, (iii) CUE Fc fusion constructs and uses thereof, which we refer to as our CUE Biologics<sup>TM</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 III clinical trials or foreign equivalent on a Licensed Product; (vi) initiation of Phase III clinical trials or foreign equivalent on a Licensed Product; (vi) initiation of Phase III clinical trials or foreign equivalent for a "new indication" for a Licensed Product, (vii) the first commercial sale of a Licensed Product; (viii) the first commercial sale of each "new indication" for one of our previously approved Licensed Products; and (ix) cumulative sales of certain Licensed Products reaching certain threshold amounts. The aggregate amount of milestone payments made under the Einstein License may equal up to \$1.85 million for each Licensed Product and up to \$1.85 million for each new indication of a Licensed Product. Additionally, the aggregate amount of one-time milestone payments based on cumulative sales of all Licensed Products may equal up to \$5.75 million.

In addition to our obligations to make the cash payments to Einstein described above, under the Einstein License we 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>TM</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>TM</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>TM</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>TM</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 34 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™ platform and drug candidates, viraTope™, MOD™ screening, MOD™ 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. More than one product candidate may receive an orphan drug designation for the same indication. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to seven years of orphan product exclusivity. During the seven-year exclusivity period, the FDA may not approve any other applications to market a product containing the same active moiety for the same disease, except in very limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Thus, orphan drug exclusivity could block the approval of one of our potential products for seven years if a competitor obtains approval of the same product as defined by the FDA and we are not able to show the clinical superiority of our product candidate or if our product candidate's indication is determined to be contained within the competitor's product orphan indication. In addition, 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™ 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 transaction-and 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 will own less than the majority of the voting power of the resulting corporation after 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™ 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>TM</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>TM</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>TM</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>TM</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 stockbased 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	\$ <u> </u>	\$ —	
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	20:	16
Revenue	\$	<u> </u>		
Operating expenses:				
General and administrative		2,914,452	1,19	3,527
Research and development		9,880,529	3,62	2,409
Total operating expenses		12,794,981	4,81	5,936
Loss from operations		(12,794,981)	(4,81	5,936)
Interest income		_		52
Net loss	\$(	(12,794,981)	\$(4,81	5,884)

# 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, stock-based 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 \$70,000,000 (or net proceeds of approximately \$66,640,000), 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 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) 6 months of base salary.

On November 15, 2017, the Company entered into an employment agreement with its Senior Vice President, General Counsel and Secretary 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, General Counsel and Secretary
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 the Maven, 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, General Counsel and Secretary

Colin Sandercock has been our Senior Vice President, General Counsel and Secretary 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 antibodydrug 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 January 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, Immusol, 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

<sup>(1)</sup> 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.

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

- (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 is employed in such year 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 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. 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 933,333 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 663/3% 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%	2.3%
Rodolfo J. Chaparro	445,000	30,000	_	475,000	4.5%	2.8%	2.3%
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%	3.5%
Christopher Marlett <sup>(6)</sup>	1,017,973	_	185,185	1,203,158	11.1%	7.2%	5.8%
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%	15.2%
Five Percent Stockholders							
MDB Capital Group, LLC(7)	1,017,973	_	185,185	1,203,158	11.1%	7.2%	5.8%
Albert Einstein College of Medicine <sup>(8)</sup>	671,572	_	_	671,572	6.3%	4.0%	3.3%
Steven C. Almo <sup>(9)</sup>	534,000	40,122	_	574,122	5.4%	3.4%	2.8%
Mark Strome <sup>(10)</sup>	615,556 <sup>(1</sup>	<sup>11)</sup> —	_	615,556	5.8%	3.7%	3.0%
Peter A. Appel <sup>(12)</sup>	655,556	_	_	655,556	6.2%	3.9%	3.2%

<sup>\*</sup> Less than one percent.

- (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 20,640,589 shares (if the maximum amount of common stock is sold) of

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

- 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 Ayenue, 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 20,640,589 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 six-month lock-up and 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 one year, including the holding period of any prior owner other than our affiliates, 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 \$70,000,000 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 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 (non-beneficial 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 co-founders 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	\$70,000,000
Underwriting commissions to be paid to the underwriters	\$ 1,920,000	\$ 3,360,000
Qualified independent underwriter fee	\$ 275,000	\$ 275,000
Net proceeds, before other Company expenses	\$ 37,805,000	\$66,365,000

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 one-year 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, 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

## CUE BIOPHARMA, INC. STATEMENTS OF OPERATIONS

	Years Ended December 31,		31,	
	2016		201	15
Revenue	\$	_	\$	_
Operating expenses:				
General and administrative	1,970,4	188	42	5,081
Research and development	5,687,8	347	1,50	3,649
Total operating expenses	7,658,3	35	1,92	8,730
Loss from operations	(7,658,3	35)	(1,92	8,730)
Interest income		52		
Net loss	\$(7,658,2	283)	\$(1,92	8,730)
Net loss per common share – basic and diluted	\$ (1.	.03)	\$	(0.34)
Weighted average common shares outstanding – basic and diluted	7,433,4	133	5,65	8,282

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

	Common Stock		Common Stock Additional Paid-in Accumulate		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

## CUE BIOPHARMA, INC. STATEMENTS OF CASH FLOWS

	Years Ended December 3	
	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	<u> </u>	\$ 773,941

#### 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 anti-dilutive.

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 transaction-and 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:

	Decem	ber 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	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:

	Deceml	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	<u> </u>	\$ <u> </u>		

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	
\$117,691	\$ 42,455	
846,818	319,091	
\$964,509	\$361,546	
	2016 \$117,691 846,818	

#### **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 becomes a reporting 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 date of issuance of 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 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 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) 6 months of base salary.

#### 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

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

		Nine Months Ended September 30,			
	2	2017 2		2016	
Revenue	\$		\$		
Operating expenses:					
General and administrative	2,	914,452	1,1	93,527	
Research and development	9,	880,529	3,6	22,409	
Total operating expenses	12,	794,981	4,8	15,936	
Loss from operations	(12,	794,981)	(4,8	15,936)	
Interest income		_		52	
Net loss	\$(12,	794,981)	\$(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	7,3	52,704	

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

	Common	Stock Additional		Common Stock			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		

## CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	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 –		
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	

#### 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 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 had been granted and 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 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 \$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 patent-related 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 patent-related 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:

	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 becomes a reporting 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 date of issuance of 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>TM</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>TM</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>TM</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>TM</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>TM</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>TM</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 9,333,333 Shares of Common Stock



Cue Biopharma, Inc.

# **PROSPECTUS**

MDB Capital Group, LLC

**Feltl and Company** 

Until January 12, 2018, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus.