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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2019

OR

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

For the Transition Period from _____ to _____

Commission File Number: 001-38707

LogicBio Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**47-1514975**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

99 Erie St.
Cambridge, MA 02139
(617) 245-0399
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	**LOGC**	**Nasdaq Global Market**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☒

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

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant was approximately $137.8 million based on the last reported sale price of the registrant's common stock on the Nasdaq Global Market on June 28, 2019. The registrant has no non-voting common stock.

As of March 10, 2020, there were 23,299,709 shares of registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2020 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2019, are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," or similar expressions, or the negative or plural of these words or expressions. These forward-looking statements include statements concerning the following:

- the initiation, cost, timing, progress and results of our current and future research and development activities and preclinical studies and potential future clinical trials, including our plans to resolve the clinical hold placed by the U.S. Food and Drug Administration on the investigational new drug application for LB-001;
- potential attributes and benefits of our GeneRide technology platform and our product candidate and any future product candidates;
- our ability to take advantage of the modular nature of our GeneRide platform to simplify and accelerate development of new product candidates;
- the potential benefits of strategic partnership agreements and our ability to enter into selective strategic partnership arrangements;
- the timing of, and our ability to obtain and maintain, regulatory approvals for our product candidate and any future product candidates;
- our ability to quickly and efficiently identify and develop additional product candidates;
- our ability to advance any product candidate into and successfully complete clinical trials;
- our intellectual property position, including with respect to our trade secrets and the duration of our patent protection; and
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing.

Factors that may cause actual results to differ materially from current expectations include, among other things, those set forth in Part I, Item 1A, "Risk Factors," herein and for the reasons described elsewhere in this Annual Report on Form 10-K. Any forward-looking statement in this Annual Report on Form 10-K reflects our current view with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Given these uncertainties, you should not rely on these forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources and we have not independently verified the data from third party sources. In some cases, we do not expressly refer to the sources from which these data are derived.

In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

In this Annual Report on Form 10-K, unless otherwise stated or as the context otherwise requires, references to "LogicBio," "LogicBio Therapeutics Inc.," the "Company," "we," "us," "our" and similar references refer to LogicBio Therapeutics Inc. and its wholly owned subsidiaries. This Annual Report on Form 10-K also contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I

Item 1. Business.

Overview

We are a genome editing company focused on developing medicines to durably treat rare diseases in patients with significant unmet medical need using GeneRide, our proprietary technology platform. Our GeneRide technology is designed to precisely integrate corrective genes into a patient's genome to provide a stable therapeutic effect. Because GeneRide is designed to have this durable therapeutic effect, we are initially targeting rare liver disorders in pediatric patients where it is critical to provide treatment early in a patient's life before irreversible disease pathology can occur. We have demonstrated proof of concept of our therapeutic platform in animal models for a number of diseases and are focusing on our lead product candidate, LB-001, for the treatment of Methylmalonic Acidemia, or MMA, a life-threatening disease that presents at birth.

GeneRide is our genome editing technology that harnesses homologous recombination, or HR, a naturally occurring DNA repair process that maintains the fidelity of the genome. We believe that by using HR, GeneRide will allow us to insert therapeutic genes, known as transgenes, into specific targeted genomic locations without using exogenous nucleases, which are enzymes engineered to cut DNA. GeneRide-directed transgene integration is designed to leverage endogenous promoters at these targeted locations to drive high levels of tissue-specific gene expression, without the detrimental issues that have been associated with the use of exogenous promoters.

We believe that GeneRide offers several key potential advantages over gene therapy and gene editing technologies that rely on exogenous promoters and nucleases. By harnessing the naturally occurring process of HR, GeneRide does not face the same challenges associated with gene editing approaches that rely on engineered bacterial nuclease enzymes. The use of these enzymes has been associated with significantly increased risk of unwanted and potentially dangerous modifications in the host cell's DNA, which can lead to an increased risk of tumor formation. Furthermore, in contrast to conventional gene therapy, GeneRide is intended to provide precise, site-specific, stable and durable integration of a corrective gene into the chromosome of a host cell. In preclinical animal studies with GeneRide constructs, we have observed integration of the corrective gene in a specific location in the genome. This gives it the potential to provide a more durable approach than gene therapy technologies that do not integrate into the genome and lose their effect as cells divide. We believe these benefits make GeneRide well-positioned to treat genetic diseases, particularly in pediatric patients.

We believe our modular approach will allow GeneRide to deliver robust, tissue-specific gene expression that will be reproducible across different therapeutics delivered to the same tissue. By substituting a different transgene within the GeneRide construct, we believe we can deliver that transgene to address a new therapeutic indication while substantially maintaining all other components of the construct. We expect this approach will allow us to leverage common manufacturing processes and analytics across our future GeneRide product candidates and could potentially shorten the development process of future programs.

Beyond LB-001, we intend to develop additional product candidates for other indications based on ongoing research and development work we perform in our own laboratories, as well as the work of our academic partners. The criteria for selecting these proposed product candidates are initially:

- **Genetically defined disease.** As with LB-001, we expect our future product candidates to target disorders associated with genetically defined mechanisms.
- **High unmet need in pediatric patients.** Because GeneRide is designed to deliver therapeutic durability, we intend to provide lifelong benefit to patients by intervening early in their lives with a treatment that restores the function of aberrant genes before irreversible declines in function can occur.
- **Liver expression.** Because of the modularity of our platform in creating new product candidates in the same tissue, we will initially focus on developing therapies for indications that can be addressed by targeting the liver. We believe providing long-lasting benefits in a growing pediatric liver requires integrating therapies. We intend to evaluate the tolerability, effective targeting and expression of our therapy in our lead program in MMA, as well as our next few product candidates, before deploying additional potential therapies based on GeneRide in other tissues.

We expect that the initial product candidates we develop, including LB-001, will address diseases by targeting the liver, including a category of diseases known as inborn errors of metabolism, a group of genetic disorders that disrupt normal metabolic processes. Our intent is to deliver transgenes for these disorders using a GeneRide construct designed to integrate immediately behind the gene coding for albumin, the most highly expressed gene in the liver. Expression of the transgenes "piggybacks" on the expression of albumin, which we believe will provide sufficient therapeutic levels of desirable proteins given the high level of albumin expression in the liver. We have developed GeneRide utilizing certain core technology licensed from Stanford University and the University of Texas.

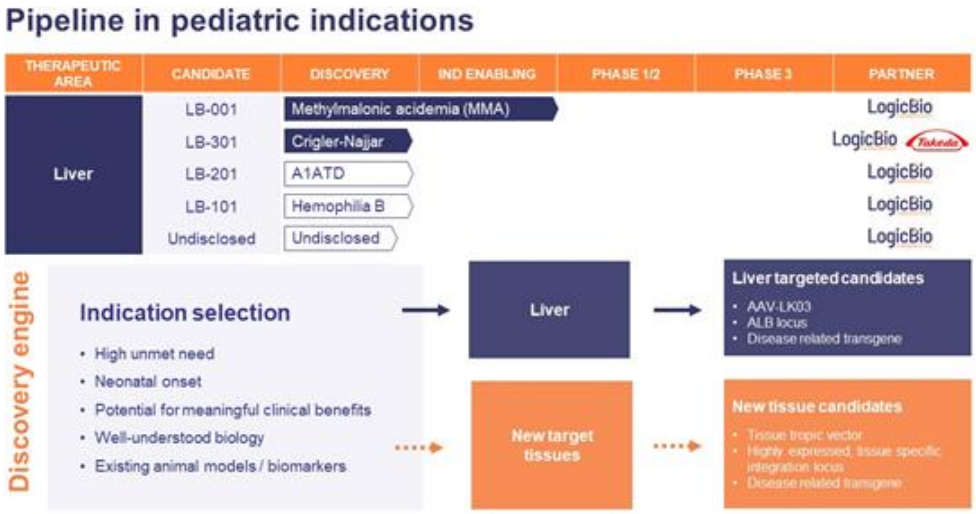
Based on our GeneRide technology, we are developing our lead product candidate, LB-001, to treat MMA. In January 2020, we announced the submission of an IND to support the initiation of a Phase 1/2 clinical trial in pediatric patients with MMA, which the FDA has placed on clinical hold. Subsequently, we received a letter from the FDA specifying its questions related to the clinical hold. The clinical hold was based on question that were clinical and nonclinical in nature, including questions related to the studies conducted for our IND filing, but did not relate to chemistry, manufacturing, and controls. We expect to have interactions with the FDA regarding their questions through mid-2020, after which we plan to provide guidance on the anticipated timing for the initiation of the Phase 1/2 clinical trial for LB-001.

We believe that achieving clinical proof of concept in an inherited liver disease such as MMA will validate our platform technology, including its potential application to other organs and diseases. In January 2020, we announced a research collaboration with Takeda Pharmaceutical Company Limited to further develop LB-301 in Crigler-Najjar syndrome, or CN, the second indication to be pursued using the GeneRide platform. In addition to MMA and CN, we have demonstrated proof of concept of our platform in hemophilia B and alpha-1-antitrypsin deficiency, or A1ATD, animal disease models. We expect to select future product candidates from these genetic diseases or others addressed by targeting the liver initially, and later by targeting the central nervous system, or CNS, and muscle.

Our proprietary GeneRide technology platform is based on research conducted by leading gene therapy scientists at the Kay Lab at Stanford University, and we have assembled a world-class team of executives, founders and advisors with years of highly relevant experience to enable the development of our genome editing platform and the advancement of our product candidates for patients with significant unmet medical needs. Led by Frederic (Fred) Chereau, our Chief Executive Officer, our team's expertise spans gene therapy, HR, rare disease drug discovery and development, technical development, clinical and regulatory strategy, manufacturing strategy and operations, as well as business strategy, intellectual property and finance. Members of this team have been involved in developing therapies for rare diseases in both large and small biotechnology companies including Genzyme, Shire, Novartis, aTyr Pharma, Translate Bio, Genethon, Intercept Pharmaceuticals and Nightstar. Collectively, members of the team have contributed to the development of an array of approved drugs, most of which are treatments for rare diseases.

We have also established an extensive network of advisors and consultants with expertise across many critical areas of our business, from drug design, manufacturing and clinical development to regulatory approval. Our consultants and advisors possess deep experience in adeno-associated virus, or AAV, capsid development, mechanisms of DNA repair and delivery technologies, which complements our internal capabilities and supports our efforts in the development of our GeneRide-based product candidates. Additionally, our management team is actively supported by a scientific advisory board, or SAB, and we believe that their expertise, combined with our network of consultants and advisors, is a pivotal asset for our product development efforts. We are committed to bringing much-needed therapies to children with serious genetic deficiencies and we work closely with patient foundations, such as the Organic Acidemia Association and the National Hemophilia Foundation.

Below is a summary of our ongoing discovery, research and development programs, as well as our discovery process using GeneRide:



Strategy

Our mission is to transform the lives of patients living with devastating genetic diseases by building the leading integrated genetic medicine company focused on developing and commercializing potentially curative therapeutics based on our GeneRide platform. Key elements of our strategy are to:

- **Advance LB-001 through successful clinical trials and ultimately into commercialization.** We chose a specific organic acidemia, MMA, as our initial indication to enter proof-of-concept trials in humans due to the high unmet medical need and the absence of therapeutic treatments for this disease. In January 2020, we announced the submission of an IND to support the initiation of a Phase 1/2 clinical trial in pediatric patients with MMA, which the FDA has placed on clinical hold pending the resolution of certain clinical and nonclinical questions. Subsequently, we received a letter from the FDA specifying its questions related to the clinical hold. The clinical hold was based on questions that were clinical and nonclinical in nature, including questions related to the studies conducted for our IND filing, but did not relate not based on questions related to chemistry, manufacturing, and controls. We plan expect to have interactions with the FDA regarding their questions through mid-2020, after which we plan to provide guidance on the anticipated timing for the initiation of the Phase 1/2 clinical trial for LB-001. Our goal is to develop LB-001 ourselves and, if approved, to retain global commercialization rights and commercialize through a small, targeted sales organization.
- **Aggressively pursue additional indications addressed by targeting the liver.** For our initial animal proof-of-concept studies, we selected liver diseases with significant unmet medical need and well-validated targets with accepted disease-correlated biomarkers, and where we believe the GeneRide platform can provide unique benefits by addressing the root cause of the disease. We selected Crigler-Najjar syndrome as the second indication to be pursued using GeneRide through a research collaboration with Takeda. We plan to continue our research to explore GeneRide in additional potential indications utilizing our modular approach and leveraging learnings from our lead program.
- **Collaborate to realize the full potential of GeneRide.** We plan to leverage strategic partnerships to accelerate advancement of our programs by accessing non-dilutive capital and disease-specific expertise in indications outside of our initial core focus. These indications could include other diseases addressable by targeting the liver. We also intend to seek collaborations to accelerate the development of the GeneRide platform in new tissues, such as the CNS and muscle.

- **Build an exceptional team and organization.** Delivering on the promise of a potential breakthrough technology like GeneRide requires an exceptional organization. We have assembled a group of leaders and scientific talent in the fields of rare diseases, genome editing and gene therapy, and expect to continue building and expanding our team, as required, to execute on our plans to develop and commercialize genetic medicines.
- **Maintain our scientific leadership in the field of genome editing.** We will strive to continue optimizing all aspects of our GeneRide technology through a combination of in-house research and work by our network of academic collaborators. Additionally, we expect to invest in the development of next-generation AAV vectors that we hope will continue to enhance the utility of our GeneRide platform, and provide us with AAV assets for potential out-licensing opportunities to companies developing conventional gene therapy products. The collaboration with the Children's Medical Research Institute, or CMRI, announced in November 2018, is a prime example of our efforts. We believe that our scientific leadership will provide us opportunities to expand our intellectual property portfolio.

Genetic Diseases and Their Treatment

There is a subset of human diseases that can be traced to changes in the DNA that are either inherited or acquired early in embryonic development. Of particular interest for developers of genetic therapies are diseases caused by a mutation in a single gene, known as monogenic diseases. There are believed to be over 6,500 monogenic diseases. Typically, any particular genetic disease caused by inherited mutations is relatively rare, but taken together, the toll of genetic-related disease is high. Well-known genetic diseases include cystic fibrosis, Duchenne muscular dystrophy, Huntington's disease and sickle cell disease. Other classes of genetic diseases include metabolic disorders, such as organic acidemias, and lysosomal storage diseases where dysfunctional genes result in defects in metabolic processes and the accumulation of toxic byproducts that can lead to serious morbidity and mortality both in the short-term and long-term.

Monogenic diseases have been of particular interest for biomedical innovators due to the perceived simplicity of their disease pathology. However, the vast majority of these diseases and disorders remain unaddressed, though this is beginning to change, largely due to innovation in two fields: gene therapy and gene editing.

Gene Therapy

Gene therapies alter the gene expression profile of a patient's cells by gene transfer, a process of delivering a therapeutic gene, called a transgene. Drug developers use modified viruses as vectors to transport transgenes into the nucleus of a cell to alter or augment the cell's capabilities. Developers have made great strides in introducing genes into cells in tissues such as the liver, the retina of the eye and the blood-forming cells of the bone marrow using a variety of vectors. These approaches have in some cases led to approved therapies and, in other cases, have shown very promising results in clinical trials. This has resulted in a growing acceptance and de-risking of the modality.

There are multiple gene therapy approaches currently being used to treat patients. In conventional AAV gene therapy, the transgene is introduced into the nucleus of the host cell, but is not intended to integrate in chromosomal DNA. The transgene is expressed from a non-integrated genetic element called an episome that exists inside the nucleus. A second type of gene therapy employs the use of a different type of virus, such as lentivirus, that inserts itself, along with the transgene, into the chromosomal DNA but at arbitrary sites.

Episomal expression of a gene must be driven by an exogenous promoter, leading to production of a protein that corrects or ameliorates the disease condition. In the case of gene therapy based on episomal expression, when cells divide during the process of growth or tissue regeneration, the benefits of the therapy typically decline because the transgenes were not intended to integrate into the host chromosome, thus not replicated during cell division. Each new generation of cells thus further reduces the proportion of cells expressing the transgene in the target tissue, leading to the reduction or elimination of the therapeutic benefit over time. We believe that this type of gene therapy will be most successful when genes are delivered into tissues that consist of stable, rather than rapidly dividing, cells.

Gene Editing

Gene editing is the deletion, alteration or augmentation of aberrant genes by introducing breaks in the DNA of cells using exogenously delivered gene editing mechanisms. Most current gene editing approaches have been limited in their efficacy due to high rates of unwanted on- and off-target modifications and low efficiency of gene correction, resulting in part from the cell trying to rapidly repair the introduced DNA break. The current focus of gene editing is on disabling a dysfunctional gene or correcting or skipping an individual deleterious mutation within a gene. Due to the number of possible mutations, neither of these approaches can address the entire population of mutations within a particular genetic disease, as would be addressed by the insertion of a full corrective gene.

Unlike the gene therapy approach, AAV-mediated gene editing allows for the repaired genetic region to propagate to new generations of cells through normal cell division. Furthermore, the desired protein can be expressed using the cell's own regulatory machinery. The traditional approach to gene editing is nuclease-based, and it uses nuclease enzymes derived from bacteria to cut the DNA at a specific place in order to cause a deletion, make an alteration or apply a corrective sequence to the body's DNA.

Once nucleases have cut the DNA, traditional gene editing techniques modify DNA using two routes: homology-directed repair, or HDR, and non-homologous end joining, or NHEJ. HDR involves highly precise incorporation of correct DNA sequences complementary to a site of DNA damage. HDR has key advantages in that it can repair DNA with high fidelity and it avoids the introduction of unwanted mutations at the site of correction. NHEJ is a less selective, more error-prone process that rapidly joins the ends of broken DNA, resulting in a high frequency of insertions or deletions at the break site.

Nuclease-Based Gene Editing

Nuclease-based gene editing uses nucleases, enzymes that were engineered or initially identified in bacteria that cut DNA. Nuclease-based gene editing is a two-step process. First, an exogenous nuclease, which is capable of cutting one or both strands in the double-stranded DNA, is directed to the desired site by a synthetic guide RNA and makes a specific cut. After the nuclease makes the desired cut or cuts, the cell's DNA repair machinery is activated and completes the editing process through either NHEJ or, less commonly, HDR.

NHEJ can occur in the absence of a DNA template for the cell to copy as it repairs a DNA cut. This is the primary or default pathway that the cell uses to repair double-stranded breaks. The NHEJ mechanism can be used to introduce small insertions or deletions, known as indels, resulting in the knocking out of the function of the gene. NHEJ creates insertions and deletions in the DNA due to its mode of repair and can also result in the introduction of off-target, unwanted mutations including chromosomal aberrations. Conventional gene editing technologies can result in genotoxicity, including chromosomal alterations, based on the error-prone NHEJ process and potential off-target nuclease activity. Because the nucleases used in conventional gene editing approaches are mostly bacterially derived, they have a higher potential for immunogenicity, which in turn limits their utility.

Nuclease-mediated HDR occurs with the co-delivery of the nuclease, a guide RNA and a DNA template that is similar to the DNA that has been cut. Consequently, the cell can use this template to construct reparative DNA, resulting in the replacement of defective genetic sequences with correct ones. We believe the HDR mechanism is the preferred repair pathway when using a nuclease-based approach to insert a corrective sequence due to its high fidelity. However, a majority of the repair to the genome after being cut with a nuclease continues to use the NHEJ mechanism. The more frequent NHEJ repair pathway has the potential to cause unwanted mutations at the cut site, thus limiting the range of diseases that any nuclease-based gene editing approaches can target at this time.

The homology-directed and non-homologous end-joining DNA repair pathways used for genome editing are illustrated in the diagram below:

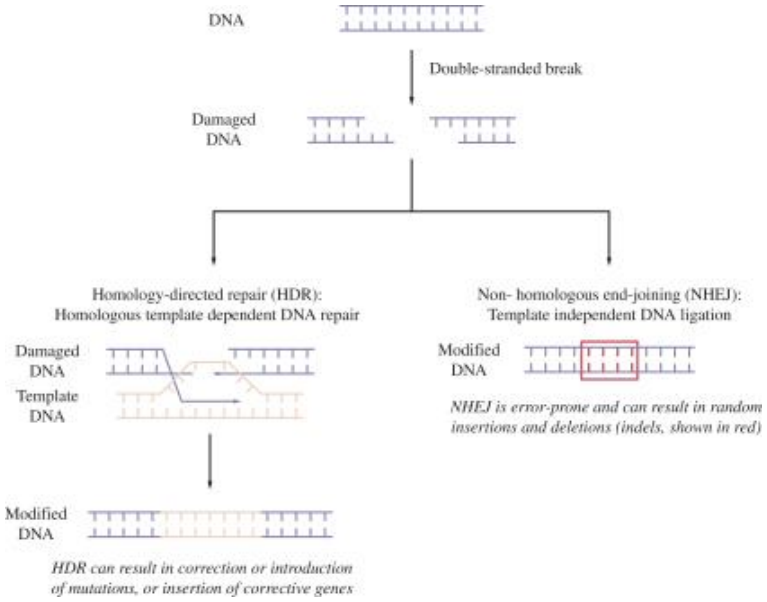


Figure 1. HDR and NHEJ DNA repair pathways.

Traditional gene editing has used one of three nuclease-based approaches: Transcription activator-like effector nucleases, or TALENs; Clustered, Regularly Interspaced Short Palindromic Repeats Associated protein-9, or CRISPR/Cas9; and Zinc Finger Nucleases, or ZFN. While these approaches have already contributed to significant advances in research and product development, we believe they have inherent limitations.

Our GeneRide™ Technology Platform

Our proprietary GeneRide platform technology has the potential to overcome some of the key limitations of both traditional gene therapy and conventional gene editing approaches in a way that we believe is well-positioned to treat genetic diseases, particularly in pediatric patients. GeneRide uses an AAV vector to deliver a gene into the nucleus of the cell. It then uses HR to stably integrate the corrective gene into the genome of the recipient at a location where it is regulated by an endogenous promoter, leading to what we believe will be lifelong protein production, even as the body grows and changes over time, which is not feasible with conventional AAV gene therapy.

Genome Editing Using GeneRide: Mechanism and Attributes

We describe our approach as genome editing rather than gene editing because it uses HR to deliver the corrective gene to one specific location in the genome. GeneRide inserts the corrective gene in a precise manner, leading to site-specific integration in the genome. Our genome editing approach does not require the use of exogenous nucleases or promoters; instead, we leverage the cell's existing machinery to integrate and initiate transcription of therapeutic transgenes.

The illustration below shows how a GeneRide construct inserts a transgene at a specific point next to the albumin gene using HR:

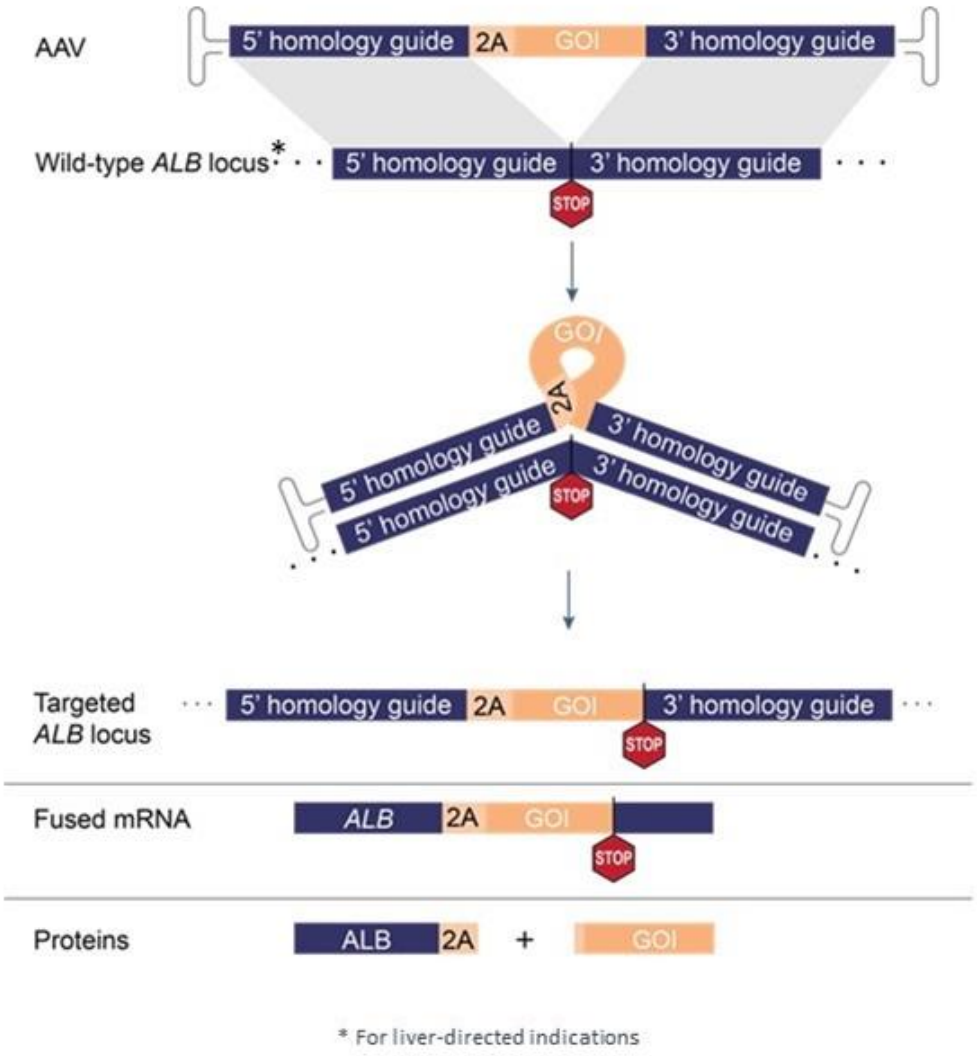


Figure 2. Schematic of the GeneRide construct before integration (AAV) and following HR-mediated integration into the genome at the targeted Albumin, or *ALB*, locus. Expression from the targeted locus results in the production of albumin and transgene, as separate proteins, at equivalent levels, which is coded for by the *ALB* gene.

The GeneRide technology consists of three fundamental components, each of which contributes to the potential benefits of the GeneRide approach:

- **Homology guides comprised of hundreds of nucleotides.** Our flanking sequences, known as homology guides, direct site-specific integration and limit off-target insertion of our construct. Each arm is hundreds of nucleotides long, in contrast to guide sequences used in CRISPR/Cas9, which are only dozens of base pairs long, and we believe this increased length promotes improved precision and site-specific integration. GeneRide's homology guides direct the integration of the transgene immediately behind a highly expressed gene, which we have observed in animal models to result in high levels of expression without the need to introduce an exogenous promoter.
- **Transgene.** We choose corrective genes, known as transgenes, to integrate into the host cell's genome. These transgenes are the functional versions of the disease associated genes found in a patient's cells. Transgenes are also referred to as genes of interest, or GOIs. We optimize the combined size of the transgenes and the homology guides to increase the likelihood that these transgenes are of a suitable sequence length to be efficiently packaged in the capsid, which we believe increases the likelihood that the transgenes will ultimately be delivered appropriately in the patient.
- **2A peptide for polycistronic expression.** We include a short sequence coding for a 2A peptide, which plays a number of important roles. First, the 2A peptide facilitates polycistronic expression, which is the production of two distinct proteins from the same mRNA. This, in turn, allows us to integrate our transgene in a non-disruptive way by coupling transcription of our transgene to a highly expressed target gene in the tissue of interest, driven by a strong endogenous promoter. For our liver-directed programs, including LB-001 and LB-301, we have chosen the albumin locus as the site of integration. Through a process known as ribosomal skipping, the 2A peptide facilitates production of the therapeutic protein at the same level as albumin in each modified cell. Second, the patient's albumin is produced normally, except for the addition of a C-terminal tag that serves as a circulating biomarker to indicate successful integration and expression of the transgene. We believe that this modification to albumin will have minimal effect on its function, based on the results of clinical trials of other albumin protein fusions that have been conducted by others. The 2A peptide has been incorporated into other potential therapeutics such as T cell receptor chimeric antigen receptors, or CAR-Ts.

A key step in applying the GeneRide platform is to identify the target genetic locus for integration. This is important because the location will dictate regulation of transgene expression, specifically the levels and tissues where the protein will be produced. For our liver-directed programs, including LB-001 and LB-301, we have selected the albumin locus as the site of integration.

Albumin is only produced at meaningful levels in the liver, where it is the most highly expressed gene. Integration of the transgene downstream of a highly expressed tissue-specific gene, like albumin, is an important feature of GeneRide. The following graphs show the expression of albumin relative to other genes in the liver and the expression of albumin in the liver compared to other tissues with the highest expression of albumin.

Top 2,000 liver expressed genes

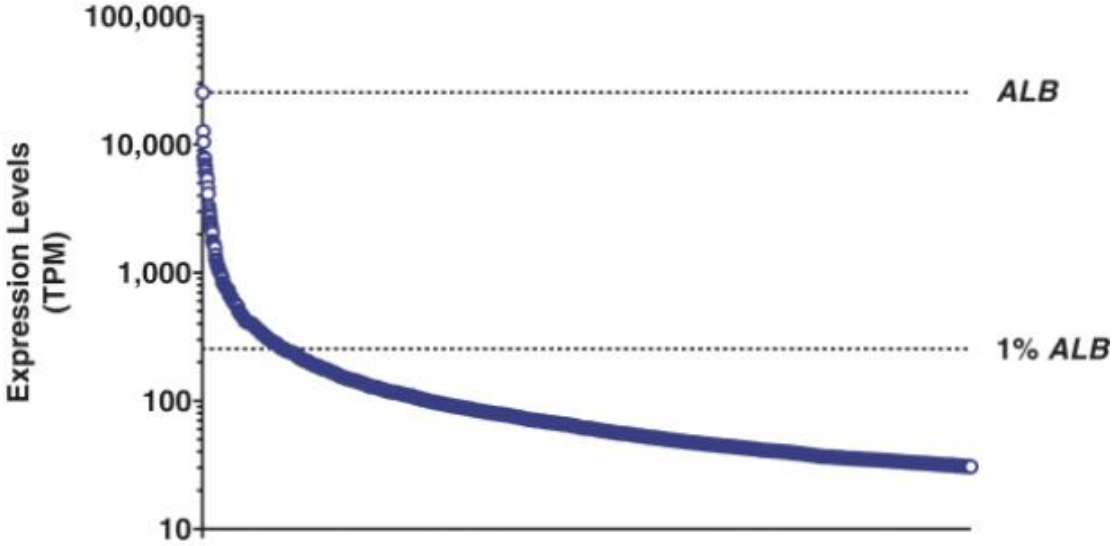


Figure 3. The most abundant genes expressed in the liver, ranked from highest (*ALB*) to number 2,000. Each circle represents an individual gene. Most genes in the liver are expressed at a small fraction of the levels of albumin. TPM=transcripts per million.

***ALB* gene expression across the 15 tissues with the highest *ALB* gene expression levels**

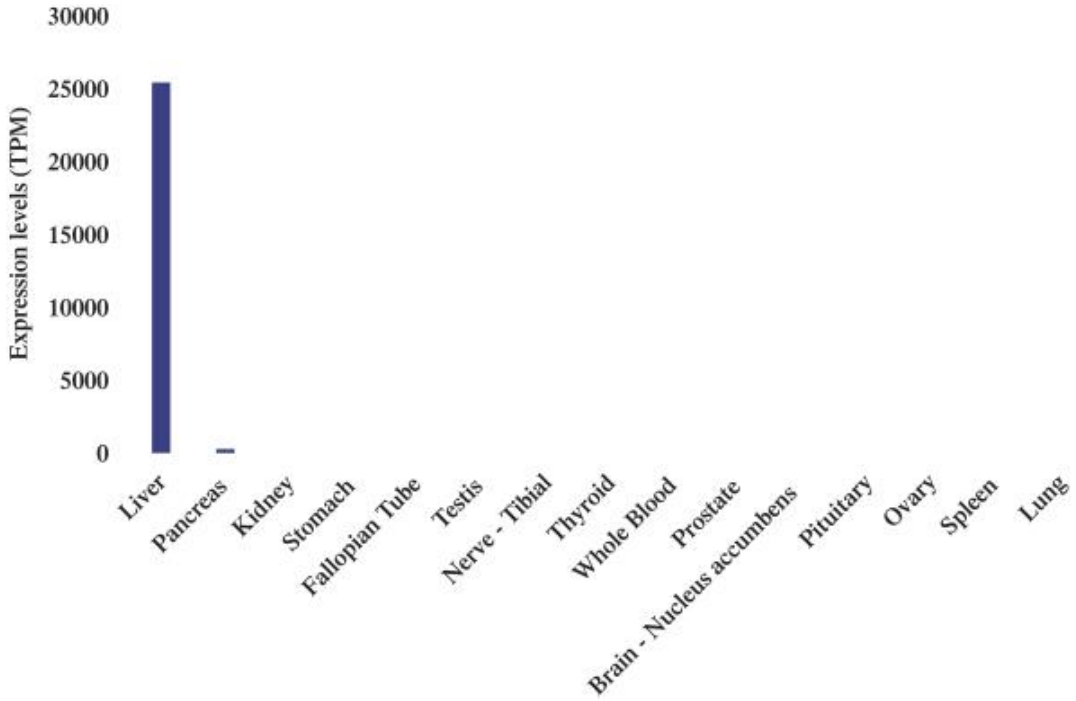


Figure 4. The liver is the organ where nearly all albumin is expressed in the body. Liver-specific GeneRide constructs targeting the *ALB* locus will predominantly be expressed in the liver.

Targeting the albumin locus allows us to leverage the strong endogenous promotor that drives the high level of albumin production to maximize the expression of our transgene. We believe that linking the expression of our transgene to albumin will allow the expression of our transgene at therapeutic levels without requiring the addition of exogenous promoters or the integration of our transgene in a majority of target cells.

This is supported by our data from animal models of MMA, Crigler-Najjar syndrome and hemophilia B. In these models, integration of the transgene into approximately 0.1 to 1% of cells resulted in therapeutic benefit. The strength of the albumin promoter overcomes the modest levels of integration to yield potentially therapeutic levels of transgene expression.

The following tables show the relative expression levels of albumin as compared to select disease-related genes in the liver, including methylmalonyl-CoA mutase, or *MUT*, the deficient gene in patients with MMA. The naming convention for the gene encoding methylmalonyl-CoA mutase recently changed from *MUT* to *MMUT* but we will maintain the previous convention for consistency.

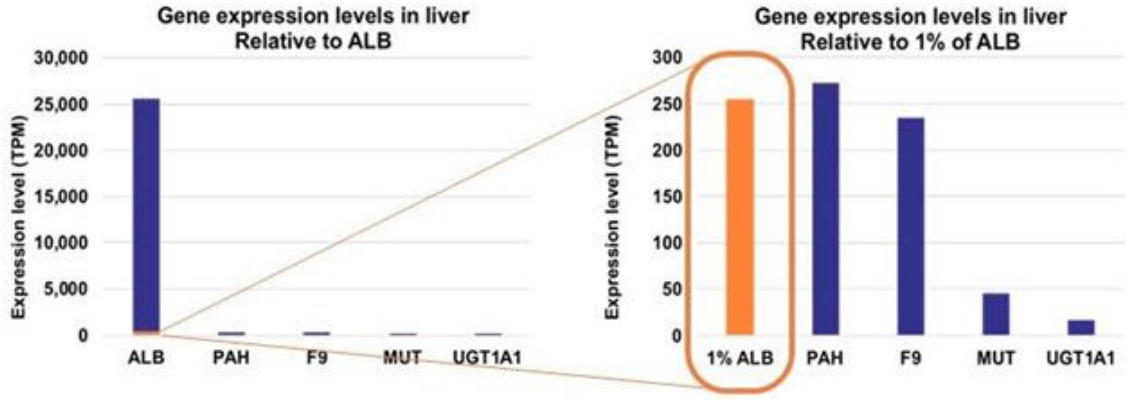
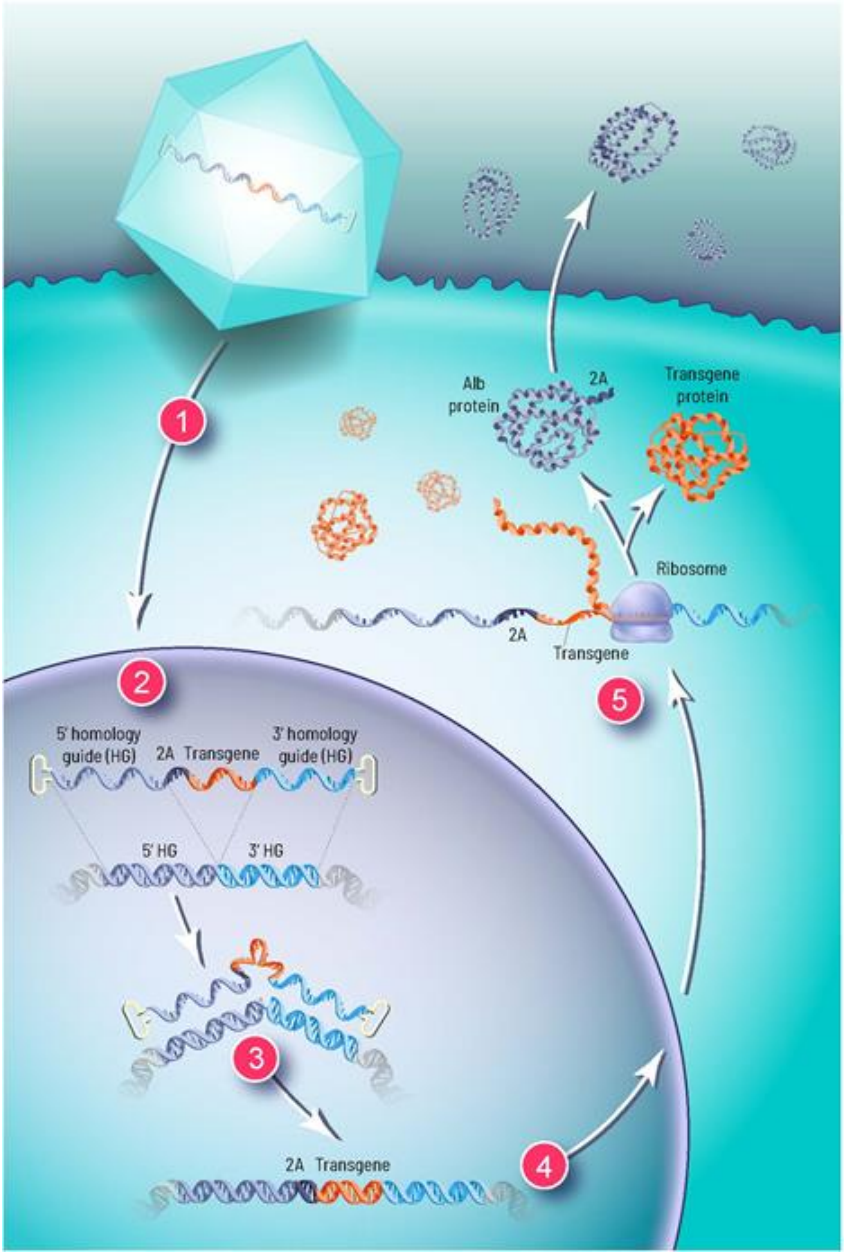


Figure 5. Albumin expression levels are 100x higher than other select liver genes associated with monogenic diseases. (*PAH*: phenylketonuria, *F9*: hemophilia B, *MUT*: MMA, *UGT1A1*: Crigler-Najjar syndrome).

We have observed that GeneRide leads to integration of the corrective gene at the albumin locus in preclinical mouse models of disease, non-human primates and human cells *(in vitro)*. In addition, we have observed that the efficiency of HR that is required for transgene expression with GeneRide is enhanced at sites of active transcription and is likely to be low in tissue where albumin is not actively expressed. We expect that our future liver-directed product candidates will also target the albumin locus for integration. This feature should make both on-target and off-target integration a more predictable process across programs. In addition, because we are using HR, GeneRide product candidates do not contain any bacterial nucleases, addressing the risk of on-target or off-target integration into other sites that are associated with bacterial nucleases. We are exploring the possibility of delivering our therapy to other tissues and target locations in the genome. In *in vitro* feasibility studies, GeneRide has been amenable to integration at other genomic positions, including rDNA, LAMA3 and COL7A1.

How GeneRide Works



First, we use a synthetic viral vector to deliver a transgene to the nuclei of the patient's cells via an infusion.

Two "homology guides," strands of DNA hundreds of nucleotides long that match a specific stretch of the patient's own genome, flank the transgene, as shown at (2) above.

Upon sensing the therapeutic DNA in the nucleus, the cell's natural DNA repair process is expected to activate and integrate the transgene at a specific site in the patient's genome, as shown at (3) above. GeneRide is designed to insert the transgene in a precise manner on the chromosome and at the gene that corresponds to the DNA sequence encoded in the homology guides. For our liver-targeted therapies, this specific location for integration is called the albumin locus.

When our therapeutic transgene is integrated at the albumin locus, it is designed to leverage the strength of this endogenous promoter to drive expression of the transgene, without disrupting albumin production, as shown at (4) above. By using an element called a 2A peptide, we believe we can efficiently produce albumin and the transgene as two separate proteins and further modify albumin in order to monitor GeneRide activity, as shown at (5) above.

Shortly after treatment, the modified cells can begin producing therapeutic levels of protein to combat the disease.

Potential advantages of our GeneRide approach include the following:

- **Targeted integration of transgene into the genome.** Conventional gene therapy approaches deliver therapeutic transgenes to target cells. In conventional gene therapy, the genes are not expected to integrate into the host cell's chromosomes and benefit from the natural processes that lead to replication and segregation of DNA during cell division. This is particularly problematic when conventional gene therapies are introduced early in the patient's life, because the rapid growth of tissues during the child's normal development will result in dilution and eventual loss of the therapeutic benefit associated with the transgene. Non-integrated genes expressed outside the genome on a separate strand of DNA are called episomes. This episomal expression can be effective in the initial cells that are transduced, some of which may last for a long time or for the life of a patient. However, episomal expression is typically transient in target tissues such as the liver, in which there is high turnover of cells and which tends to grow considerably in size during the course of a pediatric patient's life. With our GeneRide technology, the transgene is integrated into the genome, which has the potential to provide stable and durable transgene expression as the cells divide and the tissue of the patient grows, and may result in a durable therapeutic benefit.
- **Transgene expression without exogenous promoters.** With our GeneRide technology, the transgene is expressed at a location where it is regulated by a potent endogenous promoter. Specifically, we use our long homology guides to insert the transgene at a precise site in the genome that is expressed under the control of a potent endogenous promoter, like the albumin promoter. By not using exogenous promoters to drive expression of our transgene, we avoid the potential for off-target integration of promoters, which has been associated with an increased risk of cancer. We believe our choice of strong endogenous promoters will allow us to reach therapeutic levels of protein expression from the transgene with the modest integration rates typical of the highly accurate and reliable process of HR. We have observed the accurate insertion of the transgene and the resulting expression by the cells in animal models *in vivo* and human cells *in vitro*.
- **Nuclease-free genome editing.** By harnessing the naturally occurring process of HR, GeneRide is designed to avoid undesired side effects associated with exogenous nucleases used in conventional gene editing technologies. The use of these engineered enzymes has been associated with genotoxicity, including chromosomal alterations, resulting from the error-prone DNA repair of double-stranded DNA cuts. Avoiding the use of nucleases also reduces the number of exogenous components needed to be delivered to the cell.
- **Modularity.** We believe our modular approach will allow GeneRide to deliver robust, tissue-specific gene expression that will be reproducible across different therapeutics targeting the same tissue. The AAV capsid serves as the vehicle that enables delivery of the rest of the components to cells in the body. We and our research partners have done extensive work in developing vectors designed to be highly efficient in delivering their contents to specific target tissues such as the liver. The homology guides, which are independent of the transgene, are segments of DNA that each are hundreds of bases long and direct the integration of the target gene to a precise location in the genome. This location is critical because it determines which endogenous promoter will express the transgene. By substituting a different transgene within the GeneRide construct, we believe we can deliver that transgene to address a new therapeutic indication while substantially maintaining all other components of the construct. We believe, for example, that a new therapy based on liver expression of a transgene could use the same capsid and homology guides as LB-001 with the transgene for the new therapy replacing the *MUT* gene from LB-001. We are aiming to utilize this approach in the development of LB-301 in which several of the components are shared with LB-001. We expect this approach will allow us to leverage common manufacturing processes and analytics across our future GeneRide product candidates and could potentially shorten the development process of future programs.

LB-001 for the Treatment of Methylmalonic Acidemia (MMA)

We are developing our product candidate, LB-001, for the treatment of MMA. LB-001 contains a transgene coding for *MUT*, the most common gene deficiency in patients with MMA. LB-001 is designed to target liver cells and insert the *MUT* transgene into the albumin locus. We have received rare pediatric disease designation and orphan drug designation from the FDA for LB-001.

MMA Disease Background

MMA can be caused by mutations in several genes which encode enzymes responsible for the normal metabolism of certain amino acids. The most common mutations are in the gene for *MUT*, which cause complete or partial deficiencies in its activity. As a result, a substance called methylmalonic acid and other potentially toxic compounds can accumulate, causing the signs and symptoms of MMA. The following figure illustrates the effect of *MUT* deficiency in liver cells.

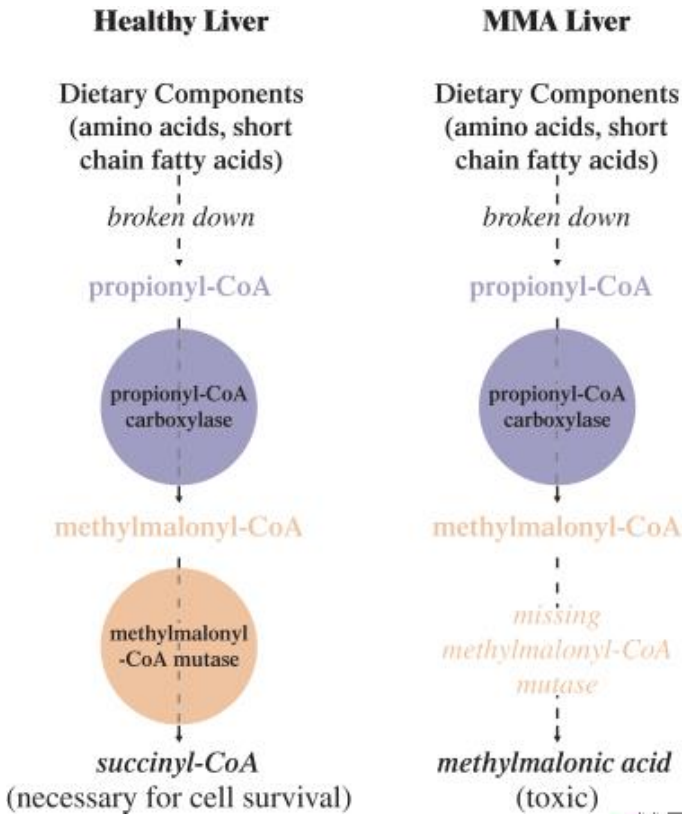


Figure 6. Mutations in *MUT* result in a disorder of the metabolic pathway for branched chain amino acids, specifically methionine, threonine, valine and isoleucine.

The effects of MMA usually appear shortly after birth and can be severe and life-threatening, with symptoms including lethargy, vomiting, dehydration, acidosis and elevated ammonia levels and failure to thrive. Without treatment, MMA leads to coma and death in infancy. Patients with MMA who survive the neonatal period or have later onset of disease are at high-risk of long-term complications including feeding problems, intellectual disability, kidney disease and pancreatitis. There are currently no approved therapies for MMA and the outlook for MMA patients remains poor. Management of the disease is limited to a low-protein, high-calorie diet, lacking amino acids normally processed by the *MUT* pathway. Despite dietary management and vigilant care, MMA patients, especially those with the most severe deficiencies in *MUT*, often suffer neurologic and kidney damage exacerbated during periods of catabolic stress when injury, infection or illness trigger the breakdown of protein in the body. Life expectancy for patients with MMA has increased over the past few decades, but is still estimated to be limited to approximately 20 to 30 years. Quality of life for both patients and their families and caregivers is significantly impacted by the disease due to the constraints it places on school life and social functioning. Early intervention in this vulnerable population is essential to combat the manifestation of irreversible clinical disease pathologies.

The incidence of MMA in the United States is reported to be 1 in 50,000 births, with a current prevalence of approximately 1,600 to 2,400 patients in the United States. The proportion of MMA patients with the *Mut* mutation is estimated at approximately 63% of the total MMA population. We estimate the number of MMA patients with the genetic deficiency targeted by LB-001 to be 3,400 to 5,100 patients in key global markets, of which 1,000 to 1,500 patients are in the United States.

Over time, patients with MMA typically develop end-stage renal disease requiring kidney transplantation in adolescence. Combined liver-kidney transplantation, or early liver transplantation, has emerged as an intervention aimed at improving metabolic control. However, the finite number of liver donors, significant risks associated with surgery, high procedural costs (in the United States, approximately $880,000 on average for liver transplantation and $1.3 million on average for combined liver and kidney transplantation) and lifetime dependence on immunosuppressive drugs limit the widespread implementation of liver transplantation in patients with MMA.

Since *MUT* is a mitochondrial enzyme, we believe deficiencies in *MUT* cannot be corrected by enzyme replacement therapy in which functional enzyme is infused into the bloodstream. The most efficient way to get *MUT* enzyme inside the cell is to have it synthesized there. Several different approaches have been explored in animal models to accomplish this, including introducing mRNA to encode *MUT* directly into cells or introducing the gene for *MUT* into cells using a viral vector. While both of these approaches help to validate that the introduction of a functional *MUT* gene can ameliorate symptoms, they also each have a key limitation in that the therapeutic benefit is transient. In the case of mRNA therapy, weekly intravenous administration of the *MUT* mRNA was required to maintain therapeutic levels of *MUT*, but it is not clear how frequently this therapy would need to be administered in patients. In the case of *MUT* gene therapy, the levels of *MUT* decreased over time. Without a treatment that is durable, multiple doses would be required. However, the patient's development of neutralizing antibodies to the viral vector used to deliver the *MUT* gene therapy limits the ability to administer subsequent doses. In addition, administration of an AAV vector bearing a strong exogenous promoter has been correlated with hepatocellular carcinoma following neonatal delivery.

We believe that introduction of a functional copy of the *MUT* gene into the genome of MMA patients would represent a much better approach, potentially providing lifelong therapeutic benefit from a single administration.

Our Solution—LB-001

LB-001 is our initial GeneRide product candidate, which we are developing for the treatment of MMA. LB-001 consists of a DNA construct including a gene encoding the human *MUT* enzyme encapsulated in an AAV capsid. The *MUT* enzyme coding sequence is coupled to the 2A peptide sequence and surrounded by homology guides that drive the integration of the *MUT* gene and the 2A peptide sequence into the chromosomal locus for the albumin gene. Based on the way our construct integrates into the albumin locus, the *MUT* gene is then expressed resulting in synthesis of *MUT* enzyme as a separate protein from albumin. We chose LK03, the AAV capsid we use in LB-001, because it has been optimized to target human liver cells.

The following graphic illustrates the GeneRide construct for LB-001 inside the LK03 AAV capsid.

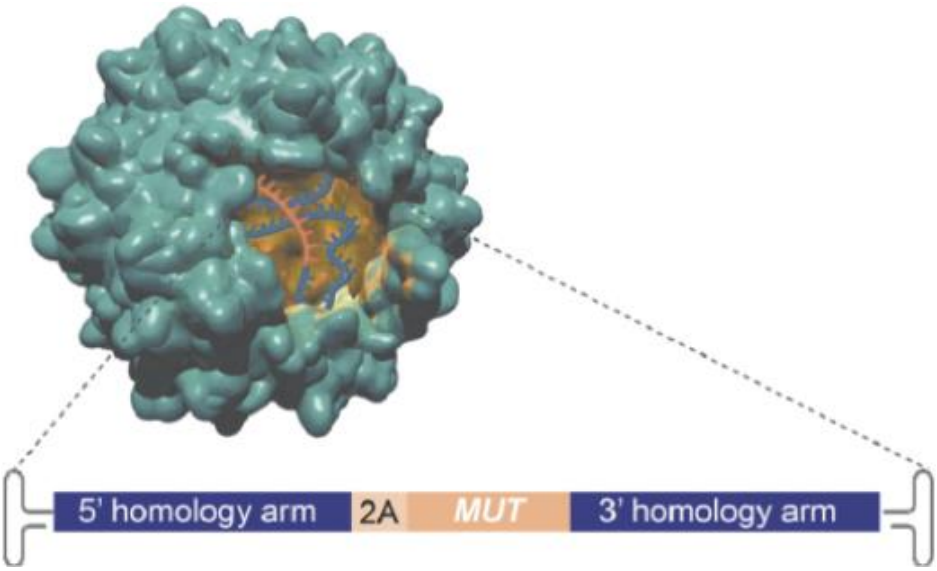
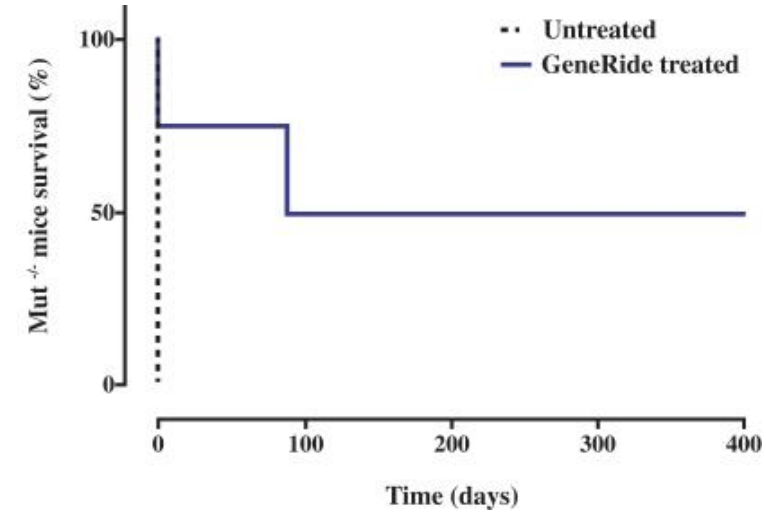


Figure 7. Structure of LB-001 GeneRide construct inside the LK03 AAV capsid.

Preclinical Data

Preclinical data for LB-001 was generated in two mouse models of MMA. In the first model, the gene for Mut had been rendered completely non-functional. This non-functional form of Mut is referred to as Mut$^{-/-}$. Mice bearing this non-functional gene are believed to have a more severe deficiency than seen in the most severe cases of MMA in patients. Left untreated, these mice die within the first few days of life. A single intraperitoneal injection of a murine GeneRide construct of LB-001 into four neonatal mice resulted in increased survival for three out of four mice, with two mice living for more than one year, as shown in the top panel of the following figure. In addition, these mice gained weight, when feeding freely, as shown in the bottom panel of the following figure.

Kaplan-Meier survival curves of
Mut $^{-/-}$ **mice treated with a GeneRide construct**



Weight of ***Mut*** $^{-/-}$ **mice over time**

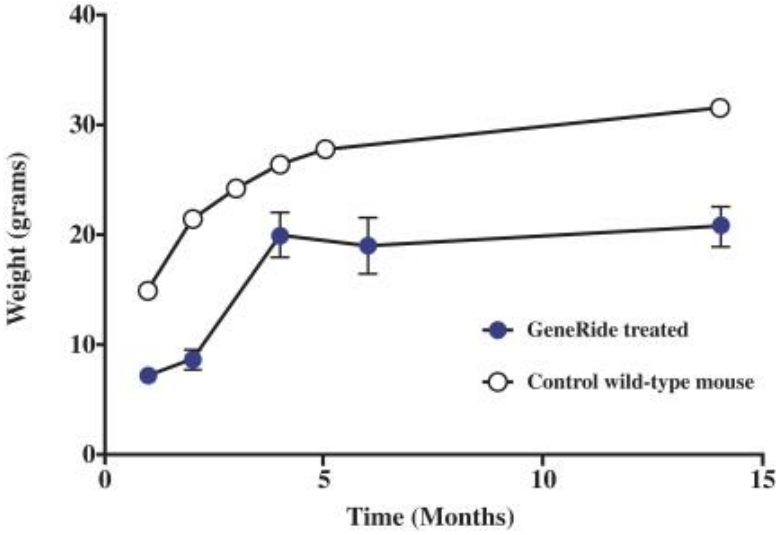


Figure 8. Mut-/- mice display enhanced survival (upper panel) and weight gain (lower panel) following neonatal treatment with a murine GeneRide construct of LB-001. Error bars indicate standard error of the mean, or SEM. Control mice were not included as a head-to-head comparator in our study; control mouse data is derived from studies completed by others.

The second mouse model of MMA, called MCK-Mut, is a modification of the Mut$^{-/-}$ mouse in which a functional copy of the mouse Mut gene is placed under the control of the creatine kinase promoter. This allows Mut expression in muscle cells, which in turn allows mice to survive longer while still exhibiting many of the phenotypic changes seen in MMA patients. Five neonatal MCK-Mut mice received single injections of a murine GeneRide construct of LB-001. Expression of Mut was observed in these mice. At one month of age, these mice had significant improvements in weight gain compared to untreated MCK-Mut mice, as shown in the following figure. These results were statistically significant. P-value is a standard measure of statistical significance, with p-values less than 0.05, representing less than a one-in-twenty chance that the results were obtained by chance, usually being deemed statistically significant.

Weight of MCK-Mut mice at 1 month

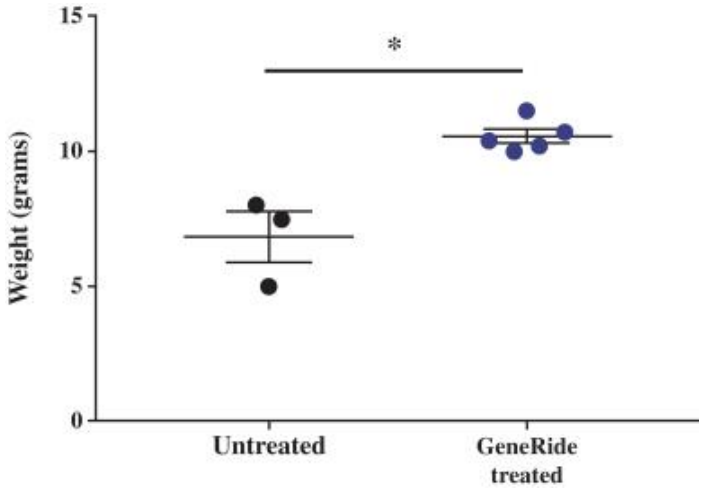


Figure 9. MCK-Mut mice treated with a murine GeneRide construct of LB-001 show significant improvement in growth at one month following a neonatal administration. * indicates p-value <0.05

GeneRide-treated MCK-Mut mice also had significant reductions in plasma levels of methylcitrate and methylmalonic acid, disease-relevant toxic metabolites and diagnostic biomarkers that accumulate in patients with MMA, as shown in the following figure.

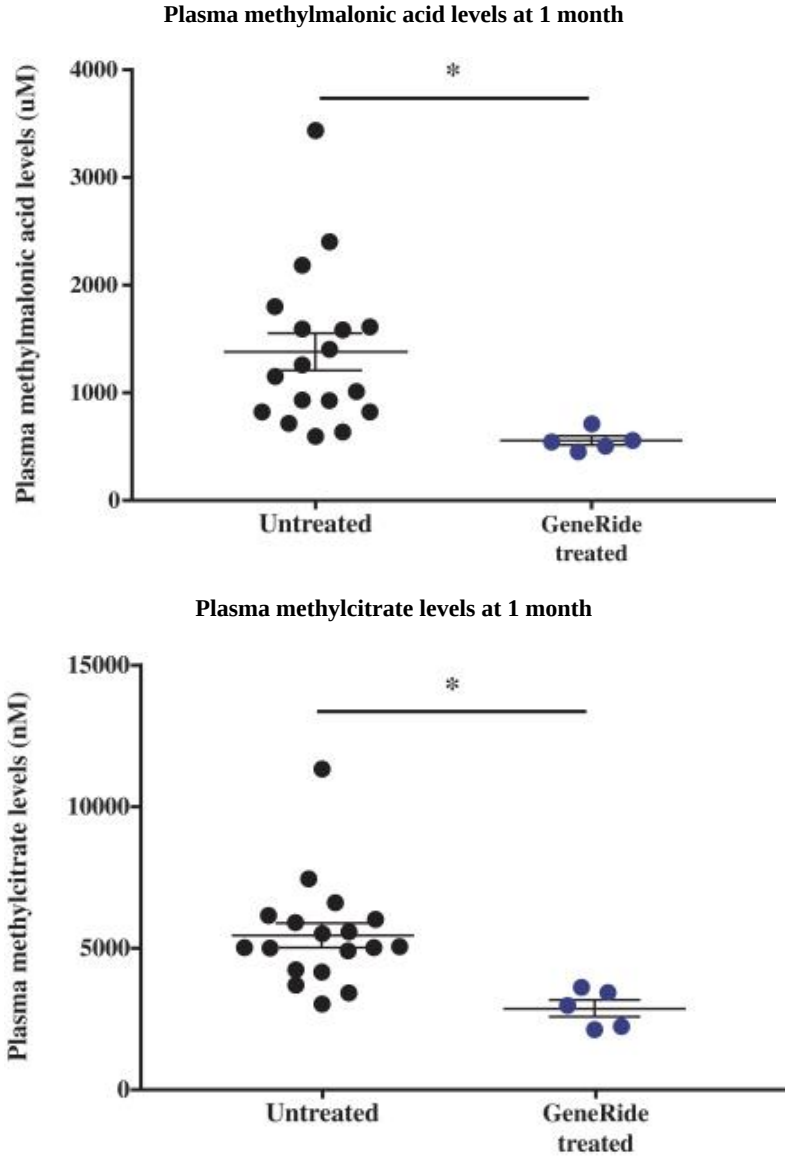


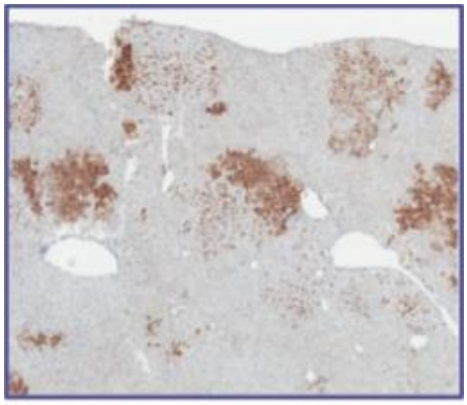
Figure 10. MCK-Mut mice treated with a murine GeneRide construct of LB-001 show significant reduction of two circulating disease related metabolites at one month, following a neonatal administration. Upper panel shows the reduction in plasma methylmalonic acid concentrations. Lower panel shows the reduction in plasma methylcitrate concentrations. Not all untreated mice were included as a head-to-head comparator. Untreated mouse data includes historical control mice. * indicates p-value <0.05

One of the limitations of AAV-directed HR gene editing has been the relatively modest rates of chromosomal integration. We address this limitation in our LB-001 program in multiple ways. First, we make use of an AAV capsid, LK03, which has been optimized to target human liver cells. Second, we target genomic insertion into the locus for the albumin gene. Albumin is the most highly expressed protein in the liver and normal expression of most other proteins is only a fraction of that of albumin. Even a modest integration rate may, therefore, express therapeutic levels of protein. Transcriptionally active genes, of which albumin is one, are more susceptible to transgene integration using HR.

Third, the presence of a functional *Mut* enzyme itself has been observed to provide a selective advantage to hepatocytes over those lacking *Mut*. Over time, this selective advantage leads to an increased proportion of liver cells that contain the functional copy of *Mut*. This can be observed in an experiment we conducted in mice in which a murine GeneRide construct was introduced into mice with and without a functioning native copy of *Mut* in the liver. The initial GeneRide integration frequencies in both sets of mice were less than 4%. Over time, the number of modified cells remained the same in mice that naturally express *Mut* in the liver (Mut+/- in liver). However, after more than one year, in the mice genetically deficient in liver *Mut* (*Mut*-/- in liver), the percent of cells expressing *Mut* increased to 24% as shown in figure 11. This selective advantage could be attributed to improvements in mitochondrial function as a result of *Mut* expression and restoration of the deficient amino acid metabolic pathway.

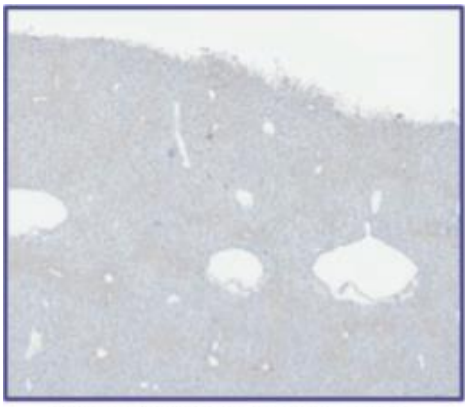
RNAscope analysis of liver sections following treatment with a GeneRide construct

Treatment of mouse deficient in liver *Mut* with a GeneRide construct



GeneRide delivered *Mut* expressed 24% of hepatocytes

Treatment of mouse expressing *Mut* in liver with a GeneRide construct



GeneRide delivered *Mut* expressed 3% of hepatocytes

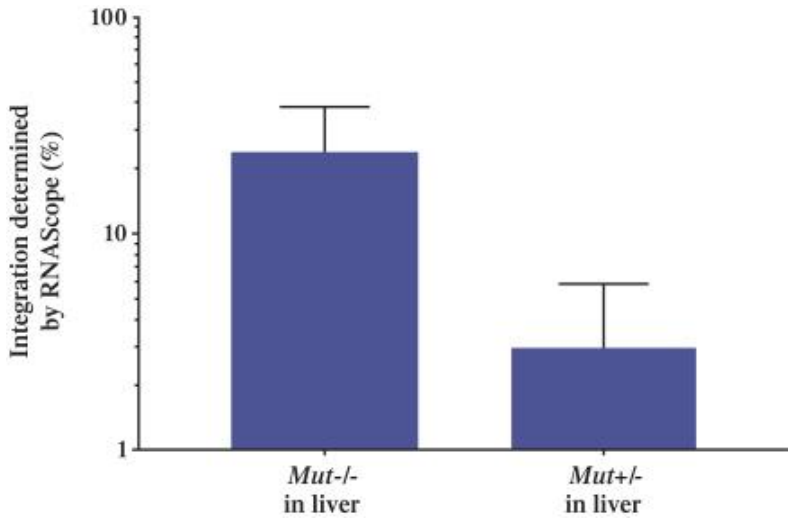


Figure 11. Treatment with GeneRide can result in a selective advantage to modified liver cells. Upper panel: RNAscope analysis of liver sections from mice treated with a murine GeneRide construct of LB-001. Mice genetically engineered without (left) and with (right) a functioning copy of *Mut* in the liver were treated neonatally. After more than one year, cells expressing the *Mut* mRNA specific to our GeneRide construct (dark staining regions) were increased in the mice lacking a natural functioning copy of *Mut* in the liver, suggestive of a beneficial selective advantage of our GeneRide construct of LB-001. Lower panel: quantitation of RNAscope sections conducted by an independent pathologist.

Additional supporting evidence for selective advantage in these mice includes (i) quantification of cells with the *Mut* gene integrated at the albumin locus by an orthogonal long-range quantitative polymerase chain reaction, or LR-qPCR, as shown in Figure 12, lower panel, and (ii) detection of an increased rate of integration at the albumin locus by LR-qPCR at more than one-year compared to one month post dose, as shown in Figure 13.

Quantitation of selective advantage observed in liver sections by DNA integration assay

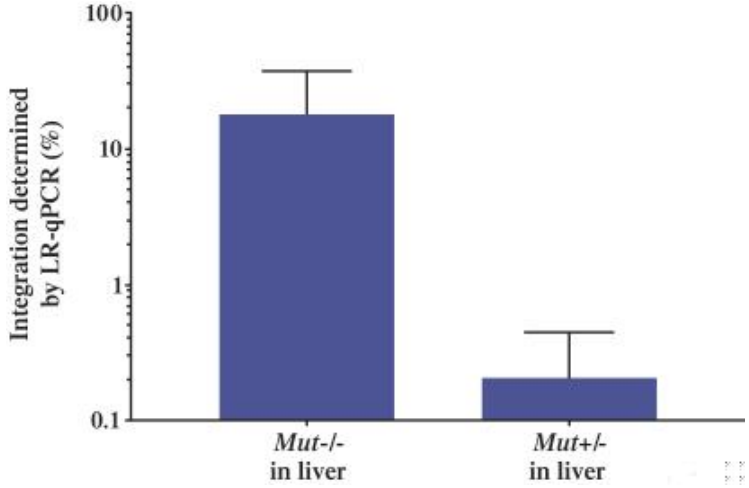


Figure 12. Percent of liver cells containing an integrated copy of the GeneRide specific *Mut* gene more than one year after a single neonatal administration of a *Mut* GeneRide construct in mice. LR-qPCR quantitation of DNA with the *Mut* gene integrated at the albumin locus. Error bars indicate SEM. LR-qPCR=long-range quantitative PCR.

Increase in DNA integration observed rate over time

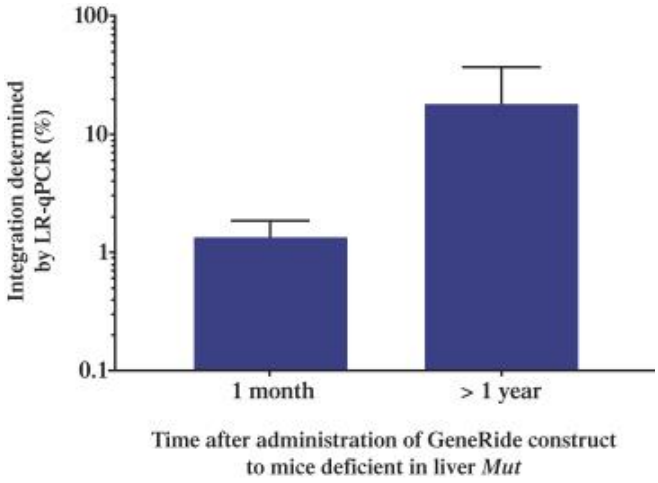


Figure 13. Increase in cells with integrated GeneRide construct observed over time. Mice deficient in liver *Mut* were administered a GeneRide construct as neonates. DNA analysis for integration at the albumin locus was conducted by LR-qPCR at 1 month and more than one-year post dose. Error bars indicate SEM.

In contrast to conventional AAV gene therapy approaches, in which the percentage of cells containing the therapy decreases over time as cells replicate and lose the virally encoded transgene, in the MMA mouse study, the percentage of cells containing a *Mut* GeneRide construct increased over time. These results support our belief that a single administration may provide lifelong benefits.

Clinical Development of LB-001

In January 2020, we announced the submission of an Investigational New Drug, or IND, application with the U.S. Food and Drug Administration, or FDA, to initiate a Phase 1/2 trial of LB-001 in pediatric patients, which has been placed on clinical hold pending the resolution of certain clinical and nonclinical questions.

LB-301 for the Crigler-Najjar Syndrome (CN)

In January 2020, we announced a research collaboration with Takeda Pharmaceutical Company Limited to further develop LB-301 in CN, the second indication to be pursued using the GeneRide platform. Takeda will provide funding for the research program under the collaboration agreement and will have an exclusive option to negotiate an exclusive, worldwide license to LogicBio's LB-301 program.

CN Disease Background

Crigler-Najjar syndrome is a rare monogenic pediatric disease caused by a deficiency in the gene known as uridine disphosphate-glucuronosyltransferase-1, or *UGT1A1*, which is primarily expressed in liver cells, resulting in severely high levels of unconjugated bilirubin in the blood starting at birth, with lifelong risk of permanent neurological damage and death. Current clinical practice consists of daily, intense phototherapy treatment for approximately 12 hours, but this treatment becomes less effective with age, ultimately leaving liver transplantation as the only therapeutic option for survival. The global incidence of CN is reported to be 1 in 1,000,000 births, with a current global prevalence of approximately 400 to 1,200 patients.

Our Solution—LB-301

LB-301 contains a transgene coding for *UGT1A1*. LB-301 is designed to target liver cells and insert the *UGT1A1* transgene into the albumin locus. A murine GeneRide construct of LB-301was used to correct the gene deficiency in an animal model of CN. The introduction of UGT1A1 into the albumin locus in mouse liver cells resulted in normalization of bilirubin levels and long-term survival of mice deficient in UGT1A1 from less than twenty days to at least one year, as shown in figure 14.

12 month survival after treatment with GeneRide construct in Crigler-Najjar syndrome mouse model

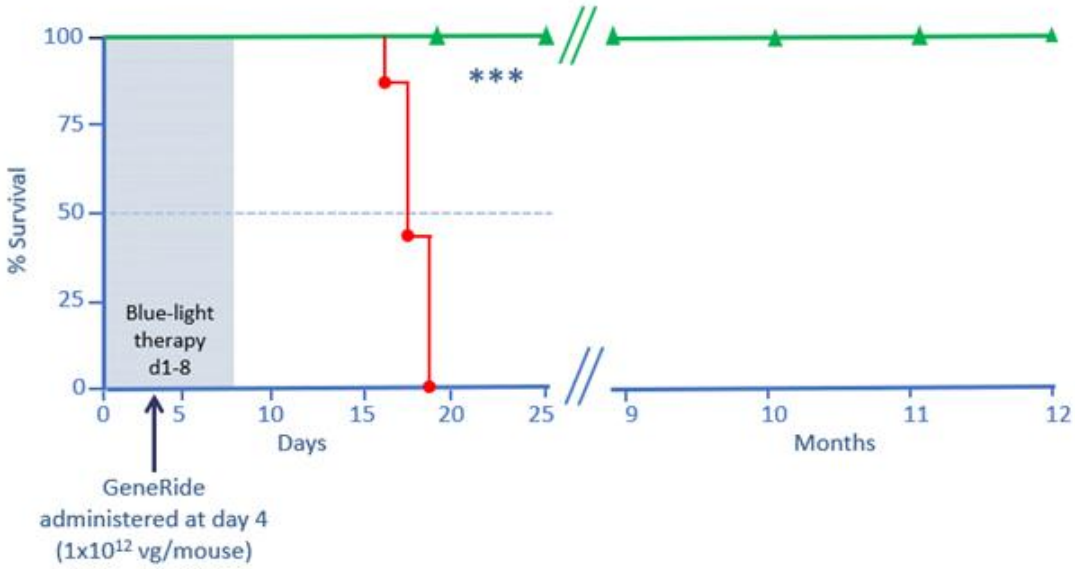


Figure 14. Increased survival in a mouse model of Crigler-Najjar syndrome following neonatal administration of a GeneRide construct delivering UGT1A1 shown in green. Untreated animals, shown in red, (n=6) all died within 20 days of birth without continued blue-light therapy. Blue-light therapy, a treatment that facilitates clearance and reduction of toxic bilirubin levels, was applied from birth to Day 8. Without continued blue-light therapy, animals treated with a GeneRide construct (n=5) survived for one year. * indicates p-value <0.001**

Future Product Opportunities

Future Liver-Directed Therapies

We expect that our future product candidates, like LB-001 and LB-301, will be liver-directed therapies. The specificity of our candidates for the liver is determined both by the AAV capsid used and by the location of integration into the host cell's DNA. LB-001 utilizes the AAV capsid, LK03, which was designed to be highly efficient for transduction of human liver and is being evaluated in a gene therapy clinical trial in the United States conducted by another company. We chose to insert the transgenes for our liver-directed candidates into the albumin gene locus, which is only produced at a meaningful level in the liver, where it is the most highly expressed gene. We believe that the choice of albumin enhances our liver specificity because the active transcription enhances the rate of homologous recombination and the tissue-specific expression of the albumin gene will drive production of our transgene in the liver.

Using Liver as In Vivo Protein Factory

The liver is a major secretory organ that produces many proteins found in circulation. We believe this attribute can allow hepatocytes to deliver key therapeutic proteins systemically to patients with genetic deficiencies. For example, we have demonstrated proof of concept in an animal model of hemophilia B using a murine GeneRide construct of LB-101, encoding human coagulation factor IX to correct a clotting deficiency. In this model, expression of human coagulation factor IX and blood coagulation was restored to normal levels after a single treatment in neonatal and adult diseased mice.

In addition, stable and therapeutic levels of human factor IX persisted for 20 weeks in neonatal wild type mice following administration of a murine GeneRide construct of LB-101, even after partial hepatectomy, or, PH, as shown in Figure 15. PH is a procedure where two-thirds of the liver is removed to trigger regenerative organ growth. With conventional AAV gene therapy, transgene expression following PH is drastically reduced.

Therapeutic and stable levels of human factor IX in plasma following treatment with a murine GeneRide construct of LB-101

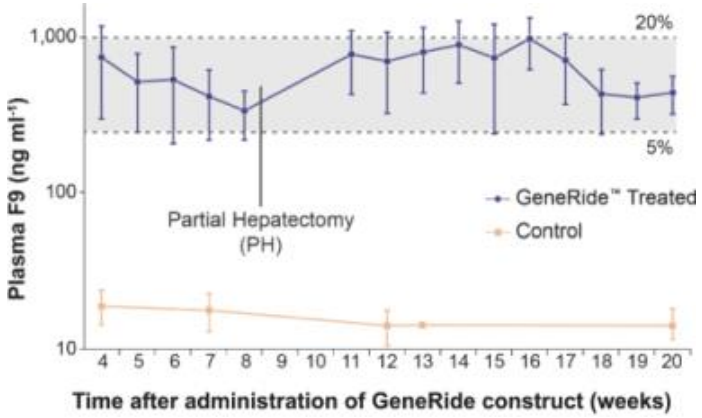


Figure 15. Therapeutic and stable levels of human factor IX with a murine GeneRide construct of LB-101. Stable and therapeutic levels of factor IX production from the liver, following neonatal administration, persisted for 20 weeks after administration, even with a PH conducted at 8 weeks of age (therapeutic levels of factor IX between 5% and 20% of normal factor IX shown by dashed lines and the shaded region). Error bars indicate standard deviation.

Multi-Organ Diseases

Some genetic mutations result in both protein deficiencies and over-expression of deleterious proteins, leading to pathogenesis. One such disease is A1ATD. In A1ATD, patients have a deficit of circulating A1AT and can develop severe liver damage, which may necessitate a liver transplant. This is because AATD is a dominant negative genetic disease, in which the defective copy of the gene is associated with symptoms even in the presence of a normal copy. AATD is another genetic disease that has been corrected in a mouse model using a murine GeneRide construct of LB-201. The GeneRide construct used in the mouse model included a normal copy of the gene as well as a microRNA that was designed to reduce the expression of the deleterious gene. Expression of the transgene and downregulation of the mutant gene were evident in these mice for at least eight months.

Discovery Engine

We continue to evaluate additional indications for our GeneRide platform. The key criteria we use in selecting development programs is unmet clinical need, the requirement to intervene early, well-understood biology, existing animal disease model, the ability to rapidly generate clinical proof of concept data and technical feasibility. We will also prioritize indications where we believe restoration of a modest level of transgene expression can provide a therapeutic benefit and where selective advantage of modified hepatocytes may further increase the proportion of corrected cells in the tissue over time. Our initial focus will be on hepatic and systemic diseases where liver-directed therapy is likely to provide therapeutic benefit. We expect that later product candidates will include products that target other tissues such as the CNS or muscle.

Continued Evolution of the GeneRide Platform

We continue to work to optimize key aspects of our platform from the design of the constructs and capsids to manufacturing at a commercial scale.

- **AAV capsid.** AAV capsids are designed to be highly efficient in delivering their contents to specific target tissues such as the liver. Extensive work has been done by our founders to identify capsids better suited for clinical use in the liver and other indications. For example, LK03, the AAV capsid we licensed from the Kay Lab at Stanford and use in LB-001, was developed to be liver selective. A published study found that the prevalence of neutralizing antibodies against LK03 is low in general (23%), particularly in late childhood, which we believe makes this capsid especially suitable for AAV gene therapy in pediatric patients. LK03 is also currently being used by other companies to treat hemophilia patients with liver selective gene therapy. In addition, we plan to develop next generation AAV capsids through collaborations with leading research institutions such as CMRI and the Kay Lab.

- **Homology guides and integration sites.** Our genome editing technology has the potential advantage that the homology guides and integration sites for one therapy can be applied to other therapies that target the same tissue. We intend to apply the knowledge we gain through the optimization of the rate of homologous recombination and gene expression levels to subsequent product candidates.
- **Targets.** We continue to evaluate a broad range of potential targets, starting with those that correspond to genes normally expressed in the liver, continuing to other tissues related to liver expression, and finally to considering targets that are best addressed directly in other tissues such as the CNS or muscle.
- **Selection.** A potential advantage of our genome editing technology is its durable nature arising from chromosomal integration. We have identified therapies where correction of a gene deficiency may provide a selective advantage to cells and drive expansion of the percentage of cells containing the transgene. We and our collaborators are also assessing methods of providing a selective advantage to treated cells even when the transgene does not provide a selection advantage at the cellular level. One such method involves adding an element to a GeneRide construct such that cells that do not incorporate the element are at a selective disadvantage when patients are treated with an external agent. We believe that these and related methods will enable us to enrich the number of cells containing the desired gene ensuring that patients derive long-term therapeutic benefit.

Manufacturing

We believe we are well-positioned to drive the continued development of our GeneRide technology for the treatment of severe genetic diseases. We have assembled extensive expertise in capsid development, AAV vector design, product development and manufacturing, as well as a broad intellectual property estate, an experienced management team and a world-class group of scientific advisors and network of leading contract development and manufacturing organizations and academic collaborators.

Additionally, we are developing an AAV vector manufacturing process technology that we believe will be both reproducible and scalable. We believe that our work and advancements in viral vector design, capsid development and related manufacturing processes will serve as a strong foundation for the industrialization of our genome editing technology and ultimately enable us to realize the full potential of our GeneRide technology and our products on a commercial scale.

Competition

The biotechnology and pharmaceutical industries, including in the gene therapy, gene editing and genome editing fields, are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property and proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing and commercialization. Not only must we compete with other companies that are focused on gene therapy, gene editing and/or genome editing technologies, any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that utilize technologies encompassing genomic medicines to create therapies, including gene therapy and gene editing. There are additional companies that are working to develop therapies in areas related to our research programs.

Our focus is the development of genetic medicines using our proprietary GeneRide technology. If our current programs are approved for the indications we are pursuing or contemplate we may pursue, they may compete with other products currently under development, including gene editing and gene therapy products. There are a number of companies developing nuclease-based gene editing technologies using CRISPR/Cas9, TALENs, meganucleases, Mega-TALs and ZFNs, including bluebird bio, Caribou Biosciences, CRISPR Therapeutics, Editas Medicine, Intellia Therapeutics, Sangamo Therapeutics and Precision BioSciences. We may also compete with companies developing gene therapy products, including Homology Medicines, Audentes Therapeutics, bluebird bio, uniQure, Generation Bio and Voyager Therapeutics. There are also companies pursuing base editing technologies, including Beam Therapeutics.

Any products we may develop could also face competition from other products approved to treat the same disease based on other types of therapies, such as small molecule, antibody or protein therapies. There are several companies developing competing products that target MMA, the indication for which we are developing LB-001. These companies include Moderna Therapeutics with an mRNA based approach, Selecta Biosciences with an AAV gene therapy, and Hemoshear Therapeutics using a small molecule. Moderna disclosed it had an open IND for mRNA-3704 in March 2019 and it had enrolled a first patient in their ongoing Phase 1/2 trial in February 2020. If any of our competitors obtain regulatory approval for a treatment for MMA, it could negatively affect our ability to successfully commercialize LB-001, if approved.

There are several companies developing competing products that target CN, the indication for which we are developing LB-301. These companies include Genethon, Selecta Biosciences and Audentes using AAV gene therapies. Genethon disclosed it had dosed a first patient in their ongoing Phase 1/2 trial in December 2018. Promethera previously completed a Phase 1/2 study that enrolled patients with Crigler-Najjar Syndrome or ornithine transcarbamylase deficiency. If any of our competitors obtain regulatory approval for a treatment for CN, it could negatively affect our ability to successfully commercialize LB-001, if approved. In addition, many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience and availability of reimbursement.

Furthermore, we rely upon a combination of patents and trade secret protection, as well as license and confidentiality agreements to protect the intellectual property related to our proprietary technologies, product candidate development programs and product candidates. Our success depends in large part on our ability to secure and maintain patent protection in the United States and other countries with respect to LB-001 and any future product candidates. Moreover, our industry is characterized by the existence of large numbers of patents and frequent allegations of patent infringement. If, therefore, we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained or in-licensed is not sufficiently broad or if the validity of such patent is threatened, we may not be able to compete effectively in our markets, as it could create opportunities for competitors to enter the market or dissuade other companies from collaborating with us to develop products and technology, any of which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved. For more information regarding these competitive risks, see “Risk Factors—Risks Related to Commercialization.”

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. We seek to protect our proprietary position by, among other things, exclusively licensing and filing U.S. and certain foreign patent applications related to our platform technology, existing and planned programs, and improvements that are important to the development of our business, where patent protection is available. We also rely on trade secrets, know-how, continuing technological innovation, and confidential information to develop and maintain our proprietary position and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We additionally rely on regulatory protection afforded through orphan drug designations, data exclusivity, market exclusivity, and patent term extensions where available.

Our in-licensed patents and patent applications are directed to various aspects of our gene insertion and gene targeting technologies, including technology applied to treatment of human diseases by targeted insertion and expression of therapeutic transgenes and viral vector technology for transgene delivery. The licenses are, in some cases, limited to certain technical fields and/or therapeutic indications. We intend to pursue, when possible, additional patent protection, including filing patent applications seeking to protect composition of matter, method of use, and process claims, directed to our product development programs. We also intend to pursue rights to existing technologies through one or more licenses from third parties.

Notwithstanding these efforts, we cannot be sure that patents will be granted with respect to any patent applications we have licensed or may license or file in the future, and we cannot be sure that any patents we have licensed or patents that may be licensed or granted to us in the future will not be challenged, invalidated, or circumvented or that such patents will be commercially useful in protecting our technology. Moreover, trade secrets can be difficult to protect. While we have confidence in the measures we take to protect and preserve our trade secrets, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

For more information regarding the risks related to our intellectual property, please see “Risk Factors—Risks Related to Our Intellectual Property.”

Our intellectual property portfolio as of February 29, 2020 is summarized below. For some of our pending patent applications, prosecution has yet to commence. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO is often significantly narrowed by the time they issue, if they issue at all. We expect this to be the case with respect to our pending patent applications referred to below.

Nucleic Acid Delivery

We have non-exclusively licensed from The Board of Trustees of the Leland Stanford Junior University, or Stanford, two families of patents and patent applications, or Family 1 and Family 2, relating to AAV capsid polypeptides with improved properties useful for nucleic acid transfer applications and their manufacture and methods of use. Family 1 includes four granted U.S. patents in the U.S. and one granted European patent. The issued U.S. patents in Family 1 are expected to expire in 2027. Patent term extensions could result in later expiration dates. Family 2 includes two granted U.S. patents and pending applications in the U.S., Europe, and Hong Kong. The issued U.S. patents in Family 2, and any which may later issue from a pending Family 2 patent application, are expected to expire in 2032. Patent term adjustments or patent term extensions could result in later expiration dates. For more information regarding the terms of our license to Family 1 and Family 2, please see “License Agreements.”

Non-Disruptive Gene Targeting

We have exclusively licensed from Stanford and the Board of Regents of the University of Texas System, or UT, patent applications relating to technology for the insertion of a gene or genes of interest at a target genomic locus without disruption of endogenous gene expression, or Family 3. Family 3 includes one pending patent application in each of the U.S. and Europe. Any patent which may issue from a pending Family 3 patent application is expected to expire in 2033. Patent term adjustments or patent term extensions could result in later expiration dates. For more information regarding the terms of our license to Family 3, please see “License Agreements.”

Genome Editing without Nucleases

We have exclusively licensed from Stanford patent applications relating to technology for the nuclease-free insertion of a gene or genes of interest at a target genomic locus without disruption of endogenous gene expression, or Family 4. Family 4 includes patent applications pending in eleven jurisdictions including the U.S., Europe, Canada, China, Korea, and Japan. Any patent which may issue from a pending Family 4 patent application is expected to expire in 2035. Patent term adjustments or patent term extensions could result in later expiration dates. For more information regarding the terms of our license to Family 4, please see “License Agreements.”

AAV Capsids which Exhibit an Enhanced Neutralization Profile and/or Increased Transduction or Tropism in Human Liver Tissue or Hepatocyte Cells

We have non-exclusively licensed from Stanford patent applications, or Family 5, relating to recombinant AAV capsids resistant to pre-existing human neutralizing antibodies and/or characterized by increased transduction or tropism in human liver tissue or hepatocyte cells, useful for nucleic acid transfer applications and their manufacture and methods of use. Family 5 includes two granted U.S. patents and patent applications pending in six jurisdictions including the U.S., Europe, Australia, Canada, China and Japan. The issued U.S. patent in Family 5, and any patent which may issue from a pending Family 5 patent application is expected to expire in 2037. Patent term adjustments or patent term extensions could result in later expiration dates.

Synthetic codon-optimized MUT gene

We have non-exclusively licensed from the U.S. Department of Health and Human Services, as represented by the National Human Genome Research Institute, an Institute of the National Institutes of Health (the "NIH"), patents and patent applications relating to synthetic polynucleotides encoding methylmalonyl-CoA mutase *(synMUT)* and exhibiting augmented expression in cell culture and/or in a subject. The *synMUT* license includes at least three granted U.S. patents, one granted European patent, and a pending application in the U.S. The issued U.S. patents under the *synMUT* license and any which may later issue from a pending patent application are expected to expire in 2034. Patent term adjustments or patent term extensions could result in later expiration dates. For more information regarding the terms of the *synMUT* license, please see "License Agreements

In addition to the above, we have also filed a U.S. Provisional application and a PCT application directed to non-disruptive gene therapy for the treatment of MMA.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the U.S., the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the U.S., a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each product and other factors. There can be no assurance that any of our pending patent applications or the pending patent applications licensed to us will issue or that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents or the pending patent applications licensed to us.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims, if granted. However, our pending patent applications, and any patent applications that we may in the future file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents or patents that we license. Any issued patents that we may receive or license in the future may be challenged, invalidated or circumvented. For example, we cannot be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications in the U.S. that also claim technology or therapeutics to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention, which could result in substantial costs to us, even if the eventual outcome is favorable to us, which is highly unpredictable. In addition, because of the extensive time required for clinical development and regulatory review of a treatment method or product candidate we may develop, it is possible that, before any of our technology can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting protection such patent would afford the respective technology and any competitive advantage such patent may provide.

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by executing collaboration agreements containing confidentiality obligations with our collaborators, and agreements containing non-competition, non-solicitation, confidentiality, and invention assignment obligations with our employees and consultants, including our scientific advisors. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that these agreements will afford us adequate protection of our intellectual property and proprietary information rights.

Trademarks

Our registered trademark portfolio currently includes pending trademark applications in the United States for the marks LOGICBIO and GENERIDE.

License Agreements

We are a party to a number of license agreements under which we license patents, patent applications, and other intellectual property from third parties. The licensed intellectual property covers some of the compositions that we are researching and developing and some of the scientific processes that we use. These licenses impose various diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future. We consider the following license agreements to be material to our business.

The Board of Trustees of the Leland Stanford Junior University License Agreements

In December 2015, as restated in January 2018, we entered into a license agreement with Stanford pursuant to which we obtained an exclusive, worldwide license to make, have made, use, import, offer to sell and sell products covered by certain patent rights to the GeneRide technology owned by Stanford within certain fields of use.

This exclusive license grant is limited to the following fields: (a) human therapeutics to treat methylmalonic acidemia, propionic acidemia, HIV, influenza, malaria, Crigler-Najjar syndrome, Tyrosinemia Type I, Wilson's disease, hemophilia B, Glycogen Storage Disease 1 and Glycogen Storage Disease 3, and (b) the prevention, treatment or diagnosis via genome editing without a nuclease of certain additional indications with respect to liver tissue and certain other tissues to be nominated by us, subject to the terms of the agreement.

Pursuant to the Stanford license agreement, we also obtained (i) a non-exclusive license to make, have made, use, import, offer to sell and sell products covered by the foregoing GeneRide patent rights in the field of human therapeutics to treat hemophilia A (via genome editing without a nuclease) and Alpha-1 antitrypsin disease; (ii) a non-exclusive license to make, have made, use, import, offer to sell and sell products covered by certain patent rights with respect to AAV capsids owned by Stanford within the same fields of use that apply to the license under the patent rights to the GeneRide technology owned by Stanford; (iii) an exclusive license to make, have made, use, import, offer to sell and sell products covered by certain capsid-related patent rights owned by Stanford within the field of the diagnosis, prevention or treatment of phenylketonuria in humans; and (iv) a non-exclusive license to certain related know-how.

The license grant from Stanford under the patent rights to the GeneRide technology owned by Stanford does not extend to autologous *ex vivo* use for non-episomal DNA delivery and maintenance for hematopoietic stem cells for sickle cell or beta thalassemia.

The rights licensed to us are sublicensable through a single tier without Stanford's consent.

Under the terms of the agreement, as amended, we paid a one-time, non-refundable upfront fee of $75,000, issued Stanford 130,894 shares of our common stock, and subsequently issued 56,097 additional shares of common stock pursuant to Stanford's anti-dilution rights under the agreement. In addition, pursuant to its rights under the agreement, Stanford purchased shares of our Series A Preferred Stock and Series B Preferred Stock. We are required to pay Stanford low single-digit royalties on net sales of products as well as a portion of non-royalty sublicensing revenues. Our obligation to pay royalties will expire (i) on country-by-country basis with respect to net sales of any specified product sold, used, manufactured or imported in an applicable country until the expiration of the last valid claim within the licensed patents in such country covering such licensed product; and (ii) with respect to net sales of any such product, ten years from the first commercial sale of any licensed product. We are also obligated to pay annual maintenance fees, which are fully creditable against any royalty payments made by us, and up to an aggregate amount of $1.3 million of development milestone payments. We were also required to reimburse Stanford for all patent prosecution costs incurred prior to the agreement with respect to the patent rights to the GeneRide technology and for all future patent prosecution costs with respect to the patent rights to the GeneRide technology. We do not have the right to control patent prosecution with respect to the licensed patent applications, but we do have the first right to enforce any patents which may issue from these patent applications.

The term of the license agreement will continue so long as there is a valid claim of a licensed patent. Stanford may terminate the agreement upon at least 60 days' notice to us if (i) we are in material default in the provision of any report or payment of any amounts due to Stanford under the agreement, (ii) we do not use commercially reasonable efforts to develop or commercialize licensed products; (iii) we do not achieve certain diligence milestones within the mutually agreed timeline; (iv) we are in material breach of any provision of the agreement; or (v) provide any materially false report to Stanford. We may terminate the agreement at any time upon at least 30 days' notice to Stanford.

The Board of Regents of the University of Texas System License Agreement

In May 2018, we entered into a license agreement with the University of Texas, pursuant to which we obtained an exclusive, worldwide license to manufacture, have manufactured, distribute, have distributed, use, offer for sale, sell, lease, loan or import products covered by certain patent rights to the GeneRide technology owned by the University of Texas (jointly with Stanford) within certain fields of use.

This exclusive license grant is limited to the following fields: (a) human therapeutics to treat methylmalonic acidemia, propionic acidemia, HIV, influenza, malaria, Crigler-Najjar Syndrome, Tyrosinemia Type I, Wilson's disease, hemophilia B, Glycogen Storage Disease 1, Glycogen Storage Disease 3 and any other human disease of liver tissue that affects less than 200,000 persons in the United States as of the effective date of the agreement, and (b) the prevention, treatment or diagnosis via genome editing without a nuclease of certain additional indications with respect to certain tissues to be nominated by us, subject to the terms of the agreement.

Pursuant to the University of Texas license agreement, we also obtained a non-exclusive license to certain related know-how.

The rights licensed to us are sublicensable through multiple tiers without the consent of the University of Texas.

Under the terms of the agreement we paid a one-time, non-refundable upfront fee of $25,000. We are required to pay the University of Texas low single-digit royalties on all net sales of products as well as a portion of any sublicensing revenues. We are also obligated to pay annual maintenance fees, which are fully creditable against any royalty payments made by us, and certain development and sales milestone payments up to $3.0 million. We are also required to reimburse the University of Texas for all future patent prosecution costs on a pro rata basis with other licensees. We do not have the right to control patent prosecution with respect to the licensed patent applications, but we do have the first right to enforce any patents which may issue from these patent applications.

The term of the license agreement will continue on a country-by-country and product-by-product basis until the later of the expiration of the last-to-expire valid claim of a licensed patent that covers such product in such country and 10 years from the date of the first commercial sale of such product in such country. The University of Texas may terminate the agreement in its entirety or with respect to any applicable part of the licensed subject matter, field of use or licensed territory, or convert the exclusive license to a non-exclusive license, if (i) we fail to timely make a required payment to the University of Texas under the agreement; (ii) we are in material breach of a provision of the agreement and fail to timely cure such breach; (iii) we breach any payment obligation under the agreement three or more times in any 12-month period; (iv) we initiate, or an affiliate or sublicense initiates, a patent challenge against a licensed patent; or (v) we become bankrupt or insolvent, our board elects to liquidate our assets or dissolve the business, we cease business operations, we make an assignment to the benefit of our creditors, or our business or assets are otherwise placed in the hands of a receiver, assignee or trustee. We may terminate the agreement in its entirety or with respect to any applicable part of the licensed subject matter, field of use or licensed territory upon at least 30 days' notice to the University of Texas.

The NIH

In December 2018, we entered into a license agreement with the NIH, pursuant to which we obtained a non-exclusive, worldwide license under certain specified patent rights relating to a synthetic codon-optimized MUT gene that is incorporated into the LB-001 GeneRide construct, to exploit products and practice processes that are covered by the licensed patent rights in the field of research, development, manufacture and commercialization of pharmaceutical products for the treatment or prevention of MMA using gene therapy constructs in humans. We have the right to grant sublicenses under the license granted by the NIH, concurrently with licenses of its proprietary or other in-licensed intellectual property rights, with the NIH's prior consent, not to be unreasonably withheld. The license grant is subject to typical statutory requirements and reserved rights as required under federal law and NIH requirements, including a requirement to manufacture substantially in the United States products used or sold in the United States that embody Licensed Products or are produced through the use of Licensed Processes.

Under the terms of the License Agreement, the NIH is entitled to receive an upfront payment of $25,000, and payments of up to an aggregate of $9.7 million upon the achievement of certain specified development, regulatory and sales-based benchmarks. The NIH is also entitled to receive running royalties on annual net sales of Licensed Products (subject to reductions for combination products that include Licensed Products), at certain low- to mid-single digit royalty rates, which rates vary based on the geographic market in which a sale occurs (subject to certain annual minimum royalty payments). The milestones and running royalties will be payable with respect to Licensed Products that are no longer covered by the licensed patent rights in a country, if the products are the subject of orphan drug exclusivity in the country. Additionally, if we receive a priority review voucher or a foreign equivalent for a Licensed Product, we have an obligation to pay to the NIH (a) a mid-single digit percentage of the sale price of the voucher, if we sell the priority review voucher, or (b) a low-single digit

percentage of the fair market value of the voucher, if the we use the voucher to obtain regulatory approval of its product for an orphan indication or in the Licensed Field. The NIH is also entitled to receive a low-single digit percentage of upfront consideration that we receive for a sublicense of the rights licensed under the License Agreement and a low-single digit percentage of any consideration received for any assignment of the License Agreement by us.

Under the terms of the License Agreement, we have an obligation to use reasonable commercial efforts to make Licensed Products and Licensed Processes reasonably available in the United States following first commercial sale, make reasonable quantities of Licensed Products or materials produced through the use of Licensed Processes available to patient assistance programs and achieve certain diligence milestones.

Unless earlier terminated, the term of the License Agreement will continue until the last to expire of the licensed patent rights and any orphan drug exclusivity covering a Licensed Product in any jurisdiction. The NIH may terminate the License Agreement if we are in default in the performance of any material obligations under the License Agreement if the default has not been remedied within ninety days after the date of notice in writing of the default. In addition, the NIH may terminate or modify, at its option, the License Agreement, if the NIH determines, taking into account the normal course of commercial development programs conducted with sound and reasonable business practices and judgment, that we (i) have willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by the License Agreement, (ii) have committed a material breach of a covenant or agreement contained in the License Agreement, (iii) are not keeping Licensed Products or Licensed Processes reasonably available to the public after first commercial sale, (iv) cannot reasonably satisfy unmet health and safety needs or (v) cannot reasonably justify a failure to comply with its domestic manufacturing requirements under the License Agreement. We have a unilateral right to terminate the License Agreement in any country or territory by giving the NIH sixty days' written notice.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, sale, distribution, post-approval monitoring and reporting, marketing and export and import of drug products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Government Regulation of Biological Products

In the United States, biological products, including gene therapy products, are subject to regulation by the U.S. Food and Drug Administration, or FDA, under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. Products also are subject to other federal, state and local statutes and regulations. Each clinical study protocol for a gene therapy product must be reviewed by the FDA. FDA approval must be obtained before marketing of biological products.

Within the FDA, the Center for Biologics Evaluation and Research, or CBER, regulates gene therapy products. The FDA has published guidance documents with respect to the development and submission of gene therapy protocols. The FDA also has published guidance documents, including as recently as January 2020, related to, among other things, the overall gene therapy development process, preclinical assessment, observing subjects in gene therapy studies for delayed adverse events, potency testing, orphan drug designation and exclusivity for gene therapy products, and chemistry, manufacturing and control information in an IND for gene therapy.

Ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of our product candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

The process required by the FDA before a biological products may be marketed in the United States generally involves the following:

- completion of extensive preclinical studies and tests in accordance with applicable regulations, including Good Laboratory Practice, or GLP, regulations and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practices, or GCPs, and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that includes substantive evidence of safety, purity, and potency from results of preclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biologic will be produced to assess compliance with good manufacturing practices, or cGMPs, to assure that the facilities, methods and controls used in product manufacture are adequate to preserve the biologic's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;
- potential FDA inspection of the preclinical study, LogicBio as clinical trial sponsor, and/or the clinical trial sites that generated the data in support of the BLA;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies);
- agreement with FDA on the final labeling for the product and the design and implementation of any required Risk Evaluation and Mitigation Strategy; and
- FDA review and approval of the BLA, including satisfactory completion of an FDA advisory committee review, if applicable, prior to any commercial marketing or sale of the product in the United States.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our investigational medicines and any future investigational medicines will be granted on a timely basis, or at all.

Preclinical Studies

Before testing any biological product candidate, including our product candidates, in humans, the product candidate must undergo rigorous preclinical testing. The preclinical development stage generally involves laboratory evaluations of the chemistry, formulation and stability of the product candidate, as well as trials to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP regulations.

The sponsor must submit the results of the preclinical studies, 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. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA also may impose clinical holds on a biological product candidate at any time before or during clinical studies due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies 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 studies to begin, or that, once begun, issues will not arise that suspend or terminate such studies.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by, or under control of, the trial sponsor, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. 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 and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about most clinical trials must be submitted within specific timeframes for publication on the *www.clinicaltrials.gov* website. Additional requirements apply when a gene therapy study is conducted at, or sponsored by, institutions receiving NIH funding, such as the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, which require, among other things, institutional biosafety committee review and approval, risk assessments to evaluate appropriate containment, physical containment guidelines, and reporting certain accidents and events to NIH.

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

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.
- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a larger number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA or, in certain circumstances, post-approval.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Annual progress reports detailing the results of the clinical studies must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, 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 studies may not be completed successfully within any specified period, if at all. The FDA or the sponsor, acting on its own or based on a recommendation from the sponsor's data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study 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 gene therapy 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 study period, the number of patients the FDA will require to be enrolled in the studies in order to establish the safety, efficacy, purity and potency of human gene therapy products, or that the data generated in these studies will be acceptable to the FDA to support marketing approval.

Concurrently with clinical trials, companies usually complete additional preclinical 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 product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. FDA may require such testing to occur on a lot-by-lot basis in order to release product for clinical use. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Review and Approval

After the successful completion of clinical studies of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological products. The BLA must include results of the preclinical studies and clinical trials, detailed information relating to the product's chemistry, manufacture, controls, proposed labeling and other relevant information. The BLA must contain proof of safety, purity, potency and efficacy and may include both negative and ambiguous results of preclinical studies and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. 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.

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. In most cases, the submission of a BLA is subject to a substantial application user fee, although the fee may be waived under certain circumstances. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original BLAs, the FDA has ten months from the 60-day filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if, among other things, the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

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 and potent, 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, or 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 the BLA without a REMS, if required.

Before approving a BLA, the FDA typically 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 a gene therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with GTPs, to the extent applicable. These are FDA regulations 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, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are tested and processed 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 studies were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP, GTP 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 ultimately may decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical studies 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 usually 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 studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If the FDA issues a complete response letter, 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 REMS, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical studies, sometimes referred to as Phase 4 clinical studies, 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.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan 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 the product available in the United States for this type of disease or condition will be recovered from sales of the product in the United States. An applicant must request orphan drug designation before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug designation entitles a party to financial incentives such as opportunities for limited grant funding towards clinical trial costs, research tax advantages, and user fee waivers. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity. That means the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, by providing a major contribution to patient care, or in instances of an inability to assure drug supply. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication; in the latter case, because health care professionals are free to prescribe products for off-label uses, the competitor’s product could be used for the orphan indication despite our orphan exclusivity. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do of the same drug and same indication, as defined by the FDA, for which we are seeking, or if our product candidate is determined to be contained within the scope of the competitor’s product for the same indication or disease. In January 2020, FDA released a draft guidance, entitled “Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations”, detailing how it will determine “sameness” of gene therapy products under the orphan drug regulations for the purposes of orphan drug designation and exclusivity. Since this guidance is subject to revision pending receipt of public comments, we cannot determine what effect it may have on obtaining orphan drug designations or exclusivity, or our business. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity.

Expedited Development and Review Programs

The FDA has various programs, including fast track designation, breakthrough therapy and Regenerative Medicine Advanced Therapy (RMAT) designations, accelerated approval, and priority review, which are intended to expedite or facilitate the process for the development and FDA review of drugs and biologics that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs and biologics to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA also may review sections of the BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the BLA.

In addition, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies also are eligible for accelerated approval. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Another program that contains the features of the breakthrough therapy designation is the RMAT designation. Unlike the breakthrough therapy designation, which generally applies to various classes of drugs and biologics, the RMAT designation is limited to regenerative medicine therapies, which include cell and gene therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, but exclude human cells, tissues, and cellular and tissue based products regulated solely under section 361 of the Public Health Service Act and 21 CFR Part 1271. This program is intended to facilitate development and expedite review of regenerative medicine therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and have the potential to address unmet medical needs for such condition as indicated by preliminary clinical evidence. A drug sponsor may request that the FDA designate a regenerative medicine therapy as a RMAT concurrently with or at any time after submission of an IND. The FDA has 60 calendar days to determine whether the regenerative medicine therapy meets the criteria. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. RMAT designation may be rescinded when a regenerative medicine therapy no longer meets the qualifying criteria, such as where another therapy is approved for the same disease or condition and there is no longer an unmet medical need. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. Like the FDA's other expedited development programs, the breakthrough therapy and RMAT designations do not change the standards for approval but may expedite the development or approval process.

Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint that can be measured earlier than survival or irreversible morbidity and is reasonably likely to predict an effect on survival, irreversible morbidity or another clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Once a BLA is submitted for a product intended to treat a serious condition, the FDA may assign a priority review designation if the FDA determines that the product, if approved, would provide a significant improvement in safety or effectiveness. Under priority review, the FDA must review an application in six months, compared to ten months for a standard review. Most products that are eligible for fast track or breakthrough therapy designation also are likely to be considered appropriate to receive a priority review.

Another way to obtain priority review for a product is through the rare pediatric disease priority review voucher program. Under this program, the sponsor of a BLA for a biologic designated to treat a rare pediatric disease may be awarded a voucher upon approval that can be used to obtain priority review for a subsequent BLA or sold and transferred to another party seeking priority review. A rare pediatric disease is a serious or life-threatening rare disease or condition, as defined under the Orphan Drug Act discussed above, in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years. The sponsor must request the voucher upon submission of the BLA for the rare pediatric disease biologic. Due to current sunset provisions, FDA may not award any rare pediatric disease priority review vouchers after September 30, 2020 unless a BLA for a rare pediatric disease biologic is designated as such on or before that date and the BLA is approved on or before September 30, 2022. We cannot predict whether this program will be reauthorized and, if so, what additional conditions or requirements may be imposed.

A biological product also can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

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 decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation, accelerated approval and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data that are adequate to assess the safety and efficacy of the product candidate 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 pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FDCA to require that a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials or other clinical development programs.

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials.

Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the 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 drugs or biologics 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. The discovery of conditions that violate these rules, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including voluntary recall.

Once approval or licensure of a drug or biologic is granted, the FDA may withdraw the approval or license if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

Biosimilars and Exclusivity

An abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Affordable Care Act. This amendment to the PHSA, in part, attempts to minimize duplicative testing. To date, the FDA has approved a number of biosimilars, and numerous biosimilars have been approved in Europe. However, no interchangeable biologic has been approved in the United States. The FDA has issued several guidance documents outlining its approach to reviewing and approving biosimilars.

Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, must be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted twelve years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. One must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and meaning of the BPCIA is subject to significant uncertainty.

On December 20, 2019, the Further Consolidated Appropriations Act, 2020 (FCAA 2020) became law. Section 610, entitled “Actions for Delays of Generic Drugs and Biological Products”, provides generic drug (ANDA and 505(b)(2)) and biosimilar developers with a private right of action to obtain sufficient quantities of reference product from the brand manufacturer, or a generic or biosimilar manufacturer, necessary for approval of the developers’ generic or biosimilar product. If a generic drug or biosimilar developer is successful in its suit, the defendant manufacturer would be required to provide sufficient quantities of product on commercially-reasonable, market-based terms and may be required to pay the developer’s reasonable attorney’s fees and costs as well as financial compensation under certain circumstances. The purpose of section 610 is to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar products. We cannot determine what effect section 610 of the FCAA 2020 may have on manufacturers that may develop biosimilar or other competing versions of our products once approved.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of other geographies, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively affect the regulatory process in others.

Other Healthcare Laws and Regulations

In addition to FDA restrictions on the marketing of pharmaceutical products, we may be subject now or in the future to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain approval. These laws include, but are not limited to the following:

- The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made under federally funded healthcare programs, such as Medicare and Medicaid. The term ‘‘remuneration’’ has been broadly interpreted to include anything of value;
- The federal civil and criminal false claims laws, including, without limitation, the federal civil monetary penalties law and the civil False Claims Act, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Actions under the civil False Claims Act may be brought by the Attorney General or as a *qui tam* action by a private individual in the name of the government. Violations of the civil False Claims Act can result in significant monetary penalties and treble damages;

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program (including private health plans) and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans, and healthcare clearinghouses and their respective business associates;
- The federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, require certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to payments and other transfers of value provided to physicians and teaching hospitals (and additional healthcare practitioners for transfer occurring during or after 2021) and physician ownership and investment interests. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties;
- The Foreign Corrupt Practices Act, or the FCPA, prohibits any United States individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts;
- The FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- The U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product; and
- State and foreign equivalents of each of the healthcare fraud and abuse laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. We may also be subject to: state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that restrict payments that may be made to healthcare providers; state laws that require pharmaceutical manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws that require the registration of pharmaceutical sales representatives; and equivalent foreign laws and regulations. Further, we may be subject to state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws. For example, the Affordable Care Act amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to clarify that liability under these statutes does not require a person or entity to have actual knowledge of the statutes or a specific intent to violate them. Moreover, the Affordable Care Act provides that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Because of the breadth and lack of uniform court interpretation of these laws, novel enforcement theories brought by government authorities, and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In addition, on October 17, 2019, the Office of the Inspector General of the Department of Health and Human Services issued a Proposed Rule: Revisions to Safe Harbors under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements to, among other things, add new safe harbors for certain value-based arrangements. Although the value-based proposals would not include pharmaceutical manufacturers among the entities that could permissibly enter into such contracting arrangements, the general trend toward outcomes and value-based contracts in the healthcare industry may continue. It is possible that payors, among other customers, could push manufacturers for novel contracting approaches, including those that would incorporate value-based principles, and these efforts could affect our business. It is unclear at this time whether this proposed rule will be adopted or, if adopted, what effect, if any, it would have on the cost and ability to comply with the federal Anti-Kickback Statute or on our business.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages and reputational harm, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any biological products for which we obtain regulatory approval. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic and biosimilar products for branded drug and biologic products, respectively. In the United States and markets in other countries, patients who are prescribed products generally rely on third party payors to reimburse all or part of the associated healthcare costs. Providers and patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. If approved, sales of our product candidates will depend, in part, on the availability of coverage and adequate reimbursement from third party payors. Third party payors include government authorities, managed care plans, private health insurers and other organizations.

In the United States, the process for determining whether a third party payor will provide coverage for a biological product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. With respect to biologics, third party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost sharing obligation imposed on patients. A decision by a third party payor not to cover our product candidates could reduce physician utilization of a product. Moreover, a third party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third party reimbursement may not be available to enable a manufacturer to maintain price levels sufficient to realize an appropriate return on its investment in product development. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. One third party payor's decision to cover a particular medical product does not ensure that other payors will also provide coverage for the medical product, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process usually requires manufacturers to provide scientific and clinical support for the use of their products to each payor separately and is a time consuming process.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and adequate reimbursement. The emphasis on cost containment measures in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Third party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning safety and efficacy. If third party payors do not consider a product to be cost effective compared to other available therapies, they may not cover that product after FDA approval or, if they do, the level of payment may not be sufficient to allow a manufacturer to sell its product at a profit.

In addition, in many foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. In the European Union, governments influence the price of products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. The downward pressure on health care costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low priced markets exert a commercial pressure on pricing within a country.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the Affordable Care Act, was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; and established the Center for Medicare and Medicaid Innovation at the Centers for Medicare and Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Certain provisions of the Affordable Care Act have been subject to legal and political challenges. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance as part of a tax reform bill. Further, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Moreover, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to accelerate closure of the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress could consider additional legislation to repeal or replace elements of the Affordable Care Act, or adopt other healthcare reform measures. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation.

Moreover, in December 2018, the U.S. District Court for the Northern District of Texas held in Texas v. Azar that, because the provisions of the Affordable Care Act requiring certain individuals to either obtain health insurance or pay a shared responsibility payment are no longer permissible under the U.S. Congress' taxing power, the entire Affordable Care Act is no longer constitutional. The decision was appealed to the U.S. Court of Appeals for the Fifth Circuit. On December 18, 2019, the Fifth Circuit issued an opinion holding that, while the individual mandate was no longer constitutional, the case must be remanded to the District Court to further evaluate whether the mandate can be severed from the Affordable Care Act or the entire Affordable Care Act must be stricken down. On January 3, 2020, petitions for *certiorari* were filed with motions to expedite requesting that the U.S. Supreme Court review the Fifth Circuit's decision and ultimately decide the constitutionality of the Affordable Care Act. While the U,S, Supreme Court denied the motions to expedite, it has not yet decided whether to grant the petitions. We are unable to predict the changes in law that may result from this ongoing lawsuit or other court challenges to the Affordable Care Act or their effect on our business.

Additional legislative changes have been adopted since the enactment of the Affordable Care Act. For example, the Budget Control Act of 2011 led to aggregate reductions of Medicare payments to providers of up to 2% per fiscal year that will remain in effect through 2029 unless additional Congressional action is taken.

More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, various drug pricing bills have been introduced by members of the U.S. House of Representatives and U.S. Senate that propose, among other things, requiring the Department of Health and Human Services ("HHS") to negotiate maximum prices for certain drugs, requiring manufacturers to pay rebates to the Medicare program for certain covered drugs, and redesigning the Medicare Part D prescription drug benefit to cap beneficiaries' annual out-of-pocket costs and to expand manufacturer discounts. Further, the Trump administration has released a number of proposals as part of its "Blueprint," or plan, to lower list prices, increase competition, and reduce patients' out-of-pocket costs. For example, in December, 2019, FDA released a proposed rule and draft guidance that set forth two pathways for the legal importation of certain drugs in an effort to control drug costs. Congress and the Trump administration have each indicated an intent to continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to address drug prices, including imposing price reporting requirements on manufacturers, negotiating value-based payment arrangements, and pursuing wholesale importation programs.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Date Privacy and Security

We may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business.

Within the United States, our operations may be affected by HIPAA as amended by HITECH and its implementing regulations, collectively, HIPAA, which impose obligations on certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) and certain of their "business associate" contractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Although we believe that we currently are neither a "covered entity" nor a "business associate" under the legislation, the law may affect our interactions with customers who are covered entities or their business associates because the law affects the ability of these entities to disclose patient health information to us. Various states also have laws that regulate the privacy and security of patient information and so may affect our business operations. For example, the California Consumer Privacy Act, or CCPA, became effective on January 1, 2020. The CCPA gives California consumers (defined to include all California residents) certain rights, including the right to ask companies to disclose the types of personal information collected, specific pieces of information collected by a company, the categories of sources from which such information was collected, the business purpose for collecting or selling the consumer's personal information, and the categories of third parties with whom a company shares personal information. The CCPA also imposes several obligations on companies to provide notice to California consumers regarding a company's data processing activities. Additionally, the CCPA gives California consumers the right to ask companies to delete a consumer's personal information and places limitations on a company's ability to sell personal information, including providing consumers a right to opt out of sales of their personal information.

Outside the United States, other data privacy and security regulations may apply. For example, the processing of personal data in the European Economic Area, or the EEA, is subject to the General Data Protection Regulation, or the GDPR, which took effect in May 2018. The GDPR increases obligations with respect to clinical trials conducted in the EEA, such as in relation to the provision of fair processing notices, exercising data subject rights and reporting certain data breaches to regulators and affected individuals, as well as how we document our relationships with third parties that process GDPR-covered personal data on our behalf. The GDPR also increases the scrutiny applied to transfers of personal data from the EEA (including from clinical trial sites in the EEA) to countries that are considered by the European Commission to lack an adequate level of data protection, such as the United States.

Compliance with data privacy and security regulation can require allocation of resources as well as changes in operations and non-compliance can result in substantial penalties. For example, the GDPR and the CCPA impose substantial fines and other regulatory penalties for breaches of data protection requirements, and they confer a private right of action on data subjects (in the case of the GDPR) and consumers (in the case of the CCPA) and their representatives for breaches of certain data protection requirements.

Employees

As of December 31, 2019, we had 41 full-time employees, including 22 with Ph.D. or other advanced degrees. Of these full-time employees, 30 are engaged in research and development and 11 are engaged in general and administrative activities. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Corporate and Other Information

LogicBio Therapeutics, Inc. was incorporated under the laws of the State of Delaware in August 2014. Our principal executive offices are located at 99 Erie St., Cambridge, Massachusetts 02139, and our telephone number is (617) 245-0399. Our website address is http://www.logicbio.com. The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider any information contained on, or that can be accessed through, our website as part of this Annual Report on Form 10-K.

We have two subsidiaries, LogicBio Australia Pty Limited, a wholly owned Australian subsidiary formed in April 2018, and LogicBio Securities Corporation, a wholly owned Delaware subsidiary formed in December 2018. During 2019, we formally liquidated LogicBio Therapeutics Research, LTD, our wholly owned Israeli subsidiary.

You may read our Securities and Exchange Commission, or SEC, filings, including our proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, over the internet at the SEC's website at *www.sec.gov*. We also maintain a website at *www.logicbio.com*, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

Item 1A. Risk Factors.

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future. We may never achieve or maintain profitability.

We are a preclinical-stage genome editing company with a limited operating history. We have incurred net losses in each year since our inception, including a net loss of $40.1 million for the year ended December 31, 2019. As of December 31, 2019, we had an accumulated deficit of approximately $67.4 million. In addition, we have not commercialized any products and have never generated any revenue from product sales. We have devoted most of our financial resources to research and development, including our preclinical development activities. We expect to continue to incur significant additional operating losses for the foreseeable future as we seek to advance LB-001, our lead product candidate, through preclinical and clinical development, expand our research and development capabilities and activities, develop new product candidates, advance the development of our GeneRide technology platform, initiate and complete clinical trials, seek regulatory approval and, if we receive approval from the U.S. Food and Drug Administration, or FDA, commercialize our product candidates. Our net losses may fluctuate significantly from quarter to quarter and year to year. Because of the numerous risks and uncertainties associated with genetic medicine product development, we are unable to accurately predict the timing or amount of increased expenses, when, if ever, we will generate revenue from the commercialization of products or whether we will achieve or maintain profitability. We anticipate that our expenses will also increase substantially if and as we:

- continue our current research programs and our preclinical development of any product candidates from our current research programs;
- initiate clinical trials for LB-001 and any other product candidates we identify and develop;
- seek to identify, assess, acquire and/or develop additional research programs and additional product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- develop, optimize, scale and validate a manufacturing process and analytical methods for any product candidates we may develop;
- establish and build out internal process and analytical development capabilities and preclinical and clinical grade production;
- obtain market acceptance of any product candidates we may develop as viable treatment options;
- address competing technological and market developments;
- maintain, expand and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- further develop our GeneRide technology platform;
- hire additional technical, quality, regulatory, clinical, scientific and commercial personnel and add operational, financial and management information systems and personnel, including personnel to support our process and product development, manufacturing and planned future commercialization efforts;
- make royalty, milestone or other payments under current or future in-license agreements;
- establish and maintain supply chain and manufacturing relationships with third parties that can provide adequate products and services, in both amount, timing and quality, to support clinical development and the market demand for any product candidate for which we obtain regulatory and marketing approval;
- lease and build new facilities, including offices and labs, to support organizational growth;
- validate and build-out clinical and commercial-scale current Good Manufacturing Practices, or cGMP, manufacturing capabilities; and
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval.

Furthermore, our ability to successfully develop, commercialize and license our product candidates and potentially generate product revenue is subject to substantial additional risks and uncertainties. Each program and any product candidate we develop, along with our GeneRide platform, will require additional preclinical and clinical development, potential regulatory approval in one or more jurisdictions, securing manufacturing supply, capacity and expertise, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. See "—Risks Related to Discovery, Development, Clinical Testing, Manufacturing and Regulatory Approval" and "—Risks Related to Commercialization."

As a result of all of the above, as well as other potential factors, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. If we are unable to develop and commercialize one or more product candidates either alone or with collaborators, or if revenue from any product candidate that receives marketing approval is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of any product candidates.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize LB-001 and any other product candidate we may identify and develop. We will require additional capital, which we may seek to raise through equity offerings, debt financings, marketing and distribution arrangements, collaborations, strategic alliances, licensing arrangements or other sources, to enable us to complete the development and potential commercialization of LB-001 and any other product candidate. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

Based upon our current operating plan, which takes into account expenditures that are contingent based on corporate developments, we believe that our cash and cash equivalents and short-term investments as of December 31, 2019 will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2021. We anticipate that we may need additional funding in order to complete the Phase 1/2 clinical trial of LB-001. These estimates are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. For example, the FDA has placed a clinical hold on our IND to support the initiation of the Phase 1/2 clinical trial of LB-001 in pediatric patients with MMA pending the resolution of certain clinical and nonclinical questions, which makes it difficult to predict the timing of the initiation of this trial. In addition, the FDA could require us to conduct preclinical studies or clinical trials beyond those that we currently anticipate will be required. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length of time and activities associated with successful development of LB-001 and any other product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and, if applicable, any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including:

- the initiation, scope, progress, timing, costs and results of drug discovery, preclinical development, laboratory testing, and planned clinical trials for LB-001 and any other product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities, including resolving any potential clinical holds that may be imposed on us;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions;
- the achievement of milestones or occurrence of other developments that trigger payments under any of our current agreements or other agreements we may enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial and other research and development costs under future collaboration agreements, if any;
- the effect of competing technological and market developments;

- the cost and timing of completion of clinical or commercial-scale manufacturing activities;
- the extent to which we in-license or acquire other products and technologies;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the cost of establishing sales, marketing and distribution capabilities for LB-001 and any other product candidates in regions where we choose to commercialize our product candidates, if approved; and
- the initiation, progress, timing and results of our commercialization of LB-001 and any other product candidates, if approved, for commercial sale.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, even if we successfully identify and develop product candidates and one or more are approved, we may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of medicines that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of LB-001 or any other product candidates. Any significant delays in our programs may also require us to reevaluate our corporate strategy, resulting in the expenditure of significant resources and time, or potentially resulting in us discontinuing our operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in increased fixed payment obligations. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, product candidates we may identify for development. To date, we have not generated any revenue from our programs or any product candidate and do not anticipate generating revenues from product sales for the foreseeable future. Our ability to generate future revenues from product sales depends heavily on our, or our collaborators', ability to successfully:

- identify product candidates and complete research and preclinical and clinical development of any product candidates we may identify;
- obtain sufficient financial and other resources to complete the necessary preclinical studies and clinical trials of LB-001 and any other product candidate we may develop;
- obtain successful data from our clinical program that supports an acceptable risk-benefit profile of any product candidates in the intended populations;
- develop safe and effective delivery mechanisms for our in vivo therapeutic programs;
- achieve desirable medicinal properties for the intended indications;

- seek and obtain regulatory and marketing approvals for any product candidate for which we complete clinical trials;
- launch and commercialize any product candidate for which we obtain regulatory and marketing approval by establishing a sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- qualify for adequate healthcare coverage and reimbursement by government and third-party payors for any product candidate for which we obtain regulatory and marketing approval;
- develop, enhance, scale and validate a manufacturing process and analytical methods for any product candidates we may develop;
- implement effective strategies and knowledge management systems to ensure the integrity of data, specifically the completeness, consistency and accuracy of data used to ensure the safety, efficacy and quality of products manufactured;
- establish and maintain supply and manufacturing relationships with third parties that remain compliant with all relevant health authority and legal requirements and can provide adequate, in amount, timing and quality, products and services to support clinical development and the market demand for any product candidate for which we obtain regulatory and marketing approval;
- compete with other therapies and treatment options;
- obtain market acceptance of any product candidates we may develop as viable treatment options;
- obtain a continued acceptable safety profile of the medicines following approval;
- address competing technological and market developments;
- implement internal systems and infrastructure, as needed;
- enter into collaborations to further the development of any product candidate;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, trade secrets, know-how and non-patent exclusivity for our medicines;
- avoid and defend against third-party interference or infringement claims; and
- attract, hire and retain qualified personnel.

Additionally, because our technology involves genome editing, we are subject to additional challenges and risks that gene therapy companies face, including:

- regulatory requirements that govern gene and cell therapy products, which have changed frequently and may continue to change in the future, and few products that involve the genetic modification of patient cells have been approved in the United States or the European Union; and
- the FDA's recommendation of a follow-up observation period of up to 15 years or longer for all patients who receive treatment using genome editing therapies, necessitating us to adopt such an observation period for any product candidate we may develop.

Our recurring losses and negative cash flows have raised substantial doubt regarding our ability to continue as a going concern.

Since inception, we have experienced recurring operating losses and negative cash flows, and we expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. As of December 31, 2019, we had an accumulated deficit of approximately $67.4 million. To date, we have received no product revenue and we have primarily funded our losses through payments received from equity and debt financings. At December 31, 2019, we had $33.1 million of cash and cash equivalents on hand. Without raising additional capital, these conditions raise substantial doubt about our ability to continue as a going concern, meaning that we may be unable to continue operations in the future or realize assets and discharge liabilities in the ordinary course of operations. If we are unable to obtain additional capital, we

could be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, or we may be unable to continue operations. Although we continue to pursue these plans, there can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations.

Risks Related to Discovery, Development, Clinical Testing, Manufacturing and Regulatory Approval

We intend to identify and develop product candidates based on our novel GeneRide technology platform, which makes it difficult to predict the time and cost of product candidate development. No genome editing product has been approved in the United States or in Europe. There have only been a limited number of human clinical trials involving a gene editing product candidate and none of those trials has involved our nuclease-free genome editing technology.

We have concentrated our research and development efforts on product candidates utilizing our GeneRide technology. Our future success depends on the successful development of this novel therapeutic approach. To date, no product that utilizes our GeneRide technology has been approved. There have been a limited number of clinical trials of gene editing technologies, however no product candidates have been approved, and none of these clinical trials involved product candidates that utilize our GeneRide technology. In addition, because our programs are all in the research or preclinical stage, we have not yet been able to assess safety in humans, and there may be long-term effects from treatment with any of our future product candidates that we cannot predict at this time. Any product candidates we may develop will act at the level of DNA, and, because animal DNA differs from human DNA, results of tests of our product candidates in animal models for either safety or efficacy may not be predictive of results that may be observed in humans. Also, animal models may not exist for some of the diseases we expect to pursue. Our GeneRide genome editing approach harnesses homologous recombination, or HR, a naturally occurring DNA repair process that maintains the fidelity of the genome. The mechanism of action of this technology is still not completely understood. Therefore, it is and will be difficult for us to determine whether any of our product candidates will be able to properly integrate corrective DNA in or deliver gene transfer constructs to enough tissue cells or otherwise result in sufficient expression of the target protein to reach therapeutic levels. We cannot be certain that any of our product candidates will be able to meet safety and efficacy levels needed to be therapeutic in humans or that they will not cause significant adverse events or toxicities. As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our GeneRide technology platform, or any similar or competitive gene therapy or gene editing platforms, will result in the identification, development and regulatory approval of any medicines, or that other genetic medicine technologies will not be considered better or more attractive for the development of medicines. Any development problems we experience in the future related to our GeneRide technology platform or any of our research programs may cause significant delays or unanticipated costs, or we may not be able to solve for the issue. We may also experience delays in developing a capable and scalable manufacturing process or transferring that process to commercial partners. Any of these factors may prevent us from completing our preclinical studies or clinical trials that we may initiate or prevent us from commercializing any product candidates we may develop on a timely or profitable basis, if at all.

Because genome editing is novel and the regulatory landscape that governs any product candidates we may develop is uncertain and may change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.

Because genome editing is novel, the regulatory requirements governing any genome editing product candidates we develop are uncertain and subject to change. For example, the FDA recently issued several guidance documents regarding gene therapy in July 2018 and January 2020. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. The same applies in the European Union. The EMA's Committee for Advanced Therapies, or CAT, is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. In the European Union, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant European Union guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any genome editing product candidates we may develop, but that remains uncertain at this point.

Adverse developments in preclinical studies or clinical trials conducted by others in the field of gene therapy products, cell therapy products or products developed through the application of gene editing technology may cause the FDA, the EMA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing genome editing technologies, either of which could materially harm our business. In addition, the clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied pharmaceutical or other product candidates. Furthermore, during the regulatory review process, we will need to identify success criteria and endpoints such that the FDA, the EMA or other regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop. As we are initially seeking to identify and develop product candidates to treat diseases in which there is little clinical experience using new technologies, there is heightened risk that the FDA, the EMA or other regulatory authorities may not consider the clinical trial endpoints that we propose to provide clinically meaningful results (reflecting a tangible benefit to patients). In addition, the resulting clinical data and results may be difficult to analyze. Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoints to a degree of statistical significance. This may be a particularly significant risk for many of the genetically defined diseases for which we plan to develop product candidates because many of these diseases have small patient populations, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Further, even if we do achieve the pre-specified criteria, we may produce results that are unpredictable or inconsistent with the results of the non-primary endpoints or other relevant data. The FDA also weighs the benefits of a product against its risks, and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Other regulatory authorities in the European Union and other countries, such as the CAT, may make similar comments with respect to these endpoints and data. Any product candidates we may develop will be based on a novel technology that makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval. No genome editing product has been approved in the United States or in Europe.

Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing genome editing technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays or other impediments to our research and development programs or the commercialization of resulting products.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, increase the scope of process development, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop.

We have no history of conducting clinical trials or commercializing genetic medicine product candidates and we may encounter difficulties transitioning from a research-stage to clinical-stage company to ultimately a commercial-stage company, which may make it difficult to evaluate the prospects for our future viability.

We are an early-stage company. We were founded in 2014 and began operations in 2015. Our operations to date have been limited to financing and staffing our company, developing our technology such as our GeneRide technology platform, identifying and developing LB-001, undertaking preclinical studies, business planning and raising capital. All of our research programs are still in the preclinical or research stage of development, and the risk of failure in the biopharmaceutical industry for programs or products candidates at such stage of development is high. We have not yet demonstrated an ability to successfully initiate, conduct or complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approval, manufacture a clinical or commercial scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes about six to ten years to develop a new drug from the time it enters Phase 1 clinical trials to when it is approved for treating patients, but in many cases it may take longer. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing genetic medicine product candidates.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research focus to a company capable of supporting clinical and, if any of our product candidates are approved, commercial activities. We may not be successful in such a transition.

Preclinical drug development is uncertain. Some or all of our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these product candidates on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain FDA approval to market a new product, we must demonstrate proof of safety, purity and potency or efficacy in humans. To satisfy these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned IND in the United States. We cannot be certain of the timely completion or outcome of our preclinical testing and studies, and we cannot predict if the FDA will accept our proposed clinical programs, if any, or if the outcome of our preclinical testing and studies will ultimately support the further development of any of our product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for any preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. For example, our investigational new drug application, or IND, for LB-001 was recently placed on clinical hold by the FDA in order to evaluate certain clinical and preclinical aspects of our submission. While we are actively working to address the FDA's questions and are planning to initiate our Phase 1/2 trial in methylmalonic acidemia, or MMA, there can be no assurance as to when or if the clinical hold will be resolved and the IND made effective.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per product candidate. Delays associated with product candidates for which we are conducting preclinical testing and studies ourselves may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the preclinical testing and studies of certain product candidates conducted by our potential partners over which we have no control. The commencement and rate of completion of preclinical studies and initiation of clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials; and
- delays in reaching a consensus with regulatory agencies on study design.

Moreover, even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

Clinical trials are expensive, difficult to design and implement, time-consuming and involve an uncertain outcome.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidates we may identify and develop, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy in humans of any such product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and there is a high failure rate for product candidates proceeding through clinical trials. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology and genetic medicine industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Even if our future clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of LB-001 for MMA or any other potential indication. Our future clinical trial results may not be successful.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

To date, we have not completed any clinical trials for any of our product candidates, including LB-001. We may experience delays in conducting any clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned to address clinical holds imposed by regulatory authorities or for other reasons, recruit and enroll patients on time or be completed on schedule, or at all. For example, our IND for LB-001 was recently placed on clinical hold by the FDA in order to evaluate certain clinical and preclinical aspects of the submissions. While we are actively working to address the FDA's questions and are planning to initiate our Phase 1/2 trial in MMA, there can be no assurance as to when or if the clinical hold will be resolved and the IND made effective. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- obtaining regulatory approval to commence a trial or to restart a trial following a clinical hold;
- reaching an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- developing and validating the companion diagnostic to be used in a clinical trial, if applicable;
- having patients complete a trial or return for post-treatment follow-up;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- clinical sites deviating from trial protocol or subjects dropping out of a trial;
- addressing patient safety concerns that arise during the course of a trial;
- occurrence of serious adverse events associated with any product candidates we may develop that are viewed to outweigh their potential benefits;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or significantly increase the cost of such trials, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- difficulty in designing well-controlled clinical trials due to ethical considerations which may render it inappropriate to conduct a trial with a control arm that can be effectively compared to a treatment arm;
- difficulty in designing clinical trials and selecting endpoints for diseases that have not been well-studied and for which the natural history and course of the disease is poorly understood;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate and we may not have funds to cover the costs;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have the product removed from the market after obtaining marketing approval;
- have regulatory authorities withdraw or suspend their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be sued; or
- experience damage to our reputation.

We could encounter delays if a clinical trial is suspended or terminated by us, either independently or based on a recommendation by the Data Safety Monitoring Board, or DSMB, for such trial, by the IRBs of the institutions in which such trials are being conducted or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including (1) failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; (2) inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; (3) unforeseen safety issues or adverse side effects; (4) failure to demonstrate a benefit from using a drug; (5) changes in governmental regulations; or (6) administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we may rely on CROs and clinical trial sites to ensure the proper and timely conduct of clinical trials and while we would have agreements governing their committed activities, we would have limited influence over their actual performance, as described in "—Risks Related to Our Dependence on Third Parties."

Our lead product candidate, LB-001, is still in preclinical development. In January 2020, we announced the submission of an IND to support the initiation of a Phase 1/2 clinical trial in pediatric patients with MMA, which the FDA has placed on clinical hold pending the resolution of certain clinical and nonclinical questions. We cannot provide any assurance that the FDA will authorize us to initiate any of our planned clinical trials on a timely basis, or at all, or that the FDA will agree with the design of our protocol. LB-001 will require extensive clinical testing before we are prepared to submit a biologic license application, or BLA, for regulatory approval. We cannot predict with any certainty if or when we might complete the development of LB-001 and submit a BLA for regulatory approval of LB-001 or whether any such BLA will be approved by the FDA. We may also seek feedback from the FDA or other regulatory authorities on our clinical development program, and the FDA or such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of LB-001 or any other product candidate we develop could be harmed. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials also ultimately may lead to the denial of regulatory approval of our product candidates.

Product development costs also will increase if we or our collaborators experience delays in testing or marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize any product candidates we may develop, could allow our competitors to bring products to market before we do and could impair our ability to successfully commercialize any product candidates we may develop, any of which may harm our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We or our collaborators may not be able to initiate or continue clinical trials for any product candidates we identify or develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or analogous regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. In addition, if patients are unwilling to participate in our genome editing trials because of negative publicity from adverse events related to the biotechnology, gene therapy or genome editing fields, competitive clinical trials for similar patient populations, clinical trials in competing products or for other reasons, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of any product candidates we may develop may be delayed.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. The enrollment of patients depends on many factors, including:

- the patient inclusion and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- severity of the disease under investigation;
- the proximity of patients to trial sites;
- the design of the trial;
- availability and efficacy of approved medications for the disease under investigation;
- availability of genetic testing for potential patients;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion;
- perceived risks and benefits of the product candidate under trial or the method by which such product candidate will be administered to patients;
- perceived risks and benefits of genome editing as a therapeutic approach;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

Our ability to successfully initiate, enroll, and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- different standard-of-care for patients with a particular disease;
- inability to locate qualified local consultants, physicians and partners; and
- potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial sites.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop LB-001 or any other product candidates, or could render further development impossible.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate we may develop, and any such approval may be for a more narrow indication than we seek.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if any product candidates we may develop meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a Risk Evaluation and Mitigation Strategy, or REMS. These regulatory authorities may require precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop. Any of the foregoing scenarios could materially harm the commercial prospects for any product candidates we may develop and materially adversely affect our business, financial condition, results of operations and prospects.

Adverse public perception of genetic medicine, and gene editing in particular, may negatively impact regulatory approval of, or demand for, our potential products.

Our product candidates involve editing the human genome. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene editing and gene therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy and gene editing are unsafe, unethical or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

In addition, gene editing technology is subject to public debate and heightened regulatory scrutiny due to ethical concerns relating to the application of gene editing technology to human embryos or the human germline. For example, in April 2015, Chinese scientists reported on their attempts to edit the genome of human embryos to modify the gene for hemoglobin beta. This is the gene in which a mutation occurs in patients with the inherited blood disorder beta thalassemia. Although this research was purposefully conducted in embryos that were not viable, the work prompted calls for a moratorium or other types of restrictions on gene editing of human eggs, sperm and embryos. The Alliance for Regenerative Medicine in Washington has called for a voluntary moratorium on the use of gene editing technologies in research that involved altering human embryos or human germline cells. Similarly, the NIH has announced that it would not fund any use of gene editing technologies in human embryos, noting that there are multiple existing legislative and regulatory prohibitions against such work, including the Dickey-Wicker Amendment, which prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. Laws in the United Kingdom prohibit genetically modified embryos from being implanted into women, but embryos can be altered in research labs under license from the Human Fertilisation and Embryology Authority. Research on embryos is more tightly controlled in many other European countries.

Although we do not use our technologies to edit human embryos or the human germline, such public debate about the use of gene editing technologies in human embryos and heightened regulatory scrutiny could prevent or delay our development of product candidates. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair our development and commercialization of product candidates or demand for any products we may develop. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing gene therapy or gene editing technologies, even if not ultimately attributable to product candidates we may discover and develop, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved, a decrease in demand for any such product candidates and a suspension or withdrawal of approval by regulatory authorities of our product candidates.

Serious adverse events in our clinical trials, or other clinical trials involving gene therapy products, particularly AAV gene therapy products such as candidates based on the same capsid serotypes as our product candidates, or occurring during use of our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

We may not be successful in our efforts to identify additional product candidates.

Part of our strategy involves identifying novel product candidates. All of our product candidates are still in the preclinical or research stage of development. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;
- potential product candidates may not be effective in treating their targeted diseases;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is too complex and difficult to navigate successfully or economically.

In addition, we may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. If we are unable to identify additional suitable product candidates for clinical development, this could harm our business, financial condition, results of operations and prospects.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

We currently have relationships with a limited number of suppliers for the manufacturing of our product candidates. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain and we may be unable to transfer or sublicense the intellectual property rights we may have with respect to such activities.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including data management) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that can impact safety, efficacy and quality, and may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's current good laboratory practices, or GLP, and cGMP regulations enforced by the FDA through its facilities inspection program. Some of our contract manufacturers have not produced a commercially-approved gene therapy product and therefore have not yet obtained the requisite FDA approvals to do so. The facilities and quality systems of some or all of our third-party contractors, as well as any facilities and quality systems we may have in the future, must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Our product candidates may cause serious adverse events or undesirable side effects or have other properties that may delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

We have not evaluated any product candidates in human clinical trials. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. In the genomic medicine field, there have been several significant adverse events from gene therapy treatments in the past, including reported cases of leukemia and death. There can be no assurance that our genome editing technologies will not cause undesirable side effects.

Serious adverse events or undesirable side effects caused by any product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, toxicities or unexpected characteristics, including death. A significant risk in many gene editing products is that the edit will be "off-target" (or "on-target," but unwanted) and cause serious adverse events, undesirable side effects, toxicities or unexpected characteristics. For example, off-target cuts could lead to disruption of a gene or a genetic regulatory sequence at an unintended site in the DNA, or, in those instances where we also provide a segment of DNA to serve as a repair template, it is possible that following off-target cut events, DNA from such repair template could be integrated into the genome at an unintended site, potentially disrupting another important gene or genomic element. While we believe our GeneRide technology obviates this through the use of HR, we cannot be certain that off-target editing will not occur in any of our planned or future clinical trials. There is also the potential risk of delayed adverse events following exposure to gene editing therapy, due to the potential for persistent biological activity of the genetic material or other product components used to carry the genetic material. In addition to serious adverse events or side effects caused by any product candidate we may develop, the administration process or related procedures also can cause undesirable side effects. If any such events occur, our clinical trials could be suspended or terminated.

If unacceptable side effects arise in the development of any of our product candidates, we, including in consultation with the DSMB, the FDA or the IRBs at the institutions in which our studies are conducted, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. In that case, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of which would harm our business, financial condition, results of operations and prospects. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further clinical development of the product candidates. Treatment-related side effects also could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

If in the future we are unable to demonstrate that such adverse events were caused by factors other than our product candidate, the FDA, the European Commission, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we are able to develop for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any product candidate we may develop, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop product candidates, which could harm our business, financial condition, results of operations and prospects.

Additionally, if we successfully develop a product candidate and it receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweighs the risks for each potential patient. A REMS may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry.

If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by any such product, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- we may be required to implement a REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- the product could become less competitive;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, which could harm our business, financial condition, results of operations and prospects.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved and the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that neither LB-001 nor any other product candidate we may seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of a BLA from the FDA. It is possible that the FDA may refuse to accept for substantive review any BLAs that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program. Depending on the extent of these or any other FDA-required studies, approval of any BLA or application that we submit may be delayed by several years, or may require us to expend significantly more resources than we have available.

Of the large number of potential products in development, only a small percentage successfully completes the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

We are heavily dependent on the success of LB-001, our lead product candidate, which is still under preclinical development, and if LB-001 does not receive regulatory approval in the United States or other jurisdictions, or is not successfully commercialized, our business will be harmed.

To date, we have invested a significant portion of our efforts and financial resources in the development of LB-001. Our future success and ability to generate product revenue is substantially dependent on our ability to successfully develop, obtain regulatory approval for and successfully commercialize this product candidate. We currently have no products that are approved for commercial sale and may never be able to develop marketable products.

We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to LB-001. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of LB-001, which may never occur. We cannot be certain that LB-001 will be successful in clinical trials, receive regulatory approval or be successfully commercialized even if we receive regulatory approval. Even if we receive approval to market LB-001 from the FDA or other regulatory bodies, we cannot be certain that our product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Additionally, the research, testing, manufacturing, labeling, approval, sale, marketing and distribution of genetic medicine products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations.

We are not permitted to market LB-001 in the United States until it receives approval of a BLA from the FDA, or in any foreign countries until it receives the requisite approval from such countries.

We have not submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future.

LB-001 is our lead product candidate, and because any other product candidate would be based on similar technology, if LB-001 shows unexpected adverse events or a lack of efficacy in the indications we intend to treat, or if we experience other regulatory or developmental issues, our development plans and business could be significantly harmed. Further, competitors may be developing products with similar technology and may experience problems with their products that could identify problems that would potentially harm our business.

Our IND for LB-001 was recently placed on clinical hold by the FDA in order to evaluate certain clinical and preclinical aspects of the submissions. While we are actively working to address the FDA's questions and are planning to initiate our Phase 1/2 trial in MMA, there can be no assurance as to when or if the clinical hold will be resolved and the IND made effective. Commencing this clinical trial, and any other clinical trials we may initiate, is also subject to finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests, the start of our first clinical trial for our MMA programs or any of our other programs may be delayed. For example, the FDA may not agree with the design or results of any preclinical studies that we may conduct as part of our plan to resolve the clinical hold on our IND for LB-001 as being adequate, which may delay the time at which we initiate our Phase 1/2 trial in MMA. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific 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. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could harm our business, financial condition, results of operations and prospects.

Genomic medicines are novel, and any product candidates we develop may be complex and difficult to manufacture. We could experience production problems that result in delays in our development or commercialization programs, limit the supply of our products or otherwise harm our business.

Due to the novel nature of our platform, any product candidates we may develop will likely require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as the product candidates we intend to develop generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, European Union or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs.

In addition, the FDA, the EMA and other regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We or our third-party contractors also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to manage and/or provide the necessary oversight of our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage. Some of the raw materials that we anticipate will be required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of any product candidates we may develop could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially harm our development timelines and our business, financial condition, results of operations and prospects.

Any problems in our manufacturing process or the facilities with which we contract could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. Problems in third-party manufacturing process or facilities also could restrict our ability to meet market demand for any products we develop and commercialize.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business.

Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, EMA rules and regulations and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, additional integrity oversight and reporting obligations, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of our CROs, third-party manufacturers, suppliers and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned 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 personal, confidential or proprietary information, we could incur liability and the further development of LB-001 or any other product candidate could be delayed.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

Interim "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim "top-line" or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Risks Related to Our Dependence on Third Parties

We currently contract with third parties for the manufacture and testing of materials. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We contract with third parties with manufacturing facilities to supply some of our discovery and preclinical research. We currently also rely on third-party manufacturers for the manufacture and some aspects of testing of our materials for preclinical studies and expect to continue to do so for clinical testing and for commercial supply of any product candidates that we may develop and for which we or our collaborators obtain marketing approval. We do not have a long-term supply agreement with any of the third-party manufacturers, and we purchase our required supply on a purchase order basis.

We may be unable to establish any agreements with third-party manufacturers for clinical and commercial supply manufacturing, or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could harm our business, financial condition, results of operations and prospects.

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are a few potential alternative manufacturers who could manufacture any product candidates we may develop, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

We intend to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.

We currently rely and expect to continue to rely on third parties to conduct some aspects of our research and preclinical testing. We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities.

We intend to rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future preclinical studies. Our reliance on CROs for clinical development activities limits our control over these activities, but we will remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

We and our CROs will be required to comply with the GLPs and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be sure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process. We will also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and preclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other product development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

If our relationship with any CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm on our business, financial condition, results of operations and prospects.

We have and may in the future enter into collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.

We may seek collaborative relationships for the development and commercialization of any product candidate we may develop. For example, in January 2020, we announced a research collaboration with Takeda Pharmaceutical Company Limited to further develop LB-301 in CN. Future collaborators could include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Under any such arrangements with third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend partly on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Failure to obtain such collaborative relationships could impair the potential for any product candidate we may develop. We also will need to enter into collaborative relationships to provide funding to support our other research and development programs. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, such as:

- a collaboration partner may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- a collaboration partner may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale or downsizing;
- a collaboration partner may delay animal studies or clinical trials, provide insufficient funding for a nonclinical program or clinical trial, stop a clinical trial, nonclinical study or abandon a product candidate, repeat or conduct new animal studies or clinical trials, or require a new formulation of a product candidate for testing;
- a collaboration partner may seek to renegotiate or terminate its relationship with us due to unsatisfactory clinical or nonclinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaboration partner may cease development in therapeutic areas which are the subject of our strategic collaboration;
- a collaboration partner may not devote sufficient capital or resources towards our product candidates;
- a collaboration partner may change the success criteria for a product candidate thereby delaying or ceasing development of such candidate;
- a collaboration partner may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner could develop a product that competes, either directly or indirectly, with our product candidate;
- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a collaboration partner may terminate a strategic alliance and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- a dispute may arise between us and a partner concerning the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources;
- a partner may use our products or technology in such a way as to invite litigation from a third party;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

If our collaborations do not result in the successful development and commercialization of products, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval, and commercialization described herein apply to the activities of our collaborators.

We may in the future decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of any product candidates we may develop. These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital. Moreover, any collaborative partners we enter into agreements with in the future may shift their priorities and resources away from our product candidates or seek to renegotiate or terminate their relationships with us.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators, such as Takeda Pharmaceutical Company Limited, or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our product candidates.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

Our collaborators or strategic partners may decide to adopt alternative technologies or may be unable to develop commercially viable products with our technology, which would negatively impact our revenues and our strategy to develop these products.

Our collaborators or strategic partners may adopt alternative technologies, which could decrease the marketability of our GeneRide technology. Additionally, because our current or future collaborators or strategic partners are likely to be working on more than one development project, they could choose to shift their resources to projects other than those they are working on with us. If they do so, this would delay our ability to test our technology and would delay or terminate the development of potential products based on our GeneRide technology. Further, our collaborators and strategic partners may elect not to develop products arising out of our collaborative and strategic partnering arrangements or to devote sufficient resources to the development, manufacturing, marketing or sale of these products. The failure to develop and commercialize a product candidate pursuant to our agreements with our current or future collaborators would prevent us from receiving future milestone and royalty payments which would negatively impact our revenues.

If we fail to comply with obligations in agreements under which we in-license or acquire development or commercialization rights to products, technology or data from third parties, including our agreements with Stanford University and the University of Texas through which we license our core technology or our agreement with the NIH for development and commercial rights to the transgene for LB-001, we could lose such rights that are important to our business, and we may be unable to continue our development or commercialization programs as a result, which would be harmful to our business.

We are a party to agreements with Stanford University and the University of Texas to license our core technology, and we are party to a license agreement with the NIH for development and commercialization rights to the transgene for LB-001. We may enter into additional agreements with other parties in the future that impose diligence, development and commercialization timelines, milestone payments, royalties, insurance and other obligations on us.

In exchange for the rights granted to us pursuant to the Stanford agreement, the University of Texas agreement and the NIH agreement, we are obligated to make payments upon the achievement of certain milestone events and to pay annual maintenance fees and specified royalties. If we fail to comply with our obligations under our agreements with Stanford University, the University of Texas, the NIH, or any future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product candidate that is covered by these agreements, which could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Our business may be adversely affected by the recent coronavirus outbreak.

In December 2019, a novel strain of coronavirus, referred to as 2019-ncov, COVID-19 coronavirus epidemic, or COVID-19, was reported to have surfaced in Wuhan, China. COVID-19 has since spread to other regions in China and other countries, including jurisdictions, such as the United States and the European Union, where we are conducting and plan to conduct clinical trials or other studies. There is a possibility that our CROs assisting with these clinical trials or other studies may become unavailable or that the clinical trials or others studies they manage may be delayed due to COVID-19 or containment efforts associated with it. Such events may lead to termination of our relationship with affected CROs, effecting the development and study of our product candidates.

More recently, COVID-19 has spread to the United States where we have our executive offices and principal operations. Infections and deaths related to COVID-19 may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay the FDA approval with respect to, our clinical trials, including our plans to work with the FDA to lift the clinical hold on our IND for LB-001 in MMA. It is unknown how long these disruptions could continue, were they to occur. In addition, other known and unknown factors caused by COVID-19 could materially delay our clinical trials, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

In addition, we source materials from the United States and other countries affected by COVID-19. There could be an increased risk of supply and other business interruption with our third party manufacturers, other service providers, suppliers and counterparties, resulting in business/operational disruption which could have a material effect on our business.

The economic impact of COVID-19's spread, which has caused a broad impact globally, such as restrictions on travel and quarantine policies put into place by businesses and governments, may adversely affect us. While the potential economic impact brought by and the duration of COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for any product candidates and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our platform technology and any proprietary product candidates and technology we develop. We seek to protect our proprietary position by in-licensing intellectual property relating to our platform technology and filing patent applications in the United States and abroad related to our technologies and product candidates that are important to our business. If we or our licensors are unable to obtain or maintain patent protection with respect to our AAV capsid technology and genome editing platform technology and any proprietary products and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed. Additionally, if we do not adequately protect our intellectual property, our competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

No consistent policy regarding the scope of claims allowable in the field of gene therapy has emerged in the United States. The scope of patent protection outside of the United States is also uncertain. Pending and future patent applications may not result in issued patents which protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States.

The patent prosecution process is expensive, time-consuming, and complex. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we, or any future partners, collaborators or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities in time to obtain patent protection. Therefore, we may miss potential opportunities to strengthen our patent position. Additionally, although we enter into agreements containing non-disclosure and confidentiality obligations with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, contract manufacturers, consultants, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If we or our partners, collaborators, licensees, or licensors, whether current or future, fail to establish, maintain, or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees, or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions that will be claimed in our future patents or future patent applications, or that we will be the first to file for patent

protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed patent applications on inventions claimed in our patents or applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or will file issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged by third parties, narrowed, circumvented invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates, or limit the duration of the patent protection of our product candidates. Consequently, we do not know whether any of our platform advances and product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting aBLAs to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable, or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Agreements through which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We have not had and do not have primary control over patent prosecution and maintenance for certain of the patents and patent applications we license, and therefore cannot guarantee that these patents and applications will be prosecuted in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability and our patents may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. We or our licensors may in the future become subject to a third party pre-issuance submission of prior art to the United States Patent and Trademark Office, or the USPTO, or to other patent offices around the world. Alternately or additionally, we or our licensors may become involved in opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceedings and other similar proceedings in the United States or elsewhere, challenging our patent rights or the patent rights of others on which we rely to protect our business. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights; limit the duration of the patent protection of our technology and products; allow third parties to commercialize our technology or products and compete directly with us, without payment to us; or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Pursuant to the terms of

some of our license agreements with third parties, some of our third party licensors have the right, but not the obligation in certain circumstances to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors, and cannot guarantee that we would receive it and on what terms. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, our competitive position and our financial condition could suffer.

Moreover, some of our in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. Additionally some of our future patent filings may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could harm our competitive position, business, financial conditions, results of operations and prospects.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our owned and in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the U.S. government has certain rights, including march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention. For example, our licensors, including Stanford, have granted the U.S. government a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States, the inventions described in certain of our in-licensed patents and patent applications, including certain aspects of our in-licensed nuclease-free genome editing technology. If the government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations, and prospects.

Our rights to develop and commercialize our technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We are heavily reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our AAV capsid technology and GeneRide platform technology.

These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. For example, pursuant to our license agreements with Stanford, the licensors may, under certain circumstances, grant a license to the patents that are the subject of such license agreements to a third party. Such third party would have full rights to the patent rights that are the subject of such licenses, which could impact our competitive position and enable a third party to commercialize products similar to our future product candidates and technology. In addition, our rights to our in-licensed patents and patent applications may be dependent, in part, on inter-institutional or other operating agreements between the joint owners of such in-licensed patents and patent applications. If one or more of such joint owners breaches such inter-institutional or operating agreements, our rights to such in-licensed patents and patent applications may be adversely affected, which could harm our competitive position, business, financial conditions, results of operations and prospects.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. For example, pursuant to our intellectual property licenses for certain patent families from Stanford, our licensors retain control of preparation, filing, prosecution, maintenance, and enforcement and defense of their patents and patent applications. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

Our licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could adversely affect our competitive position, business, financial conditions, results of operations, and prospects.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We have entered into license agreements with third parties and may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of product candidates and technologies we may develop.

In each of our license agreements, and we expect in our future agreements, we have the right under specified conditions to bring any actions against any third party for infringing on the patents we have exclusively licensed. Certain of our license agreements also require us to meet development thresholds and other obligations to maintain the license, including establishing a set timeline for developing and commercializing products. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If we fail to comply with our obligations under our license agreements, our licensors may have the right to terminate these license agreements, in which event we might not be able to market any product or technology that is covered by these agreements, or our licensors may convert the license to a non-exclusive license, which could adversely affect the value of the product candidate being developed under the license agreement. Termination of these license agreements or reduction or elimination of our licensed rights may also result in our having to negotiate new or reinstated licenses with less favorable terms.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could harm our competitive position, business, financial conditions, results of operations and prospects.

Our intellectual property licenses with third parties may be subject to disagreements over contract interpretations, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, including the amount, if any, that may become due and payable to our licensors in connection with any sublicense income. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If these events were to occur, they could harm our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights for current or future product candidates through acquisitions and in-licenses, which could delay or prevent us from commencing clinical trials and ultimately commercializing our current or future product candidates.

Because our programs may require the use of proprietary rights by third parties, the growth of our business likely will depend, in part, on our ability to acquire, in-license, or use these proprietary rights.

Many pharmaceutical companies, biotechnology companies, and academic institutions are competing with us in the field of genome editing technology and filing patent applications potentially relevant to our business. In order to avoid infringing these third party patents, or patents that issue from these third party patent applications, we may find it necessary or prudent to obtain licenses from such third party intellectual property holders. In addition, with respect to any patents we may co-own with third parties, we may require licenses to such co-owners' interest in such patents.

We may be unable to acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our technology and product candidates. The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all.

We sometimes collaborate with non-profit and academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us or we may decide not to execute such option if we believe such license is not necessary to pursue our program. If we are unable or opt not to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

It is possible that we may be unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have at a reasonable cost or on reasonable terms. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidate, which could harm our business, financial condition, results of operations, and prospects significantly.

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

Filing, prosecuting, and defending patents in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. In addition, our intellectual property license agreements may not always include worldwide rights. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products. 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 products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States or if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, misappropriation of our other intellectual property rights, or marketing of competing products in violation of our intellectual property and proprietary rights generally.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Agreements through which we license patent rights may not give us sufficient rights to permit us to pursue enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents (or control of enforcement or defense) of such patent rights in all relevant jurisdictions as requirements may vary.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts, resources and attention from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims 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. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our licensed or future owned patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process and after a patent has issued. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to some of our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could harm our business, financial condition, results of operations and prospects.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension) as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. The applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. Additionally or alternatively, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

Patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the America Invents Act, could increase those uncertainties and costs.

Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, the USPTO, and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could adversely affect our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. With respect to our GeneRide technology platform, we consider trade secrets and know-how to be an important component of our intellectual property. Trade secrets and know-how can be difficult to protect. In particular, we anticipate that with respect to our GeneRide technology platform, these trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, contract manufacturers, consultants, and other third parties. We also enter into agreements containing confidentiality and invention or patent assignment obligations with our employees and certain consultants. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our business and competitive position could be materially and adversely harmed.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our intellectual property, such as our patents or trademarks, or the patents of our licensing partners. To counter infringement or unauthorized use, we may be required to file infringement claims. Additionally or alternatively, we may be required to defend against claims of infringement filed by third parties against us. In addition, our patents or the patents of our licensing partners may in the future become involved in inventorship, priority, or validity disputes. Filing infringement claims and countering and defending against claims regarding infringement or disputes of inventorship, priority, or validity can be expensive and time consuming and divert the time and attention of our management and scientific personnel.

If we or one of our licensors were to initiate legal proceedings against a third party, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may in the future raise challenges to the validity of our patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

In any patent infringement proceeding, there is a risk that a court may decide that a patent owned or in-licensed by us is invalid or unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in any litigation or proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and may curtail or preclude our ability to assert those patents against third parties and exclude third parties from making and selling similar or competitive products. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. The monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of shares of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. Moreover, there can be no assurance that we will have sufficient financial or other resources to conduct such litigation or proceedings adequately, which can last for years before they are concluded. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace.

The intellectual property landscape around genome editing technology is highly dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could adversely affect the success of our business.

Our commercial success depends, in part, upon our ability and the ability of our collaborators to develop, manufacture, market, and sell our product candidates and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. However, the biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights, and our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Moreover, due to the intense research and development that is taking place by several companies, including us and our competitors, in the field of gene therapy, the intellectual property landscape is in flux, and it may remain uncertain for the coming years. There may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed, and other third party, intellectual property, and proprietary rights in the future. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any product candidates we may develop, including interference proceedings, post-grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the EPO. We cannot provide any assurances that third party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to products and methods of use for the treatment of the disease indications for which we are developing our product candidates. There may be third-party patents or patent applications with claims to materials, methods of manufacture, or methods for treatment related to the use or manufacture of our technologies and product candidates. If we are not able to obtain or maintain a license on commercially reasonable terms to any third-party patents that cover our product candidates or activities, such third parties could potentially assert infringement claims against us, which could harm our business.

Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on existing or future intellectual property rights. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. If any third-party patents or patent applications are found to cover our product candidates or their methods of use, we may not be free to manufacture or market our product candidates as planned without obtaining a license.

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third party patents.

The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the asserted patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence as to the invalidity of any such U.S. patent claim to overcome the presumption of validity enjoyed by issued patents. There is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs

and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing any product candidates we may develop and our technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Alternatively or additionally, it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims that we, our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees and our licensors' employees, consultants, and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, some of which may be our competitors or potential competitors. Some of these individuals executed agreements containing proprietary rights, non-disclosure and non-competition obligations, or similar agreements, in connection with such current or previous employment. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and consultants who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims listed above, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make gene therapy products that are similar to any product candidates we may develop or utilize similar gene therapy technology but that are not covered by the claims of the patents that we license or may own in the future;
- others may be able to make or utilize gene therapy technology that functions as a viable alternative to technology we may develop or technology covered by the claims of the patents that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could harm our business, financial condition, results of operations, and prospects.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Healthcare legislative reform measures and constraints on the national budget for social security systems may harm our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell any products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education

Reconciliation Act of 2010, or the Affordable Care Act, was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, and subjected manufacturers to new annual fees for certain branded prescription drugs.

Some of the provisions of the Affordable Care Act have been subject to legal and political challenges. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance as part of a tax reform bill. Further, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Moreover, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress could consider additional legislation to repeal or replace elements of the Affordable Care Act, or adopt other healthcare reform measures. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation. Thus, the full impact of the Affordable Care Act, any law replacing elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. The Budget Control Act of 2011 as amended to include aggregate reductions of Medicare payments to providers of 2% per fiscal year through 2029 unless additional Congressional action is taken.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our drug product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any denial in coverage or reduction in reimbursement from Medicare or other government programs may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties and other sanctions.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations now or in the future. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- the U.S. federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians and teaching hospitals (and additional healthcare practitioners for transfers occurring during or after 2021), as well as ownership and investment interests held by physicians and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare professionals and entities and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, additional integrity reporting and oversight obligations, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations, any of which could harm our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the European Union. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain European Union Member States must be publicly disclosed. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. 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. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could harm our business, financial condition, results of operations, and prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our research, development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruption, which could harm our reputation, business, financial condition, results of operations, and prospects.

Any third-party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health, and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could harm our reputation, business, financial condition, results of operations and prospects.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of Fred Chereau, our

President and Chief Executive Officer, as well as the other members of our management, technical, scientific, clinical and regulatory teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific, technical and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific, technical, clinical and regulatory advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

We expect to grow our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2019, we had 41 full-time employees. We expect to continue to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, technical development, clinical and regulatory affairs and sales, marketing and distribution. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities to devote time to managing these growth activities. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our inability to effectively manage the expansion of our operations may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our potential ability to generate revenue could be reduced and we may not be able to implement our business strategy.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and may face an even greater risk if we commercialize any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- the inability to commercialize any product candidates that we may develop; and
- injury to our reputation and significant negative media attention.

Our insurance coverage may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our manufacturing facilities, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could harm our business.

Risks Related to Commercialization

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

The development and commercialization of new genetic medicine products is highly competitive. Moreover, the gene editing field is characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. We will face competition with respect to any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our focus is the development of genetic medicines. There are a number of companies developing nuclease-based gene editing technologies using CRISPR/Cas9, TALENs, meganucleases, Mega-TALs and ZFNs, including bluebird bio, Caribou Biosciences, CRISPR Therapeutics, Editas Medicine, Intellia Therapeutics, Sangamo Therapeutics and Precision BioSciences. We may also compete with companies developing gene therapy products, including Homology Medicines, Audentes Therapeutics, bluebird bio, uniQure, Generation Bio and Voyager Therapeutics. There are also companies pursuing base editing technologies, including Beam Therapeutics. Any products we may develop could also face competition from other products approved to treat the same disease based on other types of therapies, such as small molecule, antibody or protein therapies. There are several companies developing competing products that target MMA, the indication for which we are developing LB-001. These companies include Moderna Therapeutics with an mRNA based approach, Selecta Biosciences with an AAV gene therapy, and Hemoshear Therapeutics using a small molecule. Moderna disclosed it had an open IND for mRNA-3704 in March 2019 and it had enrolled a first patient in their ongoing Phase 1/2 trial in February 2020. If any of our competitors obtain regulatory approval for a treatment for MMA, it could negatively affect our ability to successfully commercialize LB-001, if approved.

There are several companies developing competing products using AAV gene therapies that target CN, the indication for which we are developing LB-301. These companies include Genethon, Selecta Biosciences and Audentes. Genethon disclosed it had dosed a first patient in their ongoing Phase 1/2 trial in December 2018. Promethera previously completed a Phase 1/2 study that enrolled patients with Crigler-Najjar Syndrome or ornithine transcarbamylase deficiency. If any of our competitors obtain regulatory approval for a treatment for CN, it could negatively affect our ability to successfully commercialize LB-001, if approved.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products. Mergers and acquisitions in the pharmaceutical, biotechnology and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomic or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by third-party payors, including governmental healthcare programs such as Medicare and Medicaid, managed care organizations and private health insurers are essential for most patients to be able to afford prescription medications such as our product candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by third-party payors will have an effect on our ability to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the

reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. Assuming we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Net prices for medicines 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 medicines from countries where they may be sold at lower prices than in the United States. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. The regulations that govern marketing approvals, pricing, and reimbursement for new medicines vary widely from country to country. In the United States, third-party payors, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how third-party payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor and coverage and reimbursement by one payor does not guarantee coverage and reimbursement by another payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits. Furthermore, some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Due to the novel nature of our technology and the potential for any product candidates we may develop to offer therapeutic benefit in a single administration or limited number of administrations, we face uncertainty related to pricing and reimbursement for these product candidates.

Our initial target patient populations are relatively small, and, as a result, the pricing and reimbursement of any product candidates we may develop, if approved, must be adequate to support the necessary commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any such product candidates will be adversely affected. The manner and level at which reimbursement is provided for services related to any product candidates we may develop (e.g., for administration of our product to patients) is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products. In addition, it may be necessary for us to develop new reimbursement models in order to realize adequate value. Third-party payors may not be able or willing to adopt such new models, and patients may be unable to afford that portion of the cost that such models may require them to bear. If we determine such new models are necessary but we are unsuccessful in developing them, or if such models are not adopted by payors, our business, financial condition, results of operations and prospects could be adversely affected.

We expect the cost of a single administration of genomic medicine products, such as those we are seeking to develop, to be substantial, when and if they achieve regulatory approval. We expect that coverage and reimbursement by third-party payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of any such product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of any product candidates we may develop will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any product candidates we may develop. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

If the market opportunities for any product candidates we may develop are smaller than we believe they are, our revenues, if any, may be adversely affected, and our business may suffer. Because the target patient populations for many of the product candidates we may develop are small, we must be able to successfully identify patients and achieve a significant market share to achieve and maintain profitability and growth.

We focus our research and product development on treatments for rare pediatric diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with product candidates we may develop, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our products, or may become increasingly difficult to identify or gain access to, all of which could harm our business, financial condition, results of operations, and prospects.

If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If LB-001 or any other product candidate we may develop is approved for commercialization, it may be marketed in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international pharmaceutical operations, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- different regulatory requirements for drug and biologic approvals and rules governing drug and biologic commercialization in foreign countries;
- reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- foreign reimbursement, pricing and insurance regimes;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union, many of the individual countries in Europe and other countries outside of Europe with which we will need to comply. Many U.S.-based biotechnology companies have found the process of marketing their own products outside the United States to be very challenging.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could adversely affect the future commercial prospects for our biological products.

There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Risks Related to Our Common Stock and Indebtedness

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price may be volatile. The stock market in general, and the market for pharmaceutical and biopharmaceutical companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of companies whose stock is experiencing those price and volume limitations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual performance. As a result of this volatility, our stockholders may not be able to sell their shares of common stock at or above the price at which they purchased them. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- actual or expected changes in our growth rate relative to our competitors;
- timing and results of clinical trials of any product candidate we may develop or those of our competitors;
- developments related to our collaborations;
- regulatory actions with respect to any product candidate we may develop or our competitors' products and product candidates;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and make our product candidates less attractive;
- failure or discontinuation of any of our product development and research programs;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;

- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- results of preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results, development timelines, or recommendations by securities analysts, or those of companies that are perceived to be similar to us;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- limited public float;
- expiration of market stand-off or lock-up agreement;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- developments or changing views regarding the use of genomic medicines, including those that involve genome editing;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section and others beyond our control.

The terms of our Loan and Security Agreement place restrictions on our operating and financial flexibility.

In July 2019, we entered into a Loan and Security Agreement with Oxford Finance LLC and Horizon Technology Finance Corporation (the “Loan Agreement”), which is secured by substantially all of our assets other than our intellectual property, which is subject to a negative pledge. We borrowed $10.0 million upon execution of the Loan Agreement under an initial term A loan. Oxford Finance LLC and Horizon Technology Finance Corporation (each, a “Lender” and, collectively, the “Lenders”) will make an additional term B loan in an aggregate principal amount up to $10.0 million upon the occurrence of the Milestone Event (as defined in the Loan Agreement).

The Loan Agreement contains representations and warranties, affirmative and negative covenants applicable to us and our subsidiaries and events of default, as more fully described in the Loan Agreement. The affirmative covenants include, among others, covenants requiring us and our subsidiaries to maintain our legal existence and material governmental approvals, deliver certain financial reports, maintain insurance coverage and maintain certain cash balances in controlled accounts. The negative covenants include, among others, restrictions on dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, maintenance of collateral accounts, distributions, investments, transactions with affiliates and subordinated debt.

The Loan Agreement also includes events of default, the occurrence and continuation of which provide Oxford Finance LLC, as collateral agent, with the right to exercise remedies against us and the collateral securing the loans under the Loan Agreement, including foreclosure against our properties securing the Loan Agreement, including our cash, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. These events of default include, among other things, the nonpayment of principal or interest, violations of covenants, material adverse changes, attachment, levy, restraint on business, cross-defaults on material indebtedness, bankruptcy, material judgments, misrepresentations, subordinated debt, governmental approvals, lien priority and delisting.

Further, if we are liquidated, the Lenders’ right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The Lenders could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the Loan Agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the Lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

Our principal stockholders and management own a significant percentage of our stock and are able to exercise significant influence over matters subject to stockholder approval.

As of December 31, 2019, our executive officers and directors, combined with our stockholders who owned more than 5% of our common stock, together with their respective affiliates, beneficially owned approximately 70% of our outstanding common stock, including shares subject to outstanding options that are exercisable within 60 days after such date. Accordingly, these stockholders are able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management or board of directors, delaying or preventing a change in control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Certain holders of shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 or until the rights terminate pursuant to the terms of the investors' rights agreement between us and such holders. If additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may 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, or the JOBS Act, and may remain an emerging growth company until December 31, 2023. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. However, if certain events occur prior to December 31, 2023, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to December 31, 2023. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or SOX Section 404, in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and golden parachute payments.

We cannot predict whether investors will find our common stock less attractive if we 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 reduced or more volatile. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected to "opt out" of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance, or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

Provisions in our restated certificate of incorporation and restated by-laws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our restated by-laws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, our restated certificate of incorporation and our restated by-laws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorized our board of directors to modify, alter or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by-laws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that our stockholders could receive a premium for their common stock in an acquisition.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would be the sole source of gain for our stockholders.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock would be the sole source of gain on an investment in our common stock for the foreseeable future.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

Recently-enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, and revising the rules governing net operating losses. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses U.S. federal taxable income as a starting point for computing state and local tax liabilities.

The reduction of the corporate tax rate under the legislation may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Furthermore, under the legislation, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond will only be able to offset 80% of taxable income. This change may require us to pay U.S. federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

While some of the changes made by the tax legislation may adversely affect the Company in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis. We continue to work with our tax advisors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations.

While we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm under SOX Section 404(b). However, SOX Section 404(a) requires management to furnish a report on our internal control over financial reporting and identify any material weaknesses in our internal control over financial reporting. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting.

The presence of material weaknesses could result in financial statement errors which, in turn, could lead to errors in our financial statements, delays in our financial reporting, which could require us to restate our operating results or our auditors may be required to issue a qualified audit report. We might not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404(a). To maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended and will continue to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal control may require specific compliance training of our directors and employees, entail substantial costs to modify our existing accounting systems, take a significant period of time to complete and divert management’s attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

If either we are unable to conclude that we have effective internal control over financial reporting or, at the appropriate time, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal control over financial reporting as required by Section 404(b), investors may lose confidence in our operating results, the price of our common stock could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404, we may not be able to remain listed on Nasdaq.

Our certificate of incorporation and bylaws designate the state or federal courts in the State of Delaware and the federal district courts of the United States, respectively, as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that, unless our board of directors otherwise determines, the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to our company or our stockholders, any action asserting a claim against us or any of our directors or officers arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or by-laws, or any action asserting a claim against us or any of our directors or officers governed by the internal affairs doctrine. Additionally, our bylaws provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors and officers. However, as previously disclosed in our Current Report on Form 8-K filed with the SEC on February 28, 2018, in light of the decision issued by the Delaware Court of Chancery in *Sciabacucchi v. Salzberg*, C.A. No. 2017-0931-JTL (Del. Ch.), finding that provisions such as the federal forum selection provision in our bylaws are not valid under Delaware law, we do not intend to enforce such provision unless and until the Delaware Court of Chancery's decision is reversed by the Delaware Supreme Court on appeal or otherwise abrogated. We may incur additional costs associated with resolving such actions in other jurisdictions, which could adversely affect our results of operations and financial condition.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We occupy approximately 11,800 square feet of office and laboratory space in Cambridge, MA under a short-term lease. In November 2019, we entered into a lease agreement to replace our Cambridge, MA space for 23,901 square feet of office, laboratory and vivarium space in Lexington, MA with an estimated lease commencement date of April 1, 2020 with a term through July 1, 2025.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades on The Nasdaq Global Market under the symbol "LOGC." As of March 10, 2020, there were approximately 25 holders of record of shares of our common stock.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future.

Use of Proceeds

On October 23, 2018, we closed our IPO, in which we issued and sold 8,050,000 shares of our common stock, including 1,050,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $10.00 per share for gross proceeds of $80.5 million, before deducting underwriting discounts and commissions and offering expenses payable by us. All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-227523), which was declared effective by the SEC on October 18, 2018. Jefferies LLC, Barclays Capital Inc. and William Blair & Company, L.L.C. acted as joint book-running managers of the offering and as representatives of the underwriters. Chardan Capital Markets, LLC acted as the lead manager for the offering. The offering commenced on October 18, 2018 and did not terminate until the sale of all of the shares offered.

The net offering proceeds to us, after deducting underwriting discounts and offering costs payable by us of an aggregate of approximately $8.2 million, were approximately $72.3 million. No material offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates.

There has been no material change in our planned use of the net offering proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on October 18, 2018. We have been using and plan to continue to use the net proceeds from the IPO primarily to fund the development of LB-001 in MMA and for discovery and preclinical development of additional product candidates, and for working capital and general corporate purposes.

Item 6. Selected Financial Data

We are a smaller reporting company, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, for this reporting period and are not required to provide the information required under this item.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.

Overview

We are a genome editing company focused on developing medicines to durably treat rare diseases in patients with significant unmet medical need using GeneRide, our proprietary technology platform. Our GeneRide technology is designed to precisely integrate corrective genes into a patient's genome to provide a stable therapeutic effect. Because GeneRide is designed to have this durable therapeutic effect, we are initially targeting rare liver disorders in pediatric patients where it is critical to provide treatment early in a patient's life before irreversible disease pathology can occur. We have demonstrated proof of concept of our therapeutic platform in animal models for a number of diseases and are focusing on development of our lead product candidate, LB-001, for the treatment of Methylmalonic Acidemia, or MMA, a life-threatening disease that presents at birth.

Based on our GeneRide technology, we are developing our lead product candidate, LB-001, to treat MMA. In January 2020, we announced the submission of an IND to support the initiation of a Phase 1/2 clinical trial in pediatric patients with MMA, which the FDA has placed on clinical hold. Subsequently, we received a letter from the FDA specifying its questions related to the clinical hold. The clinical hold was based on questions that were clinical and nonclinical in nature, including questions related to the studies conducted for our IND filing, but did not relate to chemistry, manufacturing, and controls. We expect to have interactions with the FDA regarding their questions through mid-2020, after which we plan to provide guidance on the anticipated timing for the initiation of the Phase 1/2 clinical trial for LB-001.

We believe that achieving clinical proof of concept in an inherited liver disease such as MMA will validate our platform technology, including its potential application to other organs and diseases. In January 2020, we announced a research collaboration with Takeda Pharmaceutical Company Limited to further develop LB-301 in Crigler-Najjar syndrome, or CN, the second indication to be pursued using the GeneRide platform. In addition to MMA and CN, we have demonstrated proof of concept of our platform in hemophilia B and alpha-1-antitrypsin deficiency, or A1ATD, animal disease models. We expect to select future product candidates from these genetic diseases or others addressed by targeting the liver initially, and later by targeting the central nervous system, or CNS, and muscle.

Since our inception in 2014, we have devoted all of our efforts to business planning, research and development, developing and protecting our intellectual property, raising capital, recruiting management and technical staff. We do not have any products approved for sale and have not generated any revenue. As of December 31, 2019, we have raised approximately $9.8 million in net proceeds through the loan and security agreement in July 2019, approximately $72.3 million in net proceeds through our initial public offering, or IPO, in October 2018 and approximately $33.1 million in net proceeds from the sale of our convertible preferred stock in 2016 and 2017. We have incurred significant operating losses since our inception. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and commercialization of one or more of our product candidates. Our net losses were $40.1 million and $17.6 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $67.4 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future in connection with our ongoing activities.

Furthermore, we now incur additional costs associated with operating as a public company that we did not previously incur or had previously incurred at lower rates as a private company, including significant legal, accounting, investor relations and other expenses.

Initial Public Offering

On October 23, 2018, we completed our IPO, in which we issued and sold 8,050,000 shares of common stock, including 1,050,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $10.00 per share. The aggregate net proceeds to us from the IPO were approximately $72.3 million after deducting underwriting discounts and commissions and offering expenses. The shares began trading on The Nasdaq Global Market on October 19, 2018. Upon completion of the IPO, all of our outstanding shares of convertible preferred stock converted into 11,789,775 shares of our common stock.

Components of Results of Operations

Revenue

Since inception through December 31, 2019, we have not generated any revenue. We do not expect to generate any revenue from the sale of products in the near future. If our development efforts for LB-001, or other product candidates that we may develop in the future, are successful and result in regulatory approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates, and include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- license maintenance fees and milestone fees incurred in connection with various license agreements;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and, eventually, clinical trial materials;
- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, as well as academic institutions and consultants that conduct our preclinical studies and other scientific development services;
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses; and
- costs related to compliance with regulatory requirements.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued research and development expenses.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we initiate clinical trials for our product candidate LB-001 and continue to discover and develop additional product candidates. If any of our product candidates enter into later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services, travel expenses, and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our continued research and development and potential commercialization of our product candidates. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services, director and officer insurance costs, and investor and public relations costs.

Other Income (Expense), Net

Interest income consists primarily of interest on our cash and cash equivalents and investments. Interest expense consists of interest expense related to the aggregate $10.0 million principal amount of the Term A Loan borrowing under the loan and security agreement in July 2019. A portion of the interest expense on the Term A Loan is non-cash expense relating to the accretion of the debt discount and amortization of issuance costs. In the year ended December 31, 2019, we recorded $0.5 million in interest expense, of which $0.4 million relates to cash interest paid and the remainder to the accretion of the debt discount and amortization of issuance costs. Other expense, net consists primarily of foreign exchange losses.

Results of Operations

Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Operating expenses:		
Research and development	$ 30,656	$ 11,079
General and administrative	10,385	6,864
Total operating expenses	41,041	17,943
Loss from operations	(41,041)	(17,943)
Other income:		
Other income, net	935	408
Loss before income taxes	(40,106)	(17,535)
Income tax provision	(22)	(86)
Net loss	$ (40,128)	$ (17,621)

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		
	2019	2018	Increase
	(in thousands)		
LB-001 external development and manufacturing costs	$ 17,697	$ 3,628	14,069
Personnel-related costs	5,984	2,366	3,618
Other research and development costs	6,975	5,085	1,890
Total research and development expenses	$ 30,656	$ 11,079	$ 19,577

Research and development expenses for the year ended December 31, 2019 were $30.7 million, compared to $11.1 million for year ended December 31, 2018. The increase of approximately $19.6 million was primarily due to an increase of approximately $14.1 million related to external development and manufacturing expenses for our lead product candidate LB-001, $1.9 million in other research and development expenses as we increased our overall research and development activities, and $3.6 million in personnel-related costs related to an increase in headcount. Personnel-related costs for the year ended December 31, 2019 included stock-based compensation expense of $0.8 million compared to $0.3 million for the year ended December 31, 2018.

General and Administrative Expenses

General and administrative expenses were $10.4 million for the year ended December 31, 2019, compared to $6.9 million for the year ended December 31, 2018. The increase of approximately $3.5 million was primarily due to increased legal and professional fees and personnel-related costs, including salaries, stock-based compensation and bonuses. The increase in professional fees was primarily due to the increase in legal, auditing and consulting services provided. The increase in personnel-related costs was primarily due to an increase in headcount. Stock-based compensation expense included in general and administrative expenses was $1.0 million and $0.8 million for the years ended December 31, 2019 and 2018, respectively.

Other Income, Net

Other income, net was $0.9 million for the year ended December 31, 2019, compared to other income, net of $0.4 million for the year ended December 31, 2018. The change was primarily related to the increase in interest income from higher cash equivalents and investments, partially offset by interest expense related to the loan and security agreement.

Results of Operations Comparison for 2018 and 2017

For a discussion of our results of operations comparison for the years ended December 31, 2018 and 2017, refer to our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on April 1, 2019.

Liquidity and Capital Resources

Overview

Since our inception and through December 31, 2019, we have not generated any revenue and have incurred significant losses and negative cash flows from our operations. As of December 31, 2019, we had cash and cash equivalents of $33.1 million and short-term investments of $17.5 million, which we believe will be able to fund our operating expenses and capital expenditure requirements into the first quarter of 2021.

Cash Flows

The following table summarized our cash flows for each of the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (38,750)	$ (15,267)
Net cash used in investing activities	(18,505)	(579)
Net cash provided by financing activities	10,069	72,306
Effect of foreign exchange rates on cash and cash equivalents	9	17
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (47,177)	$ 56,477

Operating Activities

During the year ended December 31, 2019, net cash used in operating activities was approximately $38.8 million, primarily related to our net loss adjusted for non-cash charges and changes in the components of working capital. The $23.5 million increase in cash used in operating activities during the year ended December 31, 2019 compared to the year ended December 31, 2018, was primarily driven by an increase in our net loss due to an increase in both our research and development and general and administrative expenses.

Investing Activities

During the year ended December 31, 2019, net cash used in investing activities increased approximately $17.9 million, primarily related to net short-term investments activity of $17.1 million and a $0.8 million increase in the purchases of property and equipment as compared to the year ended December 31, 2018.

Financing Activities

During the year ended December 31, 2019, net cash provided by financing activities was $10.1 million, primarily related to net proceeds of $9.8 million under the July 2019 loan and security agreement as well as $0.2 million related to the exercise of stock options. During the year ended December 31, 2018, net cash provided by financing activities was $72.3 million, primarily from the issuance of common stock related to the IPO.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates and any future product candidates. We expect that our expenses will increase substantially if and as we:

- continue our current research programs and our preclinical development of any product candidates from our current research programs;
- initiate clinical trials for LB-001 and any other product candidates we identify and develop;
- seek to identify, assess, acquire and/or develop additional research programs and additional product candidates;
- seek marketing approvals for any product candidate that successfully complete clinical trials;
- develop, optimize, scale and validate a manufacturing process and analytical methods for any product candidates we may develop;
- establish and build out internal process and analytical development capabilities and preclinical and clinical grade production;
- obtain market acceptance of any product candidates we may develop as viable treatment options;
- address competing technological and market developments;
- maintain, expand and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- further develop our GeneRide technology platform;
- hire additional technical, quality, regulatory, clinical, scientific and commercial personnel and add operational, financial and management information systems and personnel, including personnel to support our process and product development, manufacturing and planned future commercialization efforts;
- make royalty, milestone or other payments under current and any future in-license agreements;
- establish and maintain supply chain and manufacturing relationships with third parties that can provide adequate products and services, in both amount, timing and quality, to support clinical development and the market demand for any product candidate for which we obtain regulatory and marketing approval;
- lease and build new facilities, including offices and labs, to support organizational growth;
- validate and build-out a commercial-scale current Good Manufacturing Practices, or cGMP, manufacturing facility; and
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval.

We are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates because of the numerous risks and uncertainties associated with the development of LB-001 and any other product candidates and programs we may develop and because the extent to which we may enter into collaborations with third parties for development of LB-001 and any other product candidates we may develop is unknown. For example, in January 2020, we announced the submission of an IND to support the initiation of a Phase 1/2 clinical trial in pediatric patients with MMA, which the FDA has placed on clinical hold pending the resolution of certain clinical and nonclinical questions. Our future funding requirements, both near and long-term, will depend on many factors, including:

- the initiation, scope, progress, timing, costs and results of drug discovery, preclinical development, laboratory testing, and planned clinical trials for LB-001 and any other product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or FDA, and other comparable foreign regulatory authorities, including resolving any potential clinical holds that may be imposed on us;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions;
- the achievement of milestones or occurrence of other developments that trigger payments under any of our current agreements or other agreements we may enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial and other research and development costs under future collaboration agreements, if any;
- the effect of competing technological and market developments;
- the cost and timing of completion of clinical or commercial-scale manufacturing activities;
- the extent to which we in-license or acquire other products and technologies;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the cost of establishing sales, marketing and distribution capabilities for LB-001 and any other product candidates in regions where we choose to commercialize our product candidates, if approved; and
- the initiation, progress, timing and results of our commercialization of LB-001 and any other product candidates, if approved, for commercial sale.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the research and development of that product candidate. For example, if the clinical hold on the IND for LB-001 causes significant delays in the progress of our MMA program, the FDA or another regulatory authority were to require us to conduct preclinical studies or clinical trials beyond those that we anticipate will be required, or if we experience significant trial delays due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on preclinical and clinical research and development activities. Any significant delays in our programs may also require us to reevaluate our corporate strategy, resulting in the expenditure of significant resources and time. We may never succeed in obtaining regulatory approval for our product candidates or any future product candidates.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through offerings of securities, private equity financing, debt financings, collaborations, government contracts or other strategic transactions. The terms of financing may adversely affect the holdings or the rights of our stockholders. If we are unable to obtain funding, we may be required to delay, limit, reduce or terminate some or all of our research and product development, product portfolio expansion or future commercialization efforts.

We will also continue to incur costs as a public company that we did not previously incur or have previously incurred at lower rates, including increased fees payable to the non-employee members of our board of directors, increased personnel costs, increased director and officer insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with public company reporting requirements under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and rules implemented by the SEC and the Nasdaq Global Market.

Contractual Obligations and Commitments:

We are a smaller reporting company, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, for this reporting period and are not required to provide the information required under this item.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We account for stock-based compensation transactions using a grant-date fair-value-based method under FASB Codification Topic 718, Compensation—Stock Compensation. We account for all stock-based awards granted to employees and non-employees based on their fair value on the date of the grant and recognize compensation expense of those awards, over the requisite service period, which is generally the vesting period of the respective award. We apply the straight-line method of expense recognition to all awards with only service-based vesting conditions. We have also issued restricted stock with performance-based vesting conditions and recorded the expense for these awards when we concluded that it was probable that the performance condition would be achieved. Stock-based compensation is classified in the accompanying statements of operations based on the function to which the related services are provided. We recognize stock-based compensation expense for the portion of awards that have vested. Forfeitures are accounted for as they occur.

We estimate the fair value of each stock option grant on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Recently Issued Accounting Pronouncements

Refer to Note 2 in the accompanying notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for a discussion of recent accounting pronouncements.

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

We are a smaller reporting company, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, for this reporting period and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

Our financial statements, together with the report of our independent registered public accounting firm, appear in this Annual Report on Form 10-K beginning on page F-1.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2019. Our disclosure controls and procedures are designed to ensure that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures, and is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms.

Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2019.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. Our internal control over financial reporting is a process designed under the supervision of our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in Internal Control –Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under that framework, management concluded that our internal control over financial reporting was effective as of December 31, 2019.

Attestation Report of the Registered Public Accounting Firm

This report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting.

Changes in Internal Control over Financial Reporting

Other than with respect to the remediation efforts described below, there were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fourth quarter of the year ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Remediation of Prior Material Weakness

In 2018, our Chief Executive Officer and Chief Financial Officer concluded that our internal control over financial reporting were not effective as of December 31, 2018 due to a material weakness in internal control over financial reporting. During 2019, our management, with the oversight of the Audit Committee of our Board of Directors, engaged in efforts to remediate the material weakness identified and disclosed in Item 9A of the annual report on Form 10-K for the year ended December 31, 2018. We have designed, implemented and tested enhancements to our internal control for operational effectiveness, after adding finance and accounting personnel. Based on the results of our testing, management has concluded that the controls are adequately designed and have operated effectively for a sufficient period of time during 2019. Accordingly, the material weakness was considered to be remediated as of December 31, 2019.

Item 9B. Other Information.

On March 11, 2020, Mark J. Enyedy was appointed to our board of directors effective as of March 17, 2020. Mr. Enyedy will be a Class I director to serve on our board of directors until the annual meeting of stockholders to be held in 2022 or his earlier resignation or removal. Upon his appointment, Mr. Enyedy will also serve on the audit committee and nominating and corporate governance committee of our board of directors.

Mr. Enyedy has served as President and Chief Executive Officer of lmmunoGen, Inc. since 2016. Prior to joining ImmunoGen, he served in various executive capacities at Shire PLC from 2013 to 2016, including as Executive Vice President and Head of Corporate Development from 2014 to 2016, where he led Shire's strategy, M&A, and corporate planning functions and provided commercial oversight of Shire's pre-Phase 3 portfolio. Prior to joining Shire, he served as Chief Executive Officer and a director of Proteostasis Therapeutics, Inc., a biopharmaceutical company, from 2011 to 2013. Prior to joining Proteostasis, he served for 15 years at Genzyme Corporation, most recently as President of the Transplant, Oncology, and Multiple Sclerosis divisions. Mr. Enyedy holds a J.D. from Harvard Law School and practiced law prior to joining Genzyme. Mr. Enyedy is also a director of Akebia Therapeutics and The American Cancer Society of Eastern New England. Within the past five years, he also served as a director of Fate Therapeutics, Inc. and Keryx Biopharmaceuticals, Inc.

Other than as described below with respect to equity awards, Mr. Enyedy will be compensated for his service as a director in accordance with the Company’s non-employee director compensation policy, as generally described in the Company’s definitive proxy statement on Schedule 14A, as filed with the SEC on April 29, 2019. It is anticipated that Mr. Enyedy will be awarded an option to purchase 20,000 shares on the effective date of his appointment, which option will vest annually in equal amounts over three years, with accelerated vesting if a change of control occurs prior to the option being fully vested, subject in each case to Mr. Enyedy’s continued service through the applicable vesting date.

Our board of directors has determined that Mr. Enyedy is independent in accordance with applicable Nasdaq listing rules and has no material direct or indirect interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K. There are no arrangements or understandings between Mr. Enyedy and any other person pursuant to which he was selected as a director. We plan to enter into an indemnification agreement, which will provide indemnification for Mr. Enyedy in connection with his service as a member of our board of directors.

On March 16, 2020, we announced that Tomer Kariv, Esq., has resigned from our board of directors. Mr. Kariv’s resignation is effective as of March 12, 2020. Mr. Kariv’s resignation was due to time constraints related to his other business obligations and not due to any disagreement with us.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

The information required by this Item 10 will be included under the captions “Executive Officers,” Election of Directors” and “Delinquent Section 16(a) Reports” in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included under the captions “Executive and Director Compensation” and “Compensation Committee Interlocks and Insider Participation” in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 12 will be included under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for issuance Under Equity Compensation Plans” in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included under the captions “Employment Agreements,” “Potential Payments Upon Termination or Change in Control,” “Board Determination of Independence” and “Related Person Transactions” in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be included under the captions “Audit Fees and Services” and “Pre-Approval Policies and Procedures” in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statements and Schedules.

(a)(1) Financial Statements.

For a list of the consolidated financial statements included herein, see Index to the Consolidated Financial Statements in this Annual Report on Form 10-K, which is incorporated into this Item 15 by reference.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Consolidated Financial Statements or Notes thereto.

(a)(3) Exhibits.

The exhibits listed below are filed as part of this Form 10-K other than Exhibit 32.1, which shall be deemed furnished.

Number	Description
3.1	Fourth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-38707, filed on October 29, 2018).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, File No. 001-38707, filed on October 29, 2018).
4.1	Form of Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's S-1/A, File No. 333-227523, filed on October 9, 2018).
4.2	Investors' Rights Agreement, dated as of June, 19, 2017, by and among LogicBio Therapeutics, Inc. and each of the Investors and Common Holders listed therein (incorporated by reference to Exhibit 4.2 to the Company's S-1, File No. 333-227523, filed on September 25, 2018).
4.3	Form of Warrant to Purchase Common Stock of LogicBio Therapeutics, Inc., dated as of July 2, 2019 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, File No. 001-38707, filed on July 2, 2019).
4.4*	Description of the Registrant's Securities.
10.1#	Amended and Restated Exclusive (Equity) Agreement dated January 31, 2018, between The Board of Trustees of the Leland Stanford Junior University and LogicBio Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's S-1, File No. 333-227523, filed on September 25, 2018).
10.2+*	Amendment No. 1 to Amended and Restated (Equity) Agreement, dated as of May 3, 2018, between The Board of Trustees of the Leland Stanford University and LogicBio Therapeutics, Inc.
10.3#	Amendment No. 2 to Amended and Restated (Equity) Agreement, dated as of June 24, 2019, between The Board of Trustees of the Leland Stanford University and LogicBio Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q, File No. 001-38707, filed on August 13, 2019).
10.4+*	Amendment No. 3 to Amended and Restated (Equity) Agreement, dated as of January 29, 2020, between The Board of Trustees of the Leland Stanford University and LogicBio Therapeutics, Inc.
10.5#	Patent & Technology License Agreement, dated May 7, 2018, by and between LogicBio Therapeutics, Inc. and The Board of Regents of The University of Texas System (incorporated by reference to Exhibit 10.2 to the Company's S-1, File No. 333-227523, filed on September 25, 2018).
10.6+*	Amendment No. 1 to Patent & Technology License Agreement, dated October 14, 2019, by and between LogicBio Therapeutics, Inc. and The Board of Regents of Thu University of Texas System.
10.7#	Patent License Agreement dated December 14, 2018, between the U.S. Department of Health and Human Services, as represented by the National Human Genome Research Institute, an Institute of the National Institutes of Health and LogicBio Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Form 10-K, File No. 001-38707, filed on April 1, 2019).

Number	Description
10.8†	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.3 to the Company's S-1/A, File No. 333-227523, filed on October 9, 2018).
10.9†	LogicBio Therapeutics, Inc. 2014 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.4 to the Company's S-1, File No. 333-227523, filed on September 25, 2018).
10.10†	Form of Stock Option Agreement under the LogicBio Therapeutics, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's S-1/A, File No. 333-227523, filed on October 9, 2018).
10.11†	Form of Restricted Stock Agreement under the LogicBio Therapeutics, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's S-1/A, File No. 333-227523, filed on October 9, 2018).
10.12	Consulting Agreement with Mark Kay, dated April 1, 2018 (incorporated by reference to Exhibit 10.8 to the Company's S-1, File No. 333-227523, filed on September 25, 2018).
10.13†	LogicBio Therapeutics, Inc. 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Company's S-1/A, File No. 333-227523, filed on October 9, 2018).
10.14†	LogicBio Therapeutics, Inc. 2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.9 to the Company's S-1/A, File No. 333-227523, filed on October 9, 2018).
10.15†	LogicBio Therapeutics, Inc. 2018 Cash Incentive Plan (incorporated by reference to Exhibit 10.10 to the Company's S-1/A, File No. 333-227523, filed on October 9, 2018).
10.16†	Form of Incentive Stock Option Agreement under the LogicBio Therapeutics, Inc. 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.11 to the Company's S-1/A, File No. 333-227523, filed on October 9, 2018).
10.17†	Form of Non-Statutory Stock Option Agreement under the LogicBio Therapeutics, Inc. 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.12 to the Company's S-1/A, File No. 333-227523, filed on October 9, 2018).
10.18†	Form of Amended and Restated Executive Employment Agreement, by and between LogicBio Therapeutics, Inc. and Frederic Chereau (incorporated by reference to Exhibit 10.13 to the Company's S-1/A, File No. 333-227523, filed on October 9, 2018).
10.19†	Form of Amended and Restated Executive Employment Agreement, by and between LogicBio Therapeutics, Inc. and Matthias Jaffé (incorporated by reference to Exhibit 10.14 to the Company's S-1/A, File No. 333-227523, filed on October 9, 2018).
10.20†*	Form of Executive Employment Agreement, by and between LogicBio Therapeutics, Inc. and Seokho Bryan Yoon.
10.21	Loan and Security Agreement dated as of July 2, 2019, among Oxford Finance LLC, the Lenders listed on Schedule 1.1 thereto and Horizon Technology Finance Corporation and LogicBio Therapeutics, Inc. and LogicBio Australia Pty Limited (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38707, filed on July 2, 2019).
10.22*	Lease Agreement dated as of November 4, 2019, between LogicBio Therapeutics, Inc. and HCP/King Hayden Campus LLC
21.1*	Subsidiaries of LogicBio Therapeutics, Inc.
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Rule 13a—14(a) / 15d—14(a) Certifications—Chief Executive Officer.
31.2*	Rule 13a—14(a) / 15d—14(a) Certifications—Chief Financial Officer.
32.1**	Section 1350 Certifications.

Number	Description
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.
** Furnished herewith.
† Indicates a management contract or compensatory plan.
+ Pursuant to 17 C.F.R §§230.406 and 230.83, the confidential portions of this exhibit have been omitted and are marked accordingly.
# Portions of the exhibit (indicated by asterisks) have been omitted pursuant to a confidential treatment order granted by the Securities and Exchange Commission.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

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

LOGICBIO THERAPEUTICS, INC.

Date: March 16, 2020

By: /s/ Frederic Chereau
Frederic Chereau
President and Chief Executive Officer

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

Signature	Title	Date
/s/ Frederic Chereau Frederic Chereau	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 16, 2020
/s/ Matthias Jaffé Matthias Jaffé	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 16, 2020
/s/ Leon Chen Leon Chen, Ph.D.	Director	March 16, 2020
/s/ Erez Chimovits Erez Chimovits	Director	March 16, 2020
/s/ Mark Kay Mark Kay, M.D., Ph.D.	Director	March 16, 2020
/s/ Richard Moscicki Richard Moscicki, M.D.	Director	March 16, 2020
/s/ Daniel O'Connell Daniel O'Connell, M.D., Ph.D.	Director	March 16, 2020
/s/ Michael Wyzga Michael Wyzga	Director	March 16, 2020

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of LogicBio Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of LogicBio Therapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and the need to raise additional capital to finance its future operations raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 16, 2020

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

LogicBio Therapeutics, Inc.

Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 33,107	$ 80,906
Short-term investments	17,540	—
Prepaid expenses and other current assets	2,045	1,268
Restricted cash	146	—
Total current assets	52,838	82,174
Property and equipment, net	1,696	590
Restricted cash	622	146
Operating lease right-of-use asset	504	—
TOTAL ASSETS	$ 55,660	$ 82,910
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 624	$ 1,168
Accrued expenses and other current liabilities	2,939	1,517
Total current liabilities	3,563	2,685
Long-term debt, net of issuance costs and discount	9,810	—
Total liabilities	13,373	2,685
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Preferred stock, par value of $0.0001 per share; 25,000,000 shares authorized; no shares issued and outstanding as of December 31, 2019 and 2018	—	—
Common stock, par value of $0.0001 per share; 175,000,000 shares authorized; 23,036,943 and 22,188,393 shares issued and outstanding as of December 31, 2019 and 2018, respectively	3	3
Additional paid-in capital	109,640	107,473
Accumulated other comprehensive income (loss)	14	(9)
Accumulated deficit	(67,370)	(27,242)
Total stockholders' equity	42,287	80,225
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 55,660	$ 82,910

See notes to consolidated financial statements.

LogicBio Therapeutics, Inc.

Consolidated Statements of Operations
(In thousands, except share and per share data)

	Year Ended December 31,	
	2019	**2018**
OPERATING EXPENSES:		
Research and development	$ 30,656	$ 11,079
General and administrative	10,385	6,864
Total operating expenses	41,041	17,943
LOSS FROM OPERATIONS	(41,041)	(17,943)
OTHER INCOME (EXPENSE), NET:		
Interest income	1,500	569
Interest expense	(546)	(2)
Other expense, net	(19)	(159)
Total other income, net	935	408
Loss before income taxes	(40,106)	(17,535)
Income tax provision	(22)	(86)
Net loss	$ (40,128)	$ (17,621)
Net loss per share—basic and diluted	$ (1.78)	$ (3.04)
Weighted-average common stock outstanding—basic and diluted	22,602,954	5,801,533

See notes to consolidated financial statements.

LogicBio Therapeutics, Inc.

Consolidated Statements of Comprehensive Loss
(In thousands)

	Year Ended December 31,	
	2019	**2018**
Net loss	$ (40,128)	$ (17,621)
Other comprehensive income:		
Unrealized gain on investments	14	—
Foreign currency translation adjustment	9	5
Comprehensive loss	$ (40,105)	$ (17,616)

See notes to consolidated financial statements.

LogicBio Therapeutics, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share data)

	Convertible Preferred Stock									
	Convertible Preferred Stock $0.0001 Par Value Series A		Convertible Preferred Stock $0.0001 Par Value Series B		Common Stock $0.0001 Par Value		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
BALANCE, January 1, 2018	2,976,190	$ 4,359	19,541,465	$ 28,703	1,606,360	$ 1	$ 1,035	$ (14)	$ (9,621)	$ (8,599)
Vesting of restricted stock	—	—	—	—	656,944	—	—	—	—	—
Exercise of options	—	—	—	—	29,217	—	20	—	—	20
Issuance of common stock upon initial public offering, net of issuance costs of 2,611	—	—	—	—	8,050,000	1	72,253	—	—	72,254
Issuance of common stock to Stanford	—	—	—	—	56,097	—	—	—	—	—
Conversion of Series A preferred shares upon initial public offering	(2,976,190)	(4,359)	—	—	1,558,271	—	4,359	—	—	4,359
Conversion of Series B preferred shares upon initial public offering	—	—	(19,541,465)	(28,703)	10,231,504	1	28,702	—	—	28,703
Foreign currency translation adjustment	—	—	—	—	—	—	—	5	—	5
Stock-based compensation expense	—	—	—	—	—	—	1,104	—	—	1,104
Net loss	—	—	—	—	—	—	—	—	(17,621)	(17,621)
BALANCE, December 31, 2018	—	—	—	—	22,188,393	3	107,473	(9)	(27,242)	80,225
Vesting of restricted stock	—	—	—	—	641,333	—	—	—	—	—
Exercise of options	—	—	—	—	207,217	—	224	—	—	224
Issuance of common stock warrants related to loan and security agreement	—	—	—	—	—	—	136	—	—	136
Unrealized gains on investments	—	—	—	—	—	—	—	14	—	14
Foreign currency translation adjustment	—	—	—	—	—	—	—	9	—	9
Stock-based compensation expense	—	—	—	—	—	—	1,807	—	—	1,807
Net loss	—	—	—	—	—	—	—	—	(40,128)	(40,128)
BALANCE, December 31, 2019	—	—	—	—	23,036,943	3	109,640	14	(67,370)	42,287

See notes to consolidated financial statements.

LogicBio Therapeutics, Inc.

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (40,128)	$ (17,621)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	289	89
Loss on disposal of property and equipment	—	140
Net amortization of premiums and discounts on investments	(436)	—
Stock-based compensation expense	1,807	1,104
Non-cash interest expense	101	—
Non-cash lease expense	1,168	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(777)	(150)
Other assets	—	249
Accounts payable	(527)	35
Accrued expenses and other current liabilities	(247)	887
Net cash used in operating activities	(38,750)	(15,267)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of investments	(58,490)	—
Maturities of investments	41,400	—
Purchase of property and equipment	(1,415)	(614)
Disposal of property and equipment	—	35
Net cash used in investing activities	(18,505)	(579)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock from the initial public offering	—	74,865
Proceeds from borrowings under loan and security agreement, net of issuance costs	9,845	—
Proceeds from exercise of stock options	224	20
Payment of deferred initial public offering costs	—	(2,579)
Net cash provided by financing activities	10,069	72,306
Effect on foreign exchange rates on cash and cash equivalents	9	17
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(47,177)	56,477
Cash, cash equivalents and restricted cash at beginning of year	81,052	24,575
Cash, cash equivalents and restricted cash at end of period	$ 33,875	$ 81,052
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	$ 33,107	$ 80,906
Short-term restricted cash	146	—
Long-term restricted cash	622	146
Total cash, cash equivalents and restricted cash	$ 33,875	$ 81,052
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 445	$ —
Cash paid for income taxes	$ 6	$ 164
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES:		
Right-of-use assets obtained in exchange for operating lease obligation	$ 1,461	$ —
Property and equipment purchases in accounts payable and accrued expenses	$ —	$ 20
Deferred initial offering costs in accounts payable and accrued expenses	$ —	$ 32
Conversion of preferred stock to common stock from the initial public offering	$ —	$ 33,062
Warrants issued in connection with loan and security agreement	$ 136	

See notes to consolidated financial statements.

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

LogicBio Therapeutics, Inc. ("LogicBio" or the "Company") was incorporated in 2014 as a Delaware corporation. Its principal offices are in Cambridge, Massachusetts. The Company is a genome editing company focused on developing medicines to durably treat rare diseases in pediatric patients with significant unmet medical need, using GeneRide™, its proprietary technology platform. GeneRide technology is designed to precisely and stably integrate corrective genes into a patient's genome to provide a durable therapeutic effect. The Company has demonstrated proof of concept of its therapeutic platform in animal models for a number of diseases and is focusing on its lead product candidate, LB-001, for the treatment of Methylmalonic Acidemia ("MMA"), a life-threatening disease that presents at birth.

In January 2020, the Company announced the submission of an IND to support the initiation of a Phase 1/2 clinical trial in pediatric patients with MMA, which the FDA has placed on clinical hold. Subsequently, the Company received a letter from the FDA specifying its questions related to the clinical hold. The clinical hold was based on questions that were clinical and nonclinical in nature, including questions related to the studies conducted for the Company's IND filing, but did not relate to chemistry, manufacturing, and controls. The Company expects to have interactions with the FDA regarding their questions through mid-2020, after which the Company plans to provide guidance on the anticipated timing for the initiation of the Phase 1/2 clinical trial for LB-001.

Since its inception, the Company has devoted the majority of its efforts to business planning, research and development, developing markets, raising capital, recruiting management and technical staff. The Company is subject to a number of risks similar to those of other companies conducting high-risk, early-stage research and development of product candidates. Principal among these risks are a dependency on key individuals and intellectual property, competition from other products and companies, and the technical risks associated with the successful research, development and clinical manufacturing of its product candidates. The Company's success is dependent upon its ability to continue to raise additional capital in order to fund ongoing research and development, meet its obligations and, ultimately, obtain regulatory approval of its products, successfully commercialize its products, generate revenue and attain profitable operations.

During the years ended December 31, 2019 and 2018, the Company incurred net losses of $40.1 million and $17.6 million, respectively, and reported cash used in operations totaling $38.8 million and $15.3 million, respectively. In addition, as of December 31, 2019, the Company had an accumulated deficit of $67.4 million. The Company expects to continue to generate operating losses and use cash in operations for the foreseeable future. As of December 31, 2019, the Company had cash and cash equivalents of $33.1 million and short-term investments of $17.5 million which management believes will be sufficient to fund its operating expenses and capital expenditure requirements into the first quarter of 2021. However, based on the Company's operating losses since inception, the expectation of continued operating losses for the foreseeable future, and the need to raise additional capital to finance its future operations, it has been deemed there is substantial doubt about the Company's ability to continue as a going concern within one year from the date these consolidated financial statements are issued.

The Company will require substantial additional capital to fund its research and development and ongoing operating expenses. Management's plans to mitigate this risk include raising additional capital through equity or debt financings, or through strategic transactions. These plans may also include the possible deferral of certain operating expenses unless and until additional capital is received. There can be no assurance that the Company will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to the Company, or that the Company will be successful in deferring certain operating expenses. While there can be no assurance the Company will be able to successfully reduce operating expenses or raise additional capital, management believes its historical success in managing cash flows and obtaining capital will continue in the foreseeable future.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The accompanying consolidated financial statements have been prepared by the Company in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP").

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

In January 2016, the Company formed LogicBio Research, LTD ("LogicBio Research"), a wholly owned Israeli subsidiary, for the purpose of conducting research and development activities on the Company's behalf. In September 2018, all operations ceased for LogicBio Research and the subsidiary was formally liquidated in November 2019. In April 2018, the Company formed LogicBio Australia Pty Limited ("LogicBio Australia"), a wholly owned Australian subsidiary, for the purpose of conducting research and development activities on the Company's behalf. In December 2018, the Company formed LogicBio Securities Corporation, which is a Delaware subsidiary created to buy, sell and hold securities. The accompanying consolidated financial statements include the accounts of the Company, LogicBio Research, LogicBio Australia and LogicBio Securities Corporation. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, useful lives assigned to property and equipment, the fair values of common and convertible preferred stock, stock-based compensation and income taxes. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Fair Value Measurements

Certain assets and liabilities are reported on a recurring basis at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity date of 90 days or less at the date of purchase to be cash equivalents. Cash equivalents consist principally of money market funds and overnight repurchase agreements fully collateralized by government agency securities or U.S. Treasury securities.

The Company's cash equivalents are measured at fair value on a recurring basis. As of December 31, 2019 and 2018, the carrying amount of cash equivalents was $31,094 and $80,043, respectively, which approximates fair value and was determined based upon both Level 1 and Level 2 inputs.

Investments

The Company determines the appropriate classification of its investments in debt securities at the time of purchase. All of the Company's securities are classified as available-for-sale and are reported in short-term investments or long-term investments based on maturity dates and whether such assets are reasonably expected to be realized in cash or sold or consumed during the normal cycle of business. Available-for-sale investments are recorded at fair value, with unrealized gains or losses included in accumulated other comprehensive income (loss) on the Company's Consolidated Balance Sheets, exclusive of other-than-temporary impairment losses, if any. Investments may be composed of corporate debt securities, commercial paper, U.S. government and agency securities and certificates of deposit.

Concentrations of Credit Risk

Financial instruments that potentially subject us to significant concentration of credit risk consist primarily of cash and cash equivalents. Periodically, the Company may maintain deposits in financial institutions in excess of government insured limits. The Company believes that it is not exposed to significant credit risk as our deposits are held at financial institutions that management believes to be of high credit quality and the Company has not experienced any losses on these deposits. As of December 31, 2019 and 2018, the Company's cash and cash equivalents were held with one financial institution. The Company believes that the market risk arising from its holdings of these financial instruments is mitigated based on the fact that many of these securities are either government backed or of high credit rating.

Restricted Cash

As of December 31, 2019, the Company had restricted cash of $146 classified as a current asset and restricted cash of $622 classified as a non-current asset representing security deposits in the form of cash-collateralized letters of credit for the Cambridge, MA and Lexington, MA leases, respectively. As of December 31, 2018, the Company had restricted cash of $146 classified as a non-current asset representing a security deposit in the form of a cash-collateralized letter of credit for the Cambridge, MA lease.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' (deficit) equity as a reduction of proceeds generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statement of operations. Upon the closing of the IPO in October 2018, related deferred offering costs were recorded as a reduction to shareholders' equity. As of December 31, 2019, the Company did not have any deferred offering costs recorded.

Property and Equipment

Property and equipment are recorded at cost. Expenditures for repairs and maintenance are expensed as incurred. When assets are retired or disposed of, the assets and related accumulated depreciation are derecognized from the accounts, and any resulting gain or loss is included in the determination of net loss. Depreciation is provided using the straight-line method over the estimated useful lives of the related assets as follows:

	Estimated Useful Life
Computer equipment and software	3 years
Laboratory equipment	5 years
Furniture and fixtures	5 years
Leasehold improvements	lesser of useful life or remaining lease term

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceed the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. To date, no impairments have been recognized for these assets.

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 supersedes the lease guidance under FASB ASC Topic 840, *Leases*, ("ASC 840") resulting in the creation of FASB Accounting Standards Codification ("ASC") Topic 842, *Leases* ("ASC 842"). Effective January 1, 2019, the Company adopted ASC 842 using the modified retrospective method and utilized the effective date as its date of initial application, with prior periods presented in accordance with the previous guidance under ASC 840.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Most leases with a term greater than one year are recognized on the balance sheet as a right-of-use asset and a current and non-current lease liability, as applicable. The Company elected not to recognize on the balance sheet leases with terms of one year or less. The Company typically only includes an initial lease term in its assessment of a leasing arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew the lease. The Company remeasures and reallocates the consideration in a contract when there is a modification of a lease that is not accounted for as a separate contract. A lease modification that results in a separate contract, including when the modification grants the lessee an additional right of use that is not included in the original lease, is accounted for in the same manner as a new lease. The Company monitors its material leases on a quarterly basis.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

In accordance with ASC 842, components of a lease should be split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, consumables, etc.) and non-components (e.g., property taxes, insurance, etc.). The fixed and in-substance fixed contract consideration, including any consideration related to non-components, must be allocated based on the respective relative fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is required, certain practical expedients are available. Entities may elect the practical expedient not to separate lease and non-lease components. Rather, entities would account for each lease component and the related non-lease component together as a single component. For new and amended leases beginning in 2019 and after, the Company has elected to account for the lease and non-lease components for leases for classes of all underlying assets together and allocate all of the contract consideration to the lease component only.

Guarantees and Indemnifications

As permitted under Delaware law, the Company indemnifies its officers, directors, consultants and employees for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. Through December 31, 2019, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related liabilities have been established.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates, and include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- license maintenance fees and milestone fees incurred in connection with various license agreements;
- the cost of laboratory supplies and acquiring, developing and manufacturing preclinical study and, eventually, clinical trial materials;
- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, as well as academic institutions and consultants that conduct our preclinical studies and other scientific development services;
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses; and
- costs related to compliance with regulatory requirements.

Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its vendors. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid expenses or accrued expenses and other current liabilities.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. The Company includes foreign currency translation adjustments and unrealized gains and losses on available-for-sale investments in other comprehensive loss. For the years ended December 31, 2019 and 2018, accumulated comprehensive loss included $0 and $9, respectively, of foreign currency translation adjustments. In addition, for the year ended December 31, 2019, accumulated comprehensive loss included $14 of unrealized gains on investments.

Foreign Currency Transactions

The functional currency for the Company's wholly-owned foreign subsidiary, LogicBio Australia, is the U.S. Dollar. The functional currency for the Company's wholly-owned foreign subsidiary, LogicBio Research, was the Israeli New Shekel. Assets and liabilities of LogicBio Research are translated into United States dollars at the exchange rate in effect on the consolidated balance sheet date. Income items and expenses are translated at the average exchange rate in effect during the period. Stockholders' equity (deficit) amounts are translated based on historical exchange rates as of the date of each transaction. Unrealized translation gains and losses are recorded as a foreign currency translation adjustment, which is included in the consolidated statements of convertible preferred stock and stockholder's equity (deficit) as a component of accumulated other comprehensive loss. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other (expense) income, net in the consolidated statements of operations as incurred.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is made available for evaluation by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The CODM is the Company's Chief Executive Officer. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular concentration is focused on the development and commercialization of specific genome editing and integration of the therapeutic transgene, utilizing the body's own native processes to drive durable expression.

Convertible Preferred Stock

As of December 31, 2019 and 2018 the Company did not have any convertible preferred stock outstanding.

Stock-Based Compensation

The Company accounts for all stock-based payment awards granted to employees and non-employees as stock-based compensation expense at fair value. The Company's stock-based payments include stock options and grants of common stock, including common stock subject to vesting. The measurement date for employee awards is the date of grant, and stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. The measurement date for non-employee awards is the date of grant and stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis. The Company has also issued restricted stock with performance-based vesting conditions and would have recorded the expense for these awards if the Company had concluded that it was probable that the performance condition would be achieved. Stock-based compensation is classified in the accompanying statements of operations based on the function to which the related services are provided. The Company recognizes stock-based compensation expense for the portion of awards that have vested. Forfeitures are accounted for as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company has historically been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options granted to employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is determined in the same manner as stock options granted to employees. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's consolidated financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes.

Net Loss Per Share

The Company's potentially dilutive shares, which include any outstanding stock options, warrants and unvested restricted stock, are considered to be common stock equivalents and are only included in the calculation of diluted net loss when their effect is dilutive.

The Company excluded the following potential common stock equivalents from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect for the years ended December 31, 2019 and 2018.

	December 31,	
	2019	2018
Unvested restricted stock	243,387	884,720
Options to purchase common stock	2,247,753	2,702,747
Term A loan common stock warrants	15,686	—

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842),*" which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases on their balance sheet date. ASU No. 2016-02 was effective for fiscal years beginning after December 15, 2018. In July 2018, an amendment was made that allows companies the option of using the effective date of the new standard as the initial application date (at the beginning of the period in which the new standard is adopted, rather than at the beginning of the earliest comparative period). This update includes a short-term lease exception for leases with a term of 12 months or less, in which a lessee can make an accounting policy election not to recognize the associated lease assets and lease liabilities on its balance sheet. Additionally, in March 2019, the FASB issued ASU 2019-01, *Leases (Topic 842): Codification Improvements* ("ASU No. 2019-01"). ASU No. 2019-01 clarifies the transition guidance related to interim disclosures provided in the year of adoption. Lessees will continue to differentiate between finance leases (previously referred to as capital leases) and operating leases, using classification criteria that are substantially similar to the previous guidance. For lessees, the recognition, measurement, and presentation of expenses and cash flows arising from a lease did not significantly change from previous U.S. GAAP. The modified retrospective method includes several optional practical expedients that entities may elect to apply, as well as transition guidance specific to nonstandard leasing transactions. The Company adopted ASC 842 on January 1, 2019 using a cumulative-effect adjustment on the effective date of the standard, for which comparative periods are presented in accordance with the previous guidance under ASC 840.

In adopting ASC 842, the Company elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which does not require the reassessment of the following: (i) whether existing or expired arrangements are or contain a lease, (ii) the lease classification of existing or expired leases, and (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Additionally, the Company made an accounting policy election to keep leases with a term of 12 months or less off its balance sheet.

Adoption of this standard resulted in the recording of $210 each of operating lease liabilities and a right-of-use asset on the Company's consolidated balance sheet on the effective date. The adoption of the standard did not have a material effect on the Company's consolidated statements of operations, comprehensive loss, cash flows or convertible preferred stock and stockholders' equity (deficit). Refer to Note 13 for right-of-use asset and liabilities recorded during the year ended December 31, 2019.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *"Measurement of Credit Losses on Financial Instruments"*. The guidance requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. The standard is effective for interim and annual periods beginning after December 15, 2019. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

3. FAIR VALUE MEASUREMENTS

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

Description	December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Observable Inputs (Level 3)
Assets				
Overnight repurchase agreements	$ 30,001	$ —	$ 30,001	$ —
U.S. Treasury securities	17,540	17,540	—	—
Money market funds and other cash equivalents	1,093	1,093	—	—
Total financial assets	$ 48,634	$ 18,633	$ 30,001	$ —

Description	December 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Observable Inputs (Level 3)
Assets				
Money market funds and other cash equivalents	$ 80,043	$ 80,043	$ —	$ —
Total financial assets	$ 80,043	$ 80,043	$ —	$ —

When developing fair value estimates, the Company maximizes the use of observable inputs and minimizes the use of unobservable inputs. When available, the Company uses quoted market prices to measure fair value. The valuation technique used to measure fair value for the Company's Level 1 and Level 2 assets is a market approach, using prices and other relevant information generated by market transactions involving identical or comparable assets. If market prices are not available, the fair value measurement is based on models that use primarily market-based parameters including yield curves, volatilities, credit ratings and currency rates. In certain cases where market rate assumptions are not available, the Company is required to make judgments about assumptions market participants would use to estimate the fair value of a financial instrument.

The Company did not have any transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy during the years ended December 31, 2019 and 2018.

4. INVESTMENTS

The following table summarizes the Company’s investments, which are considered available-for-sale and are included in short-term investments on the consolidated balance sheet as of December 31, 2019:

	December 31, 2019			
	Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 17,526	$ 14	$ —	$ 17,540
Total	$ 17,526	$ 14	$ —	$ 17,540

Certain short-term debt securities with original maturities of less than 90 days are included in cash and cash equivalents on the consolidated balance sheet and are not included in the table above. As of December 31, 2019, all investments have contractual maturities within one year. The Company had no short-term or long-term investments as of December 31, 2018.

5. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following:

	December 31, 2019	December 31, 2018
Computer equipment and software	$ 108	$ 36
Laboratory equipment	1,798	582
Furniture and fixtures	123	21
Leasehold improvements	5	—
Total	2,034	639
Less: Accumulated depreciation	(338)	(49)
Property and equipment, net	$ 1,696	$ 590

Depreciation expense for the years ended December 31, 2019 and 2018 was $289 and $89, respectively. Maintenance and repairs are charged to expense as incurred and any additions or improvements are capitalized.

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities at December 31, 2019 and 2018 consisted of the following:

	December 31, 2019	December 31, 2018
Accrued compensation and benefits	1,155	$ 709
Accrued professional services	1,004	585
Lease liabilities	504	—
Other	276	223
Total accrued expenses and other current liabilities	$ 2,939	$ 1,517

Accrued compensation and benefits consists primarily of accrued bonuses. Accrued professional services consists primarily of consulting services, legal services and services provided by contract research organizations (“CRO”) and contract manufacturing organizations (“CMO”).

7. DEBT

On July 2, 2019 (the “Closing Date”), the Company entered into a loan and security agreement (the “Loan Agreement”), for term loans with Oxford Finance LLC (“Oxford”) and Horizon Technology Finance Corporation (“Horizon,” and, together with Oxford, the “Lenders”). The Loan Agreement allows the Company to borrow up to $20,000 issuable in two equal tranches (the “Term Loans”). On the Closing Date, the first tranche of $10,000 was drawn down by the Company (the “Term A Loan”). The second tranche of $10,000 will be available to the Company through September 30, 2020, subject to the achievement of certain clinical milestones (the “Term B Loan”).

The outstanding loan balance will accrue interest at the greater of (i) the rate of the one-month U.S. LIBOR rate plus 6.25% and (ii) 8.75%. The Loan Agreement provides for an interest only period until July 1, 2021, followed by thirty-six equal monthly payments of principal and interest continuing through June 1, 2024 (the “Maturity Date”). The Company has the option to prepay the outstanding balance prior to maturity, subject to a prepayment fee of 1.0% to 3.0% depending upon when the prepayment occurs. Upon repayment of the Term Loans, the Company is required to make a final payment to the Lenders equal to 4.5% of the original principal amount of the Term Loans funded which will be accrued by charges to interest expense over the term of the loans using the effective interest method.

In conjunction with the Loan Agreement, the Company issued warrants to purchase 15,686 shares of common stock (“Warrants”) to the Lenders at a per share exercise price of $12.75, a maximum contractual term of 10 years and exercisable immediately. The fair value of the Warrants was accounted for as a debt discount and calculated to be approximately $136 using the Black-Scholes method. The Company determined the Warrants met the criteria for equity classification, and, as such, the fair value of the Warrants is recorded as additional paid-in capital on the condensed consolidated balance sheets. Finally, the Company incurred issuance costs of approximately $150. Both the debt discount and issuance costs will be accreted to Long-term debt, net of issuance costs and discount by charges to interest expense over the term of the Term A Loan using the effective interest method.

The Loan Agreement contains customary representations, warranties and covenants and also includes customary events of default. Events of default include, among other things, the Company’s failure to pay amounts due, a breach of certain covenants, a material adverse change event, misrepresentations and judgements. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% per annum may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable. Borrowings under the Loan Agreement are collateralized by substantially all the Company’s assets, other than its intellectual property.

Interest expense was $546 for the year ended December 31, 2019. The effective rate on the Loan Agreement, including the amortization of the debt discount and issuance costs, and accretion of the final payment, was 9.7% at December 31, 2019. The components of the long-term debt balance are as follows:

	December 31, 2019
Notes payable, gross	$ 10,000
Less: Unamortized debt discount and issuance costs	(254)
Accretion of final payment fee	64
Carrying value of notes payable	9,810
Less: Current portion of long-term debt	—
Long-term debt, net of issuance costs and discount	$ 9,810

As of December 31, 2019, the estimated future principal payments due were as follows:

	As of December 31, 2019
2020	$ —
2021	1,945
2022	3,333
2023	3,333
Thereafter	1,389
Total principal payments	$ 10,000

8. LICENSE AGREEMENTS

In December 2015, as restated in January 2018, the Company entered into a license agreement (the “Stanford Agreement”) with The Board of Trustees of the Leland Stanford Junior University (“Stanford”), a private research university, pursuant to which the Company obtained an exclusive, worldwide license to make, have made, use, import, offer to sell and sell products covered by certain patent rights to the GeneRide technology owned by Stanford within certain fields of use. As consideration for the license, the Company paid a one-time, non-refundable license fee and issued shares of common stock. The Company also agreed to pay for certain patent expenses per the terms of the Stanford Agreement. The license term extends indefinitely, unless terminated earlier by either party under certain provisions. The Company is required to pay annual license fees.

The Company is also required to reimburse Stanford for additional patent costs incurred, pay amounts up to approximately $1,300 upon achievement of certain development and commercialization milestones, pay royalties on future sales as a low single-digit percentage of net sales and royalties on sublicensing revenue as a low double-digit percentage of net sales, if any. The Company is required to pay Stanford a fee of $325 in the event of a change of control. The Company recorded research and development expense related to the Stanford Agreement of $145 and $131 in the years ended December 31, 2019 and 2018, respectively.

In May 2018, the Company entered into a license agreement (the “UT Agreement”) with The University of Texas System (“UT”), pursuant to which the Company obtained an exclusive, worldwide license to manufacture, have manufactured, distribute, have distributed, use, offer for sale, sell, lease, loan or import products covered by certain patent rights to the GeneRide technology owned by UT (jointly with Stanford) within certain fields of use. As consideration for the license, the Company paid a one-time, non-refundable license fee of $25, which was be recorded as research and development expense. The Company also agreed to pay an annual license maintenance fee, which is creditable against royalties owed the same year the maintenance fee is paid. The Company is also obligated to reimburse UT for expenses associated with the prosecution and maintenance of the UT patent rights. UT is entitled to receive clinical and regulatory milestone payments upon the first occurrence of specified milestone events and the Company is obligated to make additional payments to UT of up to $3,000 upon the first occurrence of certain sales milestones. UT is also entitled to receive royalties on net sales of licensed products ranging from below single-digit to low single-digit percentage royalties on net sales. The Company recorded research and development expense of $25 for each of the years ended December 31, 2019 and 2018.

In December 2018, the Company entered into a license agreement (the "NIH Agreement") with the NIH ("the NIH"), pursuant to which the Company obtained a non-exclusive, worldwide license under certain specified patent rights relating to a synthetic codon-optimized MUT gene that is incorporated into the LB-001 GeneRide construct, to exploit products and practice processes that are covered by the licensed patent rights in the field of research, development, manufacture and commercialization of pharmaceutical products for the treatment or prevention of MMA using gene therapy constructs in humans. As consideration for the license, NIH received an upfront payment of $25 in 2019 and is entitled to payments of up to an aggregate of approximately $9,700 upon the achievement of certain specified development, regulatory and sales-based benchmarks as well as running royalties on annual net sales of licensed products at certain low- to mid-single digit royalty rates depending on the geographic market in which a sale occurs. During the years ended December 31, 2019 and 2018, the Company recorded research and development expense of $30 and $0 related to the NIH agreement, respectively.

Any potential future milestone or royalty payment amounts have not been accrued at December 31, 2019 due to the uncertainty related to the successful achievement of these milestones.

9. CONVERTIBLE PREFERRED STOCK

The Company's Series A Convertible Preferred Stock and Series B Convertible Preferred Stock is collectively referred to as "Preferred Stock."

On October 23, 2018, upon the closing of the Company's IPO, all outstanding shares of Preferred Stock converted into 11,789,775 shares of the Company's common stock. As such, there were no outstanding shares of Preferred Stock as of December 31, 2019 and 2018.

10. COMMON STOCK

As of December 31, 2019, and 2018, the Company's certificate of incorporation authorized the Company to issue 175,000,000 shares of $0.0001 par value common stock.

In July 2018, the Company issued 56,097 shares of common stock to Stanford, pursuant to the anti-dilution right under the Stanford Agreement.

In October 2018, the Company completed an IPO in which the Company issued and sold 8,050,000 shares of its common stock, including 1,050,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $10.00 per share, for aggregate gross proceeds of $80,500. The Company received approximately $72,300 in net proceeds after deducting underwriting discounts and commissions and offering costs. In connection with this financing, all outstanding shares of Preferred Stock converted into 11,789,775 shares of the Company's common stock.

Open Market Sale Agreement

On November 15, 2019, the Company entered into an Open Market Sale Agreement (the "Open Market Sale Agreement") with Jefferies LLC, as agent ("Jefferies"), pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $50,000 (the "Open Market Shares") from time to time through Jefferies (the "Open Market Offering").

Under the Open Market Sale Agreement, Jefferies may sell the Open Market Shares by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Exchange Act of 1934, as amended. The Company may sell the Open Market Shares in amounts and at times to be determined by the Company from time to time subject to the terms and conditions of the Open Market Sale Agreement, but it has no obligation to sell any of the Open Market Shares in the Open Market Offering.

The Company or Jefferies may suspend or terminate the offering of Open Market Shares upon notice to the other party and subject to other conditions. The Company has agreed to pay Jefferies commissions for its services in acting as agent in the sale of the Open Market Shares in the amount of up to 3.0% of gross proceeds from the sale of the Open Market Shares pursuant to the Open Market Sale Agreement. The Company has also agreed to provide Jefferies with customary indemnification and contribution rights.

The Company has not sold any shares to date under the Open Market Sale Agreement.

11. STOCK-BASED COMPENSATION

Equity Incentive Plans

In December 2014, the Company adopted the LogicBio Therapeutics, Inc. 2014 Equity Incentive Plan, as amended (the "2014 Plan"), for the issuance of stock options and other stock-based awards. In October 2018, the Company's 2018 Equity Incentive Plan (the "2018 Plan") became effective and as a result, no further awards will be made under the 2014 Plan. The 2018 Plan was established to provide equity-based ownership opportunities for employees and directors, as well as outside consultants and advisors. The 2018 Plan authorized up to 1,183,214 of shares of the Company's common stock to be issued. In addition, any previously granted awards under the 2014 Plan will remain outstanding in accordance with their respective terms.

Under the 2018 Plan, there is an annual increase on January 1 of each year from 2019 until 2028, by the lesser of (i) 4% of the number of shares of common stock outstanding on December 31 of the prior year and (ii) an amount determined by the Board. On January 1, 2019, the Company increased the number of shares available for future grant under the 2018 Plan by 887,535 shares. At December 31, 2019, there were 1,085,312 shares available for future grant under the 2018 Plan.

The 2014 Plan and the 2018 Plan are collectively referred to as the "Plans".

The 2018 Plan is administered by the Board. The exercise prices, vesting and other restrictions are determined at the discretion of the Board, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the common stock on the date of grant. Stock options awarded under the 2018 Plan expire 10 years after the grant date, unless the Board sets a shorter term. Vesting periods for awards under the 2018 Plan are determined at the discretion of the Board. Incentive stock options granted to employees and shares of restricted stock granted to employees, officers, members of the Board, advisors, and consultants of the Company typically vest over four years. Non-statutory options and shares of restricted stock granted to employees, officers, members of the Board, advisors, and consultants of the Company typically vest over three or four years.

The Company recorded stock-based compensation expense for options granted of $1,542 and $801 during the years ended December 31, 2019 and 2018, respectively. The Company recorded stock-based compensation expense for restricted stock granted of $265 and $303 during the years ended December 31, 2019 and 2018, respectively.

Stock Option Valuation

The assumptions that the Company used in Black-Scholes options pricing model to determine the grant-date fair value of stock options granted to employees and non-employees for the years ended December 31, 2019 and 2018 were as follows:

	Year Ended December 31,	
	2019	2018
Weighted-average risk-free interest rate	1.99%	2.91%
Expected term (in years)	5.25 - 6.08	5.92
Expected volatility	71.50% - 75.85%	70.03%
Expected dividend yield	0.00%	0.00%

Stock Options

A summary of option activity under the Plans during the year ended December 31, 2019 is as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	2,702,747	$ 3.16	9.21	$ 19,591
Granted	431,769	10.15		-
Exercised	(207,217)	1.09		1,586
Cancelled or forfeited	(679,546)	2.82		3,417
Outstanding as of December 31, 2019	2,247,753	$ 4.80	8.42	$ 8,220
Options exercisable as of December 31, 2019	1,129,076	$ 2.26	8.01	$ 6,107
Options unvested as of December 31, 2019	1,118,677	$ 7.37	8.83	$ 2,113

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The weighted-average grant date fair value per share of options granted during the years ended December 31, 2019 and 2018 was $5.94 and $5.46, respectively. As of December 31, 2019, there was $4,720 of unrecognized stock-based compensation expense related to unvested employee and non-employee stock options estimated to be recognized over a period of 2.7 years.

The total fair value of options vested during the years ended December 31, 2019 and 2018 was $1,708 and $232, respectively.

Shares of Restricted Common Stock

The Company has granted shares of restricted common stock with time-based and performance-based vesting conditions. A summary of restricted stock activity under the Plans during the year ended December 31, 2019 is as follows:

	Restricted Stock	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2018	884,720	$ 0.63
Granted	—	—
Vested or Released	(641,333)	0.41
Unvested as of December 31, 2019	243,387	$ 1.21

No shares of restricted common stock were granted during the year ended December 31, 2019. The weighted-average grant date fair value per share of restricted stock granted during the year ended December 31, 2018 was $4.02. As of December 31, 2019, there was $260 of unrecognized stock-based compensation expense related to unvested employee and non-employee restricted stock estimated to be recognized over a period of 1.9 years.

The total fair value of restricted stock vested during the years ended December 31, 2019 and 2018 was $266 and $160, respectively.

Stock-Based Compensation Expense

Total stock-based compensation expense recorded as research and development and general and administrative expenses, respectively, for employees, directors and non-employees during the years ended December 31, 2019 and 2018 is as follows:

	Year Ended December 31,	
	2019	2018
Research and development	$ 760	$ 284
General and administrative	1,047	820
Total stock-based compensation expense	$ 1,807	$ 1,104

12. INCOME TAXES

During the years ended December 31, 2019 and 2018, the Company recorded full valuation allowance on federal and state deferred balances since management does not forecast the Company to be in a profitable position in the near future.

Loss before the provision for income taxes for the years ended December 31, 2019 and 2018 consisted of the following:

	Year Ended December 31,	
	2019	2018
United States	$ (39,063)	$ (17,284)
Foreign	(1,043)	(337)
	$ (40,106)	$ (17,621)

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2019	2018
U.S. federal statutory income tax rate	21.0%	21.0%
State taxes, net of federal benefit	9.4	2.4
Foreign rate differential	0.2	0.1
Research and development tax credits	3.4	2.4
Stock based compensation	0.1	(0.7)
Valuation allowances	(33.8)	(25.2)
Rate changes	-	(0.1)
Other	(0.3)	0.1
Effective income tax rate	—%	—%

Net deferred tax assets as of December 31, 2019 and 2018 consisted of the following:

	December 31,	
	2019	2018
Net operating loss carryforwards	$ 16,768	$ 6,089
Reserves & accruals not currently deductible	932	324
Federal & state credit carryforwards	2,697	433
Total deferred tax assets	20,397	6,846
Valuation allowance	(20,397)	(6,846)
Net deferred tax assets	$ —	$ —

At December 31, 2019, the Company had available net operating loss carryforwards for federal and state income tax purposes of approximately $62,973 and $55,852, respectively, which if not utilized earlier, will begin to expire in 2035. The Company had federal research credits of approximately $1,854, which, if not utilized earlier, will begin to expire in 2036, and state research credits of approximately $1,068.

At December 31, 2018, the Company had available net operating loss carryforwards for federal and state income tax purposes of approximately $25,854 and $9,324, respectively, which if not utilized earlier, will begin to expire in 2035. The Company had federal research credits of approximately $204, which, if not utilized earlier, will begin to expire in 2035, and state research credits of approximately $290.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2019 and 2018 related primarily to the increases in net operating loss carryforwards and research and development tax credit carryforwards and were as follows:

	Year Ended December 31,	
	2019	2018
Valuation allowance at beginning of year	$ (6,846)	$ (2,412)
Increases recorded to income tax provision	(13,683)	(4,443)
Decreases recorded to income tax provision	132	9
Valuation allowance at end of year	$ (20,397)	$ (6,846)

The Company's U.S. federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2014 through December 31, 2017 . There are currently no pending income tax examinations. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

13. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company has historically entered into lease arrangements for its facilities and certain equipment. As of December 31, 2019, the Company had three operating leases with required future minimum payments. In applying the transition guidance under ASC 842, the Company determined the classification of these leases to be operating leases and recorded a right-of-use asset and lease liabilities as of the effective date. The Company's leases generally do not include termination or purchase options. From time to time, leases may include options to renew the lease after the expiration of the initial lease term. A renewal period is included in the lease term only when it reasonably certain that the Company will exercise such renewal options. As of December 31, 2019, no renewal options existed that the Company felt were reasonably certain of being exercised.

In November 2019, the Company entered into a lease agreement for office, laboratory and vivarium space located at 65 Hayden Avenue Lexington, Massachusetts ("65 Hayden Ave Lease") to replace the Company's current headquarters located at 99 Erie Street Cambridge, Massachusetts. Under the terms of the 65 Hayden Ave Lease, the Company will lease approximately 23,901 square feet of space and pay an initial annual base rent of approximately $1,494, which is subject to scheduled annual increases, plus certain operating expenses and taxes. The Company anticipates it will take possession of the space on April 1, 2020 ("Lease Commencement Date") and continue through July 1, 2025 ("Lease Termination Date"). The Company has one option to extend the lease for a term of 5 years. Upon execution of the lease, the Company executed a $622 cash-collateralized letter of credit. Lease payments are anticipated to begin three months after the Lease Commencement Date and will continue in monthly installments through the Lease Termination Date.

The Company will assess the lease classification of the 65 Hayden Ave Lease and commence recognition of the associated rent expense upon the Lease Commencement Date.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases for the year ended December 31, 2019. Note that rent expense under the Company's operating leases was $880 for the year ended December 31, 2018.

	Year Ended December 31, 2019
Operating leases	
Lease cost	
Operating lease cost	$ 1,208
Variable lease cost	330
Total lease cost	$ 1,538
Other year-to-date lease information	
Operating cash flows used for operating leases	$ 1,143
Operating lease liabilities arising from obtaining right-of-use assets	$ 1,461

	As of December 31, 2019
Other operating lease information	
Operating lease liabilities — short term	$ 504
Operating lease liabilities — long term	$ —
Weighted average remaining lease term	0.7 years
Weighted average discount rate	7.04%

The variable lease costs for the year ended December 31, 2019 include common area maintenance and other operating charges. As the Company's leases do not provide an implicit rate, the Company utilized its incremental borrowing rate based on what it would normally pay to borrow on a collateralized basis over a similar term for an amount equal to the lease payments at the commencement date in determining the present value of lease payments. As of December 31, 2019, the Company classified its short-term operating lease liabilities within accrued expenses and other current liabilities.

Future minimum lease payments under the Company's operating leases as of December 31, 2019 and 2018, respectively, were as follows:

	2019	2018
Maturity of lease liabilities		
2019	$ —	$ 1,028
2020	523	223
Thereafter	—	—
Total lease payments	$ 523	$ 1,251
Less: imputed interest	(19)	
Total operating lease liabilities	$ 504	

Research Agreements

Refer to Note 8, *License Agreements*, for any potential future milestone or royalty payment amounts. These are not currently probable or estimable.

Litigation

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

14. RELATED PARTIES

From time to time, the Company is or has been party to consulting service agreements with each of its three founders. Under the terms of each agreement, the Company pays an annual fee of $68 for research and development consulting services. For the years ended December 31, 2019 and 2018, the Company charged $152 and $118, respectively, to research and development expenses under these consulting service agreements. In addition, beginning in 2018, each founder receives $5 annually for their participation on the Scientific Advisory Board. Each founder has also received stock options for their services as either a board member or member of the Scientific Advisory Board.

In March 2017, the Company subleased to an affiliate certain space in Tel Aviv, Israel, through June 2018. For the year ended December 31, 2018, the Company recognized income of $21 in other income related to this arrangement.

15. SUBSEQUENT EVENTS

LB-301 for the Crigler-Najjar Syndrome (CN)

In January 2020, we announced a research collaboration with Takeda Pharmaceutical Company Limited to further develop LB-301 in CN the second indication to be pursued using the GeneRide platform. Takeda will provide funding for the research program under the collaboration agreement and will have an exclusive option to negotiate an exclusive, worldwide license to LogicBio's LB-301 program.

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Exhibit 4.4

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of our common stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Fourth Amended and Restated Certificate of Incorporation (our "certificate of incorporation") and our Amended and Restated Bylaws (our "bylaws"), each of which has been filed with the Securities and Exchange Commission as an exhibit to this Annual Report on Form 10-K or incorporated by reference therein. The summary below is also qualified by provisions of applicable law.

General

Our authorized capital stock consists of 175,000,000 shares of common stock, par value $0.0001 per share, and 25,000,000 shares of preferred stock, par value $0.0001 per share. Our common stock is registered under Section 12 of the Securities Exchange Act of 1934, as amended, and is listed on The Nasdaq Global Market under the symbol "LOGC."

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. A contested election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election; otherwise, a nominee is elected if the votes properly cast for such nominee exceed the votes properly cast against such nominee. Holders of common stock are entitled to receive any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation, dissolution or winding up, whether voluntary or involuntary, the holders of common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Delaware Anti-Takeover Law and Certain Charter and Bylaw Provisions

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"). In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or owned within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which 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 voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Anti-Takeover Effects of Our Certificate of Incorporation and Our Bylaws

Our certificate of incorporation and bylaws contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of the company unless such takeover or change in control is approved by the board of directors.

These provisions include:

Classified Board. Our certificate of incorporation provides that our board of directors is divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our board. Our certificate of incorporation also provides that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors.

Action by Written Consent; Special Meetings of Stockholders. Our certificate of incorporation provides that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our certificate of incorporation and bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called pursuant to a resolution adopted by a majority of our board of directors. Except as described above, stockholders are not permitted to call a special meeting or to require the board of directors to call a special meeting.

Removal of Directors. Our certificate of incorporation provides that our directors may be removed only for cause by the affirmative vote of at least 75% of the voting power of our outstanding shares of capital stock, voting together as a single class. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board.

Advance Notice Procedures. Our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting are only able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

Super Majority Approval Requirements. The DGCL generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. Our certificate of incorporation and our bylaws provide that the affirmative vote of holders of at least 75% of the total votes eligible to be cast in the election of directors is required to amend, alter, change or repeal specified provisions. This requirement of a supermajority vote to approve amendments to our certificate of incorporation and our bylaws could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but Unissued Shares. Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive Forum. Our certificate of incorporation requires, to the fullest extent permitted by law, that derivative actions brought in the name of the company, actions against directors, officers and employees for breach of a fiduciary duty and other similar actions may be brought only in specified courts in the State of Delaware. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

Additionally, our bylaws provide that, unless the company consents in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act"), referred to as the Federal Forum Provision. However, in light of the decision issued by the Court of Chancery of the State of Delaware in *Sciabacucchi v. Salzberg*, C.A. No. 2017-0931-JTL (Del. Ch.), declaring that provisions in certificates of incorporation of Delaware companies that purport to require claims under the Securities Act be brought in federal court are ineffective and invalid under Delaware law, we do not intend to enforce the Federal Forum Provision unless and until the Court of Chancery's decision in *Sciabacucchi* is reversed by the Delaware Supreme Court on appeal or otherwise abrogated. In the event that the Delaware Supreme Court affirms the Court of Chancery's *Sciabacucchi* decision or otherwise makes a determination that provisions such as the Federal Forum Provision are invalid, our board of directors intends to amend promptly our bylaws to remove the Federal Forum Provision.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is P.O. Box 505000, Louisville, KY 40233-5000.

Exhibit 10.2

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO LOGICBIO THERAPEUTICS, INC. IF PUBLICLY DISCLOSED

Execution Version

AMENDMENT NO. 1
TO
AMENDED AND RESTATED EXCLUSIVE (EQUITY) AGREEMENT

THIS AMENDMENT NO. 1 TO THE AMENDED AND RESTATED EXCLUSIVE (EQUITY) AGREEMENT (the "**Amendment**") is made as of May 3, 2018, by and between The Board of Trustees of the Leland Stanford Junior University, an institution of higher education having powers under the laws of the State of California ("**Stanford**"), and LogicBio Therapeutics, Inc., a Delaware corporation ("**LogicBio**"). Capitalized terms not otherwise defined herein shall have the meanings ascribed to them in that certain Amended and Restated Exclusive (Equity) Agreement, dated as of January 31, 2018, by and between Stanford and LogicBio (the "**Original Agreement**," and as amended by this Amendment, the "**Agreement**").

RECITALS

WHEREAS, the Parties desire to revise the definition of Biological Materials in the Original Agreement to include the **[***]** and the **[***]**;

WHEREAS, pursuant to Section 19.4 of the Original Agreement, the Original Agreement may be amended in writing executed by authorized representatives of Stanford and LogicBio; and

WHEREAS, in accordance with Section 19.4 of the Original Agreement, Stanford and LogicBio desire to amend the Agreement in the manner provided herein.

AGREEMENT

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound, Stanford and LogicBio hereby agree as follows:

1. Amendment of Agreement.

    a. Section 2.2 of the Agreement is hereby amended and restated as follows:

    "Biological Material" means (a) pAAV-DJ and pHelper vectors, (b) NP59 Capsid, (c) LK03 Capsid, (d) **[***]** and (e) **[***]**, in each case provided by Stanford to LogicBio under this Agreement.

2. Continued Validity of Agreement. Except as specifically amended hereby, the Agreement shall continue in full force and effect as originally constituted and is ratified and affirmed by the parties hereto.

3. Successors and Assigns. The terms and conditions of this Amendment shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. Nothing in this Amendment, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations or liabilities under or by reason of this Amendment, except as expressly provided in this Amendment.

4. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of California, United States of America, applicable to agreements negotiated, executed, and performed within California.

5. Electronic Copy. This parties to this Amendment agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The parties further waive any right to challenge the admissibility or authenticity of this document in a court of law based solely on the absence of an original signature.

[*Signature Pages to Follow*]

The parties execute this Amendment in duplicate originals by their duly authorized officers or representatives.

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY

Signature: /s/ Mona Wan

Name: Mona Wan

Title: Associate Director

LOGICBIO THERAPEUTICS, INC.

Signature: /s/ Frederic Chereau

Name: Frederic Chereau

Title: Chief Executive Officer

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO LOGICBIO THERAPEUTICS, INC. IF PUBLICLY DISCLOSED

AMENDMENT NO. 3
TO
AMENDED AND RESTATED EXCLUSIVE (EQUITY) AGREEMENT

THIS AMENDMENT NO. 3 TO THE AMENDED AND RESTATED EXCLUSIVE (EQUITY) AGREEMENT (the "**Amendment No. 3**") is made as of January 29, 2020 ("**Amendment No. 3 Effective Date**"), by and between The Board of Trustees of the Leland Stanford Junior University, an institution of higher education having powers under the laws of the State of California ("**Stanford**"), and LogicBio Therapeutics, Inc., a Delaware corporation ("**LogicBio**"). Capitalized terms not otherwise defined herein shall have the meanings ascribed to them in that certain Amended and Restated Exclusive (Equity) Agreement, dated as of January 31, 2018, by and between Stanford and LogicBio, as amended by that certain Amendment No. 1 dated as of May 3, 2018, and amended again by that certain Amendment No. 2, dated June 3, 2019, to Amended and Restated Exclusive (Equity) Agreement (the "**Original Agreement**," and as amended by this Amendment No. 3, the "**Agreement**").

RECITALS

WHEREAS, the Parties desire in the future to revise the timeline for and/or definition of the Nomination of Tissues in the Original Agreement and revise certain timelines and diligence milestones set forth in the Original Agreement;

WHEREAS, LogicBio desires an additional few months to consider the tissue designations and timelines of the diligence milestones, as set forth in the Agreement;

WHEREAS, pursuant to Section 19.4 of the Original Agreement, the Original Agreement may be amended in writing executed by authorized representatives of Stanford and LogicBio; and

WHEREAS, in accordance with Section 19.4 of the Original Agreement, Stanford and LogicBio desire to amend the Agreement in the manner provided herein.

AGREEMENT

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound, Stanford and LogicBio hereby agree as follows:

1. Amendment of Agreement.

    a. Section 2.32 of the Original Agreement is hereby amended and restated in its entirety as follows:

2.32 "Tissue Field of Use" means:

(A) prior to [***]:

(1) the diagnosis, prevention or treatment of human disease, including, for clarity, hemophilia A and Alpha-1 antitrypsin disease, via genomic editing without a nuclease.

(B) from [***] until [***]

(1) the diagnosis, prevention or treatment of any human disease of liver tissue that affects less than 200,000 persons in the United States as of [***] via genome editing without a nuclease; and

(2) the diagnosis, prevention or treatment of human disease of the Nominated Tissues via genome editing without a nuclease.

(C) from [***] onward

(1) the prevention, treatment or diagnosis of Active Indications via genome editing without a nuclease.

b. Section 3.3 of the Original Agreement is hereby amended and restated in its entirety as follows:

3.3 Nomination of Tissues. At any time on or prior to [***], LogicBio may provide to Stanford a written notice listing up to [***] human tissues that will be the subject of LogicBio's development efforts with respect to the technology licensed under this Agreement. By way of example, and without limiting the foregoing, for purposes of this Agreement "human tissue" includes skeletal muscle tissue, lung tissue and the central nervous system. Beginning on the date on which LogicBio provides such written notice to Stanford, such tissues shall be deemed "Nominated Tissues"; provided that if LogicBio does not incur at least $[***] in research and development expenses with respect to the application of GT and VT to a Nominated Tissue in the [***]-month period beginning on [***] or [***] of any subsequent year, then such tissue will no longer be deemed a "Nominated Tissue" following the end of such [***]-month period.

c. Section 6.3 of the Original Agreement is hereby amended and restated in its entirety as follows:

6.3 Progress Report. By March 1 of each year, LogicBio will submit a written annual report to Stanford covering the preceding calendar year. The report will include information sufficient to enable Stanford to satisfy reporting requirements of the U.S. Government and for Stanford to ascertain progress by LogicBio toward meeting this Agreement's diligence requirements (including without limitation LogicBio's diligence obligations with respect to Nominated

Tissues and Active Indications). Each report will describe, where relevant: (a) LogicBio's progress toward commercialization of Licensed Product, including work completed, key scientific discoveries, summary of work-in-progress, current schedule of anticipated events or milestones, market plans for introduction of Licensed Product, (b) significant corporate transactions involving Licensed Product, (c) beginning with the first annual report following [***], LogicBio's research and development efforts with respect to each Nominated Tissue, and (d) beginning with the first annual report following [***], LogicBio's research and development efforts with respect to each Active Indication. LogicBio will specifically describe how each Licensed Product is related to each Licensed Patent.

d. Appendix C – Milestones of the Agreement is hereby amended by replacing Appendix C in the Original Agreement in its entirety with Appendix A to this Amendment No. 3.

2. Continued Validity of Agreement. Except as specifically amended hereby, the Original Agreement shall continue in full force and effect as originally constituted and is ratified and affirmed by the parties hereto.

3. Successors and Assigns. The terms and conditions of this Amendment No. 3 shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. Nothing in this Amendment No. 3, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations or liabilities under or by reason of this Amendment No. 3, except as expressly provided in this Amendment No. 3.

4. Governing Law. This Amendment No. 3 shall be governed by and construed in accordance with the laws of the State of California, United States of America, applicable to agreements negotiated, executed, and performed within California.

5. Electronic Copy. This parties to this Amendment No. 3 agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The parties further waive any right to challenge the admissibility or authenticity of this document in a court of law based solely on the absence of an original signature.

[*Signature pages to follow*]

The parties execute this Amendment in duplicate originals by their duly authorized officers or representatives.

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY

Signature: /s/ Mona Wan

Name: Mona Wan

Title: Associate Director

LOGICBIO THERAPEUTICS, INC.

Signature: /s/ Bryan Yoon

Name: Bryan Yoon

Title: Chief Administrative Officer & General Counsel

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Exhibit 10.6

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO LOGICBIO THERAPEUTICS, INC. IF PUBLICLY DISCLOSED

AMENDMENT NO. 1 TO PATENT & TECHNOLOGY LICENSE AGREEMENT

This Amendment No. 1 to Patent & Technology License Agreement ("Amendment One") is made and entered into as of October 14, 2019 (the "Effective Date") by and between LogicBio Therapeutics, Inc. a Delaware corporation, having a principal place of business at 99 Erie Street, Cambridge, MA 02139 ("LogicBio") and The Board of Regents ("Board") of The University of Texas System ("System", an agency of the State of Texas whose address is 210 West 7th Street, Austin, Texas 78701, on behalf of The University of Texas Southwestern Medical Center ("UT Southwestern"), a component institution of System, whose address is 5323 Harry Hines Boulevard, Dallas, Texas 75390-9094.

WHEREAS, the parties entered into a Patent & Technology License Agreement effective as of May 7, 2018 ("Agreement")

WHEREAS, the parties desire to modify the Agreement to reflect the understandings they have reached with respect to their relationship; and

WHEREAS, capitalized terms used in this Amendment One but not otherwise defined shall have the meaning ascribed to such terms in the Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. **Amendments**. Section 2.7(b) is hereby deleted and replaced with the following:

(b) fulfill the following milestone events by the deadlines indicated:

Diligence Milestone Events	**Deadlines**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

If the obligations under this Section 2.7 are not fulfilled, Licensor may treat such failure as a breach in accordance with Section 7.3(b). For the avoidance of doubt, initiation of a clinical trial means the dosing of the first patient in said clinical trial.

Notwithstanding the foregoing, if Licensee believes that, despite using commercially reasonably efforts, it will not achieve any Diligence Milestone Event set forth in this Section 2.7 by the relevant deadline, it may notify Licensor in writing thereof in advance of the deadline. Licensee shall include with such notice a reasonable explanation of the reasons for such failure. If Licensee so notifies Licensor and such explanation is acceptable to Licensor (in its reasonable discretion), or, in any event, if such failure to meet the Diligence Milestone Event is due to circumstances beyond Licensee's reasonable control (such as patent infringement or regulatory issues), then the Parties shall negotiate in good faith an initial extension of the deadlines for said Diligence Milestone Event and all later Diligence Milestone Events (the "Initial Extended Milestones") so that Licensee shall not be deemed to be in breach of achieving said Diligence Milestone Event by its deadline. In the event that Licensee believes that, despite using commercially reasonable efforts, it will not achieve one or more such Initial Extended Milestones, then Licensee may notify Licensor in writing thereof in advance of the relevant deadline and the Parties shall negotiate in good faith a second extension of deadlines for said Diligence Milestone Event and all later Diligence Milestone Events (the "Second Extended Milestones") so that Licensee shall not be deemed to be in breach of achieving said Diligence Milestone Event by its deadline. Upon agreement of the Parties with respect to the deadlines for such Second Extended Milestones, Licensee shall make a non-creditable payment of one-half of the Milestone Fee of the Milestone Event corresponding to said Diligence Milestone Event.

2. **Miscellaneous**. Except as expressly modified and amended by this Amendment One, all other terms, conditions and provisions of the Agreement shall remain in full force and effect as provided therein, and in all other respects is ratified and confirmed by the parties.

3. **Execution.** This Amendment One may be executed (including by industry standard electronic signature software) in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. A party may evidence its execution and delivery of this Amendment One by transmission of a signed copy of the Amendment One via facsimile, email, or other reliable electronic means, which transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Amendment One.

IN WITNESS WHEREOF, the parties have caused this Amendment One to be executed by their duly authorized representatives as of the date set forth in the introductory paragraph of this Amendment One.

LOGICBIO THERAPEUTICS, INC.

By: /s/ Matthias Jaffé

Matthias Jaffé
CFO

Date: October 14, 2019

BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM

By: /s/ Arnim Dontes

Arnim Dontes
Executive Vice President for Business Affairs
UT Southwestern Medical Centre

Date: October 24, 2019

Approved as to Content:

By: /s/ Claire Aldridge

Claire Aldridge, Ph.D.
Associate Vice President
Commercialization and Business Development

Date: October 24, 2019

Exhibit 10.20

LOGICBIO THERAPEUTICS, INC. EXECUTIVE EMPLOYMENT AGREEMENT

This Employment Agreement (this **"Agreement")** is entered as of the last date set forth on the signature page below (the **'''Effective date")** by and between LogicBio Therapeutics, Inc. (the **"Company")** and Seokho Bryan Yoon **("Executive").**

1 Duties and Scope of Employment.

(a) Positions and Duties. The Company hereby agrees to employ Executive, its Chief Administrative Officer, General Counsel and Corporate Secretary, and Executive hereby agrees to serve the Company in such capacity, during the Employment Term. Subject to your acceptance of the terms in this Agreement, your anticipated start date is November 11, 2019. Executive will render such business and professional services in the performance of his duties, consistent with Executive's position within the Company, as will reasonably be assigned to Executive by the Company's President and Chief Executive Officer (the **"CEO").** The period of Executive's employment under this Agreement is referred to herein as the **"Employment Term."**

(b) Obligations. During the Employment Term, Executive will perform his duties faithfully and to the best of his ability and will devote his full business efforts and time to the Company. For the duration of the Employment Term, Executive agrees not to actively engage in any other employment, occupation, or consulting activity for any direct or indirect remuneration without the prior approval of the CEO or the Company's Board of Directors (the "Board").

2. At-Will Employment. The parties agree that Executive's employment with the Company will continue to be "at-will" employment and may be terminated at any time with or without cause or notice. However, as described in this Agreement, Executive may be entitled to severance benefits depending on the circumstances of Executive's termination of employment with the Company.

3. Compensation.

(a) Base Salary. During the Employment Term, the Company will pay Executive an annual salary (the "Base Salary") of $380,000 as compensation for Executive's services. The Base Salary will be paid periodically in accordance with the Company's normal payroll practices. Executive's Base Salary will be subject to review by the Compensation Committee (the "Compensation Committee") of the Board and adjustments to the Base Salary may be made in its discretion.

(b) Bonus. During the Employment Term, Executive will be eligible to receive an annual bonus, with a target annual bonus equal to thirty five percent (35%) of the Base Salary, upon achievement of certain performance objectives to be determined by the Compensation Committee. The amount, terms and conditions of any annual bonus will be determined by the Compensation Committee in its discretion and any annual bonus will be subject to the terms and conditions of the applicable Company bonus plan, as in effect from time to time. Any earned annual bonus will be paid as soon as reasonably practicable after the Compensation Committee determines that such bonus has been earned, but in no event shall the bonus be paid after the March 15 th following the end of the calendar year to which the bonus relates, in accordance with the Company's normal payroll practices. The payment of any annual bonus will be subject to Executive's continued employment through the payment date, except as set forth in Section 6 or 7 below or as otherwise provided in an applicable bonus plan.

(c) Equity Compensation. During the Employment Term, Executive will be eligible to receive equity and equity-based awards in the discretion of the Board or the Compensation Committee and on such terms and conditions as are determined by the Board or the Compensation Committee in its discretion. At the earliest time after the Start Date, the Company will recommend to its board of directors (the “Board) that you be granted stock options to purchase 110,000 shares of the of the Company’s common stock at an exercise price equal to the fair market value per share on the date of the grant (the "Option"). Any equity and equity-based awards granted to Executive, whether before or after the Effective Date, will be governed by the terms and conditions of the applicable Company equity incentive plan(s), as in effect from time to time, and the award agreements governing such equity or equity-based awards (any such plan and award agreements, collectively, the **"Equity Agreements").**

(d) Employee Benefits. During the Employment Term, Executive will be entitled to participate in the employee benefit plans maintained by the Company as in effect from time to time of general applicability to other senior executives of the Company. The Company reserves the right to cancel or change any of its employee benefit plans at any time.

(e) Indemnification. Executive will be entitled to the same indemnification rights as the Company grants to other senior executives of the Company, subject to the provisions of the Company's by-laws and ce1iificate of incorporation.

4. Vacation. Executive will be entitled to paid annual vacation in accordance with Company policy for other senior executive officers, as in effect from time to time.

5. Expenses.

(a) Subject to Section 5(b), the Company will reimburse Executive for all reasonable and necessary expenses incurred by Executive in connection with the performance of Executive's duties hereunder.

(b) The Company will provide Executive with reimbursement up to $3,500 per month through the end of August 2020 for housing expenses, subject to (i) Executive’s primary residence not being located in the Greater Boston area and (ii) Executive's continuing employment with the Company through such date. If Executive’s primary residence is relocated to the Greater Boston area prior to the end of August 2020, such reimbursement will only apply through the end of the month during which the Executive completes his relocation.

(c) Subject to any applicable policy established by the Company as in effect from time to time, the Company will reimburse Executive for expenses incurred pursuant to Section 5(a) upon Executive's having submitted valid receipts to the Company, provided that Executive is an employee of the Company on the date on which the expenses are incurred. Executive's right to payment or reimbursement for expenses hereunder shall be subject to the following additional rules:
(i) the amount of expenses eligible for payment or reimbursement during any calendar year shall not affect the expenses eligible for payment or reimbursement in any other calendar year, (ii) payment or reimbursement shall be made not later than December 31 of the calendar year following the calendar year in which the expense or payment was incurred, and (iii) the right to payment or reimbursement is not subject to liquidation or exchange for any other benefit.

6. Severance.

(a) Termination for other than Cause, Death or Disability or Resignation for Good Reason. If the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment with the Company other than for Cause (as defined below) and other than due to Executive's death or Disability (as defined below), or Executive resigns with Good Reason (as defined below), then, subject to

Section 8, Executive will be entitled to (i) receive severance pay at a rate equal to Executive's Base Salary, as then in effect, for six (6) months from the date of such termination, which will be paid in equal installments in accordance with the Company's normal payroll practices; (ii) an amount equal to Executive's target annual bonus for the year in which such termination of employment occurs, multiplied by .5, payable in equal installments in accordance with the Company's normal payroll practices over six (6) months from the date of such termination; and

(iii) if Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended **("COBRA")** for Executive and his eligible dependents within the time period prescribed pursuant to COBRA, the Company will reimburse Executive for the COBRA premiums for such coverage until the earlier of (A) a period of three (3) months from the last date of employment of Executive with the Company, or (B) the date upon which Executive ceases to be eligible for coverage under COBRA. COBRA reimbursements will be made by the Company to Executive consistent with the Company's normal expense reimbursement policy. However, if the Company determines in its sole discretion that it cannot provide the foregoing COBRA benefits without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring additional taxes, the Company will in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue his group health coverage in effect on the date of his termination of employment (which amount will be based on the premium for the first month of COBRA coverage) for the time period described in clause (A) in equal installments in accordance with the Company's normal payroll practices. In addition to the amounts described above, Executive will be entitled to receive Executive's accrued and unpaid Base Salary through the date Executive's employment terminates, any unreimbursed expenses due under Section 5 of above, and any vested benefits required to be paid or provided under the terms and conditions of the Company's benefit plans (collectively, the **"Accrued Benefits")** if Executive's employment terminates in the circumstances described in this Section 6(a).

(b) Termination for Cause or Death or Disability; Voluntary Resignation. If Executive's employment with the Company (or any parent or subsidiary or successor of the Company) is terminated voluntarily by Executive without Good Reason, for Cause by the Company or due to Executive's death or Disability, then Executive will be entitled to receive the Accrued Benefits and no further compensation or benefits will be paid to Executive under this Agreement.

(c) Exclusive Remedy. In the event of a termination of Executive's employment with the Company (or any parent or subsidiary or successor of the Company), the provisions of this Section 6 and Section 7 below are intended to be and are exclusive and in lieu of any other rights or remedies to which Executive or the Company may otherwise be entitled in connection with the termination of Executive's employment under any employee compensation or benefit plan which provides benefits severance or continuation pay.

7. Termination for other than Cause, Death or Disability or Resignation for Good Reason within 24 months following a Change in Control. If the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment with the Company other than for Cause (as defined below) and other than due to Executive's death or Disability (as defined below), or Executive resigns with Good Reason (as defined below), in either case, within 24 months following a Change of Control (as defined below) then, subject to Section 8 and in lieu of the payments set forth in Section 6 above, Executive will be entitled to (i) receive a severance payment equal to one times (1x) the sum of (A) Executive's annual Base Salary, as then in effect, and (B) Executive's target annual bonus for the year in which such termination of employment occurs, (ii) continued group health coverage in effect on the date of his termination of employment for a period of 9 months under COBRA as further described below; and (iv) accelerated vesting as to one hundred percent (l 00%) of Executive's then outstanding and unvested equity and equity-based awards (with any performance-vesting awards vesting at target levels). All amounts payable under prong (i) of this Section 7 will be paid in a lump sum on the first normal payroll date of the Company following the Release Deadline (as defined below) in accordance with the Company's normal payroll practices. In relation to prong (ii) of this Section 7, Executive

and where applicable, Executive's spouse and eligible dependents, will continue to be eligible to receive reimbursement for COBRA coverage premiumsunder the Company's medical plans in accordance with the terms of the applicable plan documents. Further, notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the such premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the U.S. Public Health Service Act), regardless of whether Executive or Executive's dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, on the first day of each calendar month following the termination date, a cash payment equal to the applicable premium plus estimated income tax attributable to such additional income. In addition to the amounts described above, Executive will be entitled to receive the Accrued Benefits.

8. Conditions to Receipt of Severance; No Duty to Mitigate.

(a) Separation Agreement and Release of Claims. The receipt of any severance pursuant to Sections 6 or 7 will be subject to Executive signing and not revoking a separation agreement and general release of claims in a form reasonably satisfactory to the Company (the **"Release"**) and provided that such Release becomes effective and irrevocable no later than sixty (60) days following the termination date (such deadline, the **"Release Deadline"**). If the Release does not become effective and irrevocable by the Release Deadline, Executive will forfeit any rights to severance or benefits under this Agreement. In no event will severance payments or benefits be paid or provided until the Release becomes effective and irrevocable. Subject to Section 8(b), any cash severance pay to which Executive is entitled pursuant to Section 6 or 7 (other than the Accrued Obligations) will be paid, or will begin to be paid, on the first normal payroll date of the Company following the Release Deadline, with such payment to include all amounts that would have been paid prior to such date but for this Section 8(a).

(b) Section 409A.

(i) Notwithstanding anything to the contrary in this Agreement, no severance pay or benefits to be paid or provided to Executive, if any, pursuant to this Agreement that, when considered together with any other payments or benefits, would be considered deferred compensation under Code Section 409A and the final regulations and any guidance promulgated thereunder (collectively, **"Section 409A")** (together, the **"Deferred Payments")** will be paid or otherwise provided until Executive has incurred a "separation from service" within the meaning of Section 409A.

(ii) Notwithstanding anything to the contrary in this Agreement, if Executive is a "specified employee" within the meaning of Section 409A at the time of Executive's termination (other than due to death), then the Deferred Payments that are payable within the first six
(6) months following Executive's separation from service, will become payable on the first payroll date that occurs on or after the date six (6) months and one (1) day following the date of Executive's separation from service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if Executive dies following Executive's separation from service, but prior to the six
(6) month anniversary of the separation from service, then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of Executive's death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(iii) Any amounts paid under this Agreement that satisfies the requirements of the "short-term deferral" rule set forth in Section l.409A-1(b)(4) of the Treasury Regulations will not constitute Deferred Payments for purposes of clause (i) above.

(iv) Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section l.409A-l(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit (as defined below) will not constitute Deferred Payments for purposes of clause (i) above.

(v) All payments under this Agreement are intended to be exempt from, or comply with, the requirements of Section 409A so that none of the payments and benefits provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. The Company and Executive agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Executive under Section 409A. In no event will the Company, any of its subsidiaries or affiliates be liable to Executive by reason of any acceleration of income or any additional tax (including any interest and penalties) asserted with respect to the failure of any payments or benefits provided under this Agreement to satisfy the applicable requirements of Section 409A.

(c) Confidential Information Agreement. Executive's continuing receipt of any payments or benefits under Section 6 or 7 will be subject to Executive continuing to comply with the terms of the Confidential Information Agreement (as defined in Section 11). In the event Executive breaches the provisions of the Confidential Information Agreement and is unable to cure such breach, if curable, within thirty (30) days following receipt from the Company of written notice of such breach, then all payments and benefits to which Executive may otherwise be entitled pursuant to Sections 6 or 7 will immediately cease.

9. No Duty to Mitigate. Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any earnings that Executive may receive from any other source reduce any such payment.Definitions.

(a) Cause. For purposes of this Agreement, **"Cause"** is defined, as determined by the Company in its reasonable judgment, as (i) breach of this Agreement or the Confidential Information Agreement by Executive; (ii) intentional and continued nonperformance or misperformance of Executive's duties or refusal to abide by or comply with the reasonable directives of the CEO or the Board, or the Company's policies and procedures, which, if reasonably susceptible to cure (as determined by the Company), is not cured within fifteen (15) days following Executive's receipt of written notice from the Company describing in reasonable detail the nature of the nonperformance, midperformance or refusal, as applicable; (iii) Executive's gross negligence in the performance of his material duties under this Agreement; (iv) Executive's fraud or willful misconduct with respect to the business or affairs of the Company; (v) Executive's conviction of, or a plea of nolo contendere to, a felony or other crime involving moral turpitude; or (vi) the commission of any act in direct or indirect competition with or materially detrimental to the best interests of Company. For purposes of this Agreement, any act, or failure to act, shall not be deemed willful or intentional unless it is done, or omitted to be done, by Executive in bad faith or without a reasonable good faith belief that Executive’s action or omission was in the best interests of the Company. Notwithstanding the preceding sentence, in order for an event to qualify as “Cause”, the Company must not terminate Executive’s employment with the Company without first providing Executive with written notice of the acts or omissions constituting the grounds for “Cause”.

(b) Change of Control. For purposes of this Agreement, **"Change of Control"** is defined as:

(i) the acquisition of the Company by another entity by means of any transaction or series of related transactions (including, without limitation, any reorganization, merger or consolidation or stock transfer, but excluding any such transaction effected primarily for the purpose of changing the domicile of the Company), unless the Company's stockholders of record immediately prior to such transaction or series of related transactions hold, immediately after such transaction or series of related transactions, at least fifty percent (50%) of the voting power of the surviving or acquiring entity *(provided* that the sale by the Company of its securities for the primary purpose of raising additional funds shall not constitute a Change of Control hereunder); or

(ii) a sale, license or other disposition of all or substantially all the assets, intellectual property or technology of the Company.

Notwithstanding the foregoing provisions of this definition, a transaction will not be deemed a Change of Control unless the transaction qualifies as a "change in control event" within the meaning of Section 409A.

(c) Code. For purposes of this Agreement, **"Code"** means the Internal Revenue Code of 1986, as amended.

(d) Disability. For purposes of this Agreement, **"Disability"** means that Executive has been unable to perform Executive's Company duties as the result of Executive's incapacity due to physical or mental illness for at least twenty-six (26) weeks after the commencement of such incapacity or for one-hundred and eighty (180) days in any consecutive twelve (12) month period, which incapacity is determined to be total and permanent by a physician selected by the Company or its insurers and acceptable to Executive or Executive's legal representative (such agreement as to acceptability not to be unreasonably withheld).

(e) Good Reason. For purposes of this Agreement, **"Good Reason"** means Executive's resignation within thirty (30) days following the expiration of any Company cure period (described below) following the occurrence of one or more of the following, without Executive's consent:

(i) a material diminution of Executive's authority, duties, or responsibilities with the Company in effect immediately prior to such assignment;

(ii) a material breach of this Agreement by the Company; or

(iii) any successor to the Company (whether pursuant to any Change in Control or otherwise) does not assume this Agreement; or

(iv) any reduction in Executive's base salary in effect immediately prior to such termination, unless the Company also similarly reduces the base salaries of all other similarly situated employees of the Company.

Executive will not resign for Good Reason without first providing the Company with written notice of the acts or omissions constituting the grounds for "Good Reason" within ninety (90) days of the initial existence of the grounds for "Good Reason" and a cure period of thirty (30) days following the date of such notice.

(f) Section 409A Limit. For purposes of this Agreement, **"Section 409A Limit"** will mean two (2) times the lesser of: (i) Executive's annualized compensation based upon the annual rate of pay paid to Executive during Executive's taxable year preceding Executive's taxable year of his separation from service as determined under Treasury Regulation Section l.409A l (b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 40l(a)(l 7) of the Internal Revenue Code for the year in which Executive's separation from service occurred.

10. Limitation on Payments.

If Executive receives, is provided or may receive or be provided any payment or benefit that constitutes a "parachute payment" (as defined in Section 280G(b)(2) of the Code), and the net after-tax amount of any such parachute payment is less than the net after-tax amount if the aggregate payments and benefits to be made to Executive were three times Executive's "base amount" (as defined in Section 280G(b)(3) of the Code), less $1.00, then the aggregate of the amounts constituting the parachute payments shall be reduced to an amount equal to three times Executive's base amount, less $1.00. For purposes of determining the "net after-tax amount," the Company will cause to be taken into account all applicable federal, state and local income and employment taxes and the excise taxes (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a reduction pursuant to this Section 10 is to occur, (x) Executive will have no rights to any additional payments and/or benefits that are being reduced, and (y) reduction in payments and/or benefits will occur in the following order: (i) reduction of cash payments, if any, which shall occur in reverse chronological order such that the cash payment owed on the latest date following the occurrence of the event triggering such excise tax will be the first cash payment to be reduced; (ii) cancellation of accelerated vesting of equity awards other than stock options, if any; (iii) cancellation of accelerated vesting of stock options, if any; and (iv) reduction of other payments or benefits, if any, paid or provided to Executive, which shall occur in reverse chronological order such that the payment or benefit owed on the latest date following the occurrence of the event triggering such excise tax will be the first benefit to be reduced. In the event that acceleration of vesting of equity awards or stock options is to be reduced, such acceleration of vesting will be cancelled in the reverse order of the date of grant. If two or more equity awards or stock options are granted on the same date, each award or stock option will be reduced on a pro-rata basis. Notwithstanding, any excise tax imposed will be solely the responsibility of Executive. In no event shall Executive have any discretion with respect to the ordering of his payment reductions.

(a) Unless the Company and Executive otherwise agree in writing, any determination required under this Section 10 will be made in writing by a nationally recognized firm of independent public accountants selected by the Company, the Company's legal counsel or such other person or entity to which the Parties mutually agree (the **"Firm"),** whose determination will be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required by this Section 10, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 2800 and 4999 of the Code. The Company and Executive will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section 10. The Company will bear all costs the Firm may reasonably incur in connection with any calculations contemplated by this Section 10.

11. Confidential Information. Executive agrees that Executive will be bound by the Confidential Information, Invention Assignment, Restricted Activities, and Arbitration Agreement (the **"Confidential Information Agreement")** by and between Executive and the Company, in accordance with its terms.

12. Assignment. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors and legal representatives of Executive upon Executive's death and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "**successor**" means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all the assets or business of the Company. None of the rights of Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance or other disposition of Executive's right to compensation or other benefits will be null and void.

13. Notices. All notices, requests, demands and other communications called for hereunder will be in writing and will be deemed given (i) on the date of delivery if delivered personally, (ii) one (1) day after being sent by a well-established commercial overnight service, or (iii) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing:

If to the Company:
LogicBio Therapeutics, Inc. 99 Erie St
Cambridge, Massachusetts 02139
Attn: Chief Executive Officer

If to Executive:

at the last residential address known by the Company.

14. Severability. In the event that any provision hereof becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement will continue in full force and effect without said provision.

15. Arbitration. Executive agrees that any and all controversies , claims, or disputes with anyone (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from Executive's service to the Company, shall be subject to arbitration in accordance with the provisions of the Confidential Information Agreement.

16. Integration. This Agreement represents the entire agreement and understanding between the parties as to the subject matter herein and supersedes all prior or contemporaneous agreements whether written or oral. This Agreement may be modified only by agreement of the parties by a written instrument executed by the parties that is designated as an amendment to this Agreement.

17. Waiver of Breach. The waiver of a breach of any term or provision of this Agreement, which must be in writing, will not operate as or be construed to be a waiver of any other previous or subsequent breach of this Agreement.

18. Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

19. Tax Withholding. All payments made pursuant to this Agreement will be subject to withholding of applicable taxes and other legally required amounts.

20. Governing Law. This Agreement will be governed by the laws of the Commonwealth of Massachusetts without regard to any conflict of laws principles that would result in the application of the laws of any other jurisdiction. Executive agrees to submit to the exclusive jurisdiction of the courts of or in the Commonwealth of Massachusetts in connection with any dispute arising out of this Agreement.

21. Acknowledgment. Executive acknowledges that he has had the opportunity to discuss this matter with and obtain advice from his private attorney, has had sufficient time to, and has carefully read and fully understands all the provisions of this Agreement, and is knowingly and voluntarily entering into this Agreement.

22. Counterparts. This Agreement may be executed in counterparts, and each counterpart will have the same force and effect as an original and will constitute an effective, binding agreement on the part of each of the undersigned.

[Signature Page Follows.]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by their duly authorized officers, as of the day and year written below.

COMPANY:

LOGICBIO THERAPEUTICS, INC.

By: /s/ Frederic Chereau Date: 10/29/2019
Name: Frederic Chereau
Title: President & Chief Executive Officer

EXECUTIVE:

/s/ Seokho Bryan Yoon Date: 10/29/2019
Seokho Bryan Yoon

Exhibit 10.22

65 HAYDEN AVENUE
LEXINGTON, MASSACHUSETTS 02421

LEASE SUMMARY SHEET

Execution Date:	November 4, 2019
Tenant:	**LOGICBIO THERAPEUTICS, INC.**, a Delaware corporation
Tenant's Mailing Address Prior to Occupancy:	99 Erie Street, Cambridge, MA 02139
Landlord:	**HCP/KING HAYDEN CAMPUS LLC**, a Delaware limited liability company
Building:	65 Hayden Avenue, Lexington, Massachusetts 02421. The Building consists of approximately 213,005 rentable square feet, including a four-story garage with 298 spaces (the "**65 Hayden Garage**"). The Building consists of two wings—the North Building and the South Building. The land (the "**Land**") on which the Building and the Garage are located is described as "**Parcel Three**" and "**Parcel Four**" on Exhibit 2 attached hereto and made a part hereof.
Campus:	All of the land described on Exhibit 2 (including the Land described above) together with the Building described above, the buildings now known as and numbered 45 Hayden Avenue, 55 Hayden Avenue, and 75 Hayden Avenue ("**Building 75**"), and any other building and/or improvements constructed on the Land. The Campus includes a parking garage at Building 75 (collectively, along with the 65 Hayden Garage, the "**Garage**").

Premises: Areas on the first (1st) and second (2nd) floors of the South portion of the Building, containing approximately 23,901 rentable square feet in the aggregate. The Premises consist of:

Prime Premises, which are located on the second (2nd) floor;

PH System Premises, which are located on the first (1st) floor. The PH System Premises are located in a room (the "**PH System Room**") which contains the PH systems of other tenants;

The term "**Premises**" shall mean the Prime Premises and PH System Premises, as applicable. The Premises are shown the Lease Plans attached hereto as Exhibit 1A and Exhibit 1B and made a part hereof (the "**Lease Plans**").

Landlord and Tenant stipulate and agree that the Rentable Square Footage of the Building and the Rentable Square Footage of the Premises are correct and shall not be remeasured.

Property: The Building, the Garage, the Land, and other improvements located on, and to be constructed on, the Land.

Parking Areas: The parking structures (surface lots and parking decks, including the Garage adjacent to the Building) located on the Campus that Landlord provides for parking by all tenants of space on the Property.

Term Commencement Dates:

The earlier of (i) the date that Tenant first commences to use the Premises, or any portion thereof, for the Permitted Use and (ii) the Substantial Completion, as hereinafter defined, of the Landlord's Work, as hereinafter defined, subject to the completion of the Vivarium Work, as hereinafter defined, subsequent to the Term Commencement Date, as more particularly set forth in Section 3.1 below.

Rent Commencement Date:

The date that occurs three (3) months after the Term Commencement Date.

Expiration Date: Five (5) years after the Rent Commencement Date, except that if the Rent Commencement Date does not occur on the first day of a calendar month, then the Expiration Date shall be the last day of the calendar month in which the fifth (5th) anniversary of the Rent Commencement Date occurs.

Extension Term(s): Subject to Section 1.2 below, one (1) extension term of five (5) years.

Permitted Uses: Subject to Legal Requirements, general office, research, development and laboratory use, and other ancillary uses (including, but not limited to, vivarium uses) related to the foregoing.

Base Rent:

RENT YEAR	ANNUAL BASE RENT	MONTHLY PAYMENT
1	$1,493,812.50	$124,484.38
2	$1,538,626.88	$128,218.91
3	$1,584,785.68	$132,065.47
4	$1,632,329.25	$136,027.44
5	$1,681,299.13	$140,108.26

Rent Year:	Rent Year 1 shall be the twelve-(12)-month period commencing as of the Rent Commencement Date, except that if the Rent Commencement Date occurs on other than the first day of a calendar month, then Rent Year 1 shall commence as of the Rent Commencement Date and shall end on the last day of the calendar year in which the first anniversary of the Rent Commencement Date occurs. Each Rent Year after Rent Year 1 shall be the twelve-(12)-month period immediately following the preceding Rent Year.
Operating Costs and Taxes:	See Sections 5.2 and 5.3.
Tenant's Share:	A fraction, the numerator of which is the number of rentable square feet in the Premises and the denominator of which is the number of rentable square feet in the Building. As of the Execution Date, Tenant's Share with respect to the Premises is 11.22%
Security Deposit/ Letter of Credit:	$622,421.88
Guarantor:	N/A

EXHIBIT 1A	LEASE PLAN - PRIME PREMISES
EXHIBIT 1B	LEASE PLAN - PH SYSTEM PREMISES
EXHIBIT 1C	TENANT'S ROOFTOP PREMISES
EXHIBIT 2	LEGAL DESCRIPTION - LAND
EXHIBIT 3	Intentionally Deleted
EXHIBIT 4	WORK LETTER
EXHIBIT 4-1	BASE BUILDING WORK
EXHIBIT 4-2	INITIAL PLAN
EXHIBIT 4-3	EQUIPMENT LIST
EXHIBIT 5	BASE BUILDING CAPACITIES
EXHIBIT 6	FORM OF LETTER OF CREDIT
EXHIBIT 7	LANDLORD'S SERVICES
EXHIBIT 8	TENANT'S HAZARDOUS MATERIALS
EXHIBIT 9	RULES AND REGULATIONS
EXHIBIT 9-1	BUILDING RULES AND REGULATIONS
EXHIBIT 9-2	CONSTRUCTION RULES AND REGULATIONS
EXHIBIT 10	TENANT'S WORK INSURANCE SCHEDULE
EXHIBIT 11	TENANT CONTROL AREAS

TABLE OF CONTENTS

THIS INDENTURE OF LEASE (this "**Lease**") is hereby made and entered into on the Execution Date by and between Landlord and Tenant.

Each reference in this Lease to any of the terms and titles contained in any Exhibit attached to this Lease shall be deemed and construed to incorporate the data stated under that term or title in such Exhibit. All capitalized terms not otherwise defined herein shall have the meanings ascribed to them as set forth in the Lease Summary Sheet which is attached hereto and incorporated herein by reference.

1. LEASE GRANT; TERM; APPURTENANT RIGHTS; EXCLUSIONS

1.1 Lease Grant. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, the Premises upon and subject to terms and conditions of this Lease, for a term of years commencing on the Term Commencement Date and, unless earlier terminated or extended pursuant to the terms hereof, ending on the Expiration Date (the "**Initial Term**"; the Initial Term and any duly exercised Extension Terms are hereinafter collectively referred to as the "**Term**").

1.2 Extension Terms.

(a) Provided that the following conditions, which may be waived by Landlord in its sole discretion, are satisfied (i) Tenant, an Affiliated Entity (hereinafter defined) and/or a Successor (hereinafter defined) is/are then occupying seventy-five percent (75%) of the Premises; and (ii) no Event of Default nor an event which, with the passage of time and/or the giving of notice would constitute an Event of Default has occurred (1) as of the date of the Extension Notice (hereinafter defined), and (2) at the commencement of the applicable Extension Term (hereinafter defined), Tenant shall have the option to extend the Term for one (1) additional term(s) of five (5) years (the "**Extension Term**"), commencing as of the expiration of the Initial Term. Tenant must exercise such option to extend, if at all, by giving Landlord written notice (the "**Extension Notice**") on or before the date that is nine (9) months prior to the expiration of the then-current Term of this Lease, *time being of the essence*. Upon the timely giving of such notice, the Term shall be deemed extended upon all of the terms and conditions of this Lease, except that Base Rent during the Extension Term shall be calculated in accordance with this Section 1.2, Landlord shall have no obligation to construct or renovate the Premises and Tenant shall have no further right to extend the Term. If Tenant fails to give timely notice, as aforesaid, Tenant shall have no further right to extend the Term. Notwithstanding the fact that Tenant's proper and timely exercise of such option to extend the Term shall be self-executing, the parties shall promptly execute a lease amendment reflecting such Extension Term after Tenant exercises such option. The parties' mutual execution of such lease amendment shall be deemed presumptive evidence that Tenant has satisfied the conditions under this Section 1.2.

(b) The Base Rent during the Extension Term (the "**Extension Term Base Rent**") shall be determined in accordance with the process described hereafter. Extension Term Base Rent shall be the greater of (i) Base Rent for the last Rent Year of the prior Term, or (ii) the fair market rental value of the Premises then demised to Tenant as of the commencement of the Extension Term as determined in accordance with the process described below, for renewals of first class office/research/laboratory building/campus in the Route 128/Route 2/Alewife corridor real estate market (the "**Market Area**") of equivalent quality, size, utility and location, with the

length of the Extension Term, the credit standing of Tenant and all other relevant factors to be taken into account. Within thirty (30) days after receipt of the Extension Notice, Landlord shall deliver to Tenant written notice of its determination of the Extension Term Base Rent for the Extension Term. Tenant shall, within thirty (30) days after receipt of such notice, notify Landlord in writing whether Tenant accepts or rejects Landlord's determination of the Extension Term Base Rent ("**Tenant's Response Notice**"). If Tenant fails timely to deliver Tenant's Response Notice, Landlord's determination of the Extension Term Base Rent shall be binding on Tenant.

(c) If and only if Tenant's Response Notice is timely addressed to Landlord and indicates both that Tenant rejects Landlord's determination of the Extension Term Base Rent and desires to submit the matter to arbitration, then the Extension Term Base Rent shall be determined in accordance with the procedure set forth in this Section 1.2(c). In such event, within ten (10) days after receipt by Landlord of Tenant's Response Notice indicating Tenant's desire to submit the determination of the Extension Term Base Rent to arbitration, Tenant and Landlord shall each notify the other, in writing, of their respective selections of an appraiser (respectively, "**Landlord's Appraiser**" and "**Tenant's Appraiser**"). Landlord's Appraiser and Tenant's Appraiser shall then jointly select a third appraiser (the "**Third Appraiser**") within ten (10) days of their appointment. All of the appraisers selected shall be individuals with at least five (5) consecutive years' commercial appraisal experience in the area in which the Premises are located, shall be members of the Appraisal Institute (M.A.I.), and, in the case of the Third Appraiser, shall not have acted in any capacity for either Landlord or Tenant within five (5) years of his or her selection. The three appraisers shall determine the Extension Term Base Rent in accordance with the requirements and criteria set forth in Section 1.2(b) above, employing the method commonly known as Baseball Arbitration, whereby Landlord's Appraiser and Tenant's Appraiser each sets forth its determination of the Extension Term Base Rent as defined above, and the Third Appraiser must select one or the other (it being understood that the Third Appraiser shall be expressly prohibited from selecting a compromise figure). Landlord's Appraiser and Tenant's Appraiser shall deliver their determinations of the Extension Term Base Rent to the Third Appraiser within five (5) days of the appointment of the Third Appraiser and the Third Appraiser shall render his or her decision within ten (10) days after receipt of both of the other two determinations of the Extension Term Base Rent. The Third Appraiser's decision shall be binding on both Landlord and Tenant. Each party shall bear the cost of its own appraiser and the cost of the Third Appraiser shall be paid by the party whose determination is not selected. For any part of the Extension Term during which the Base Rent is in dispute or has otherwise not finally been determined, Tenant shall make payment of Base Rent at the rate equal to the final month of the original Term and the parties shall adjust for any overpayments or underpayments upon the final determination of Base Rent.

1.3 Appurtenant Rights.

(a) Common Areas. Subject to the terms of this Lease and the Rules and Regulations (hereinafter defined), Tenant shall have, as appurtenant to the Premises, rights to use in common with others entitled thereto, without additional charge (unless otherwise expressly provided in this Lease, such as through Operating Costs), the following areas (such areas are hereinafter referred to as the "**Common Areas**"): (i) the common loading docks, hallways, lobby, and elevator of the Building serving the Premises, (ii) the common lavatories located on the floor(s) on which the Premises are located, (iii) common walkways and driveways necessary for access to the Building, (iv) the Parking Areas, and (v) other areas and facilities located in the Building, on

the Land, or elsewhere on the Campus designated by Landlord from time to time for the common use of tenants of the Building and other entitled thereto; and no other appurtenant rights or easements. **"Rules and Regulations"** shall be defined as the rules and regulations promulgated by Landlord pursuant to, and subject to, the provisions of Section 18.1 of the Lease. The three (3) loading docks, receiving area, and freight elevators shown on Exhibit 12, attached hereto and incorporated herein, are available for the use of the tenants in the Building and are part of the Common Areas.

(b) Parking. During the Term, and any extension thereof, and commencing on the Commencement Date, Landlord shall, subject to the terms hereof, make available up to sixty (60) parking spaces for Tenant's use free of charge (except that the costs of maintenance and repair of the parking areas shall, subject to the provisions of Section 5.2, be included in Operating Costs) in the Parking Areas serving the Building, of which up to five (5) parking spaces may be reserved spaces designated for use by Tenant. The number of parking spaces in the parking areas reserved for Tenant, as modified pursuant to this Lease or as otherwise permitted by Landlord, are hereinafter referred to as the "**Parking Spaces**." Tenant shall have no right to hypothecate or encumber the Parking Spaces, and shall not sublet, assign, or otherwise transfer the Parking Spaces other than to employees of Tenant occupying the Premises or to a Successor (hereinafter defined), an Affiliated Entity (hereinafter defined), or a transferee pursuant to an approved Transfer under Section 13 of this Lease. Subject to Landlord's right to reserve parking for other tenants of the Building, said Parking Spaces will be on an unassigned, non-reserved basis, and shall be subject to such Rules and Regulations, as may be in effect for the use of the parking areas from time to time. Reserved and handicap parking spaces must be honored. Notwithstanding anything to the contrary contained herein, Landlord shall have the right during any period of time that Landlord is performing construction or maintenance work on the Campus, upon at least three (3) months' prior written notice to Tenant, to temporarily relocate all or any portion of the Parking Spaces in to other portions of the Property and/or parking areas owned, controlled or leased by Landlord and located on Hayden Avenue in Lexington. If Landlord elects to relocate Tenant's Parking Spaces, Landlord (at its sole cost and expense) shall provide, for the duration of such temporary relocation, shuttle service to and from such temporary parking location. In addition, Landlord may, at its election, implement valet parking in order to accommodate the parking needs of the Property from time to time.

(c) Rooftop Premises. During the Term, and any extension thereof, Tenant shall have the non-exclusive license, at no additional cost, to use a portion of the rooftop of the Building designated by Landlord and in the location shown on Exhibit 1C (the "**Rooftop Premises**") for the installation of a dedicated exhaust system for the Tenant's vivarium installed by Landlord as part of the Tenant Improvement Work (any equipment installed within the Rooftop Premises, as the same may be modified, altered or replaced during the Term, is collectively referred to herein as "**Tenant's Rooftop Equipment**"). Landlord shall have the right to relocate Tenant's Rooftop Equipment, at Landlord's sole cost and expense, if Landlord determines that Tenant's Rooftop Equipment is interfering with that of any other occupant of the Building or with Landlord's configuration of the roof or rooftop equipment, provided that such relocation will not materially interfere with Tenant's use of such Tenant's Rooftop Equipment. Landlord's approval of alterations or modifications to such equipment shall not be unreasonably withheld, conditioned or delayed provided Tenant demonstrates to Landlord's reasonable satisfaction that the proposed alterations or modifications (i) do not interfere with any base building equipment operated by

Landlord on the roof; (ii) will not affect the structural integrity of the Building or impact the roof or the roof membrane in any manner; (iii) shall be adequately screened so as to minimize the visibility of such equipment; and (iv) shall be adequately sound-proofed to meet all requirements of Legal Requirements and Landlord's specified maximum decibel levels for equipment operations. Tenant shall not install or operate Tenant's Rooftop Equipment until Tenant has obtained and submitted to Landlord copies of all required governmental permits, licenses, and authorizations necessary for the installation and operation thereof. In addition, Tenant shall comply with all reasonable construction rules and regulations promulgated by Landlord in connection with the installation, maintenance and operation of Tenant's Rooftop Equipment. Landlord shall have no obligation to provide any services including, without limitation, electric current or gas service, to the Rooftop Premises or to Tenant's Rooftop Equipment. Tenant shall be responsible for the cost of repairing and maintaining Tenant's Rooftop Equipment and the cost of repairing any damage to the Building, or the cost of any necessary improvements to the Building, caused by or as a result of the installation, replacement and/or removal of Tenant's Rooftop Equipment. In connection with any repairs and/or maintenance work by Landlord affecting the roof of the Building ("**Roof Repairs**"), Landlord may request the temporary removal or relocation of Tenant's Rooftop Equipment. Upon such request, Tenant shall relocate and reinstall Tenant's Rooftop Equipment in such alternate location indicated by Landlord and where its location will not interfere with Tenant's use of such equipment, and Landlord shall pay for said relocation and reimburse Tenant for all other reasonable out-of-pocket costs and expenses incurred by Tenant in the course of such relocation and reinstallation. Additionally, Landlord shall be responsible for repairing any damage incurred with respect to Tenant's Rooftop Equipment to the extent caused by any Roof Repairs and/or incidental to the equipment's relocation.

(d) Cafeteria. During the Term and any extension thereof, Tenant, its employees, contractors, and visitors shall have the right to use the Cafeterias at no additional cost (unless otherwise expressly provided in this Lease, such as through Operating Costs), as hereinafter defined, in common with others entitled thereto. The "**Cafeterias**," as the same may be relocated as hereinafter set forth, shall be defined as food services facilities which provide food to tenants and occupants of the Campus. As of the Execution Date, one Cafeteria is located in Building 55 (the "**Building 55 Cafeteria**"), and a second Cafeteria is being constructed in Building 75 (the "**Building 75 Cafeteria**"), which, upon the completion of such Building 75 Cafeteria, will be available for use by Tenant, its employees, contractors, and visitors in the same manner as the Building 55 Cafeteria. Tenant hereby acknowledges that the Cafeterias may be relocated, from time to time, to other buildings located on the Campus. A third-party provider is currently contemplated to operate the Cafeterias. Any amounts paid by Landlord on account of the operation of the Cafeterias in excess of the net revenues derived from the operation of the Cafeterias shall be included in Operating Costs, as shall all of Landlord's costs of cleaning, maintaining, and repairing the Cafeterias. Card readers shall, at no cost to Tenant, be installed and maintained at appropriate access points to the Cafeterias and identification cards shall be issued to authorized users.

(e) Fitness Center. During the Term and any extension thereof, Tenant, its employees and visitors shall have the right to use the Fitness Center, as hereinafter defined, in common with others entitled thereto at no additional cost (unless otherwise expressly provided in this Lease, such as through Operating Costs). The "**Fitness Center**" shall be a work-out facility for the use of tenants and occupants of the Campus. As of the Execution Date, the Fitness Center

is located in the Building. Tenant acknowledges that the Fitness Center may be relocated, from time to time, to other buildings located on the Campus. Card readers shall, at no cost to Tenant, be installed and maintained at appropriate access points to the Fitness Center and identification cards shall be issued to authorized users. Users of the fitness center shall be required to execute such liability waivers as Landlord shall reasonably require. Any amounts paid by Landlord on account of the operation of the Fitness Center in excess of any net revenues derived from the operation of the Fitness Center shall be included in Operating Costs, as shall all of Landlord's costs of cleaning, maintaining, and repairing the Fitness Center. If for any reason Landlord decides to cease operating a Fitness Center, then, within thirty (30) days after delivery of written notice from Landlord to Tenant of Landlord's decision, then Tenant shall no longer have the right to use the Fitness Center.

1.4 Tenant's Access. From and after the Term Commencement Date and until the end of the Term and any extension thereof, Tenant shall have access to the Premises twenty-four (24) hours a day, seven (7) days a week, subject to Landlord's reasonable Building security requirements, causes beyond Landlord's reasonable control, Legal Requirements, the Rules and Regulations, the terms of this Lease, Force Majeure (hereinafter defined) and matters of record.

1.5 No recording // Notice of Lease. Neither party shall record this Lease. Tenant shall not record a memorandum of this Lease and/or a notice of this Lease. Notwithstanding the foregoing, if the Initial Term plus any Extension Term(s) exceed in the aggregate seven (7) years, Landlord agrees to join in the execution, in recordable form, of a statutory notice of lease and/or written declaration in which shall be stated the Term Commencement Date, the Rent Commencement Date, the number and length of the Extension Term(s) and the Expiration Date, which notice of lease may be recorded by Tenant with the Middlesex South Registry of Deeds and/or filed with the Middlesex South Registry District of the Land Court, as appropriate (alternatively and collectively, the "**Registry**") at Tenant's sole cost and expense. If a notice of lease was previously recorded with the Registry, upon the expiration or earlier termination of this Lease, Landlord shall deliver to Tenant a notice of termination of Lease and Tenant shall promptly execute, acknowledge, and deliver the same (together with any other instrument(s) that may be necessary in order to record and/or file same with the Registry) to Landlord for Landlord's execution and recordation with the Registry, which obligation shall survive the expiration or earlier termination of the Lease.

1.6 Exclusions. The following are expressly excluded from the Premises and reserved to Landlord: all the perimeter walls of the Premises (except the inner surfaces thereof), the Common Areas, and any space in or adjacent to the Premises used for shafts, stacks, pipes, conduits, wires and appurtenant fixtures, fan rooms, ducts, electric or other utilities, sinks or other Building facilities, and the use of all of the foregoing, except as expressly permitted pursuant to Section 1.3(a) above.

1.7 Acid Neutralization Tank.

(a) There currently exists an acid neutralization tank (the "**Acid Neutralization Tank**") that is located in the PH System Premises. Tenant acknowledges and agrees that Tenant is leasing the Acid Neutralization Tank in its "AS IS," "WHERE IS" condition and with all faults on the Execution Date, without representations or warranties, express or implied, in fact or by law,

of any kind, or recourse to Landlord. Tenant shall have the exclusive right, throughout the Term of the Lease, as the same may be extended, to use the Acid Neutralization Tank in accordance with Legal Requirements. Tenant shall obtain and maintain all governmental permits and approvals necessary for the operation and maintenance of the Acid Neutralization Tank. Tenant shall be responsible for all costs, charges and expenses incurred from time to time in connection with or arising out of the operation, use, maintenance, repair and replacement of the Acid Neutralization Tank, including all clean-up costs relating to the Acid Neutralization Tank (collectively, "**Tank Costs**"), except, subject to Section 14.5, to the extent such costs are caused by the negligence or willful misconduct of any of the Landlord Parties (as hereinafter defined).

(b) Tenant shall be responsible for assuring that the maintenance, operation and repair of the Acid Neutralization Tank shall in no way damage any portion of the Building or Property. To the maximum extent permitted by Law, the Acid Neutralization Tank and all appurtenances thereto shall be at the sole risk of Tenant, and Landlord shall have no liability to Tenant if the Acid Neutralization Tank or any appurtenant installations are damaged for any reason. Except for Landlord's negligence or willful misconduct, Tenant agrees to be responsible for any damage caused to the Building or Property in connection with the maintenance, operation or removal of the Acid Neutralization Tank. Except (subject to Section 14.5) with respect to Claims, to the extent caused by the negligence or willful misconduct of Landlord or any Landlord Parties, Tenant shall indemnify, save, defend (at Landlord's option and with counsel reasonably acceptable to Landlord) and hold the Landlord Parties, as hereinafter defined, harmless from and against any and all Claims (as hereinafter defined), including (i) diminution in value of the Premises or any portion thereof, (ii) damages for the loss of or restriction on use of rentable or usable space of the Premises, (iii) damages arising from any adverse impact on marketing of space in the Premises or any portion thereof, and (iv) sums paid in settlement of Claims that arise during or after the Term, subject to the applicable statute of limitations, as a result of Tenant's improper use of the Acid Neutralization Tank in violation of applicable Legal Requirements. This indemnification by Tenant includes costs actually incurred by Landlord: (1) in connection with any investigation required by any Governmental Authority of site conditions, (2) in connection with any investigation required by Landlord pursuant to which it is determined that Tenant has breach its obligations with respect to the Acid Neutralization Tank, and (3) any clean-up, remediation, and/or removal of any Hazardous Materials and/or restoration of the Property required by any Governmental Authority caused by Tenant's improper use of the Acid Neutralization Tank.

(c) At the expiration or earlier termination of the Term, Tenant shall decommission the Acid Neutralization Tank in accordance with applicable Legal Requirements and shall provide any associated documentation of decommissioning to Landlord upon request therefor.

(d) Landlord shall have no obligation to provide any services, including, without limitation, electric current, to Tenant's Acid Neutralization Tank.

2. RIGHTS RESERVED TO LANDLORD

2.1 Additions and Alterations. Landlord reserves the right, at any time and from time to time, to make such changes, alterations, additions, improvements, repairs or replacements in or to the Property (including the Premises but, with respect to the Premises, only for purposes of repairs, maintenance, replacements and the exercise of any other rights expressly reserved to Landlord herein, provided that Landlord shall give Tenant at least five (5) business days' prior notice thereof) and the fixtures and equipment therein, as well as in or to the street entrances and/or the Common Areas, as it may deem necessary or desirable, provided, however, that there be no material obstruction of permanent access to, or material interference with the use and enjoyment of, the Premises by Tenant. Subject to the foregoing, Landlord expressly reserves the right to temporarily close all, or any portion, of the Common Areas for the purpose of making repairs or changes thereto.

2.2 Additions to the Property.

(a) Landlord may at any time or from time to time (i) construct additional building(s) and improvements and related site improvements (collectively, "**Future Development**") in all or any part of the Property and/or (ii) change the location or arrangement of any improvement outside the Building in or on the Property or all or any part of the Common Areas, or add or deduct any land to or from the Property; provided that there shall be no material increase in Tenant's obligations or material interference with Tenant's rights under this Lease in connection with the exercise of the foregoing reserved rights and any such construction or changes shall be subject to Tenant's rights under Section 23 of this Lease.

(b) In case any excavation shall be made for building or improvements or for any other purpose upon the land adjacent to or near the Premises, Tenant will afford without charge to Landlord, or the person or persons, firms or corporations causing or making such excavation (provided that Landlord shall give Tenant at least five (5) business days' prior notice thereof), license to enter upon the Premises for the purpose of doing such work as Landlord or such person or persons, firms or corporation shall deem to be necessary to preserve the walls or structures of the Building from injury, and to protect the Building by proper securing of foundations.

(c) Tenant acknowledges and agrees that this Lease is subject and subordinate to (i) The Hayden Science Center Condominium (the "**Condominium**"), which was established by Master Deed dated December 1, 2017, recorded in Book 70325, Page 108, in the Middlesex South District Registry of Deeds and filed as Document No. 195793 in the Middlesex South Registry District of the Land Court, (ii) the Condominium Floor Plans and Site Plans dated December 1, 2017, and filed with the Middlesex Registry of Deeds, Southern District, as Plan No. 1090, Pages 1 through 13, and (iii) the Declaration of Trust of The Hayden Science Center Condominium Trust dated December 1, 2017, recorded in Book 70325, Page 148, in the Middlesex South District Registry of Deeds and filed as Document No. 195794 in the Middlesex South Registry District of the Land Court (the Master Deed, Declaration of Trust, and the Plans are being referred to herein as the "**Condominium Documents**"). Tenant agrees that the Condominium Documents may be amended and that this Lease shall remain subject to and subordinate to the Condominium Documents, as so amended, so long as such amendments do not materially adversely affect Tenant's rights or obligations under this Lease and subject to Tenant's right to quiet enjoyment set forth in Section 23 of this Lease.

(d) Landlord and Tenant each hereby acknowledges and agrees that, in connection with any Future Development, (i) Landlord shall have the right to enter into, and subject the Property to the terms and conditions of, a commercially reasonable reciprocal easement agreement with any one or more of the neighboring property owners in order to create a commercial campus-like setting ("**REA**"); (ii) upon Landlord's request in connection with the recording of the REA, Tenant shall execute a commercially reasonable instrument in recordable form making this Lease subject and subordinate to the REA; (iii) Landlord shall have the right to subdivide the Property so long as Tenant continues to have all of the rights and obligations contained in this Lease (e.g., the appurtenant right to use all Common Areas); and (iv) Tenant shall execute such reasonable documents (which may be in recordable form) evidencing the foregoing promptly upon Landlord's request.

2.3 Name and Address of Building. Landlord reserves the right at any time and from time to time to change the name or address of the Building and/or the Property, provided Landlord gives Tenant at least three (3) months' prior written notice thereof.

2.4 Landlord's Access.

(a) Subject to the terms hereof, Tenant shall (a) upon not less than forty-eight (48) hours' advance notice, which may be oral (except that no notice shall be required in emergency situations), permit Landlord and any holder of a Mortgage (hereinafter defined) (each such holder, a "**Mortgagee**"), and the agents, representatives, employees and contractors of each of them, each of whom must be at all times accompanied by a designated representative of Tenant while in the Premises (provided that Tenant shall make a designated representative available at all reasonable times for the purposes of accompanying Landlord and its designees), to have reasonable access to the Premises at all reasonable hours for the purposes of inspection, making repairs, replacements or improvements in or to the Premises or the Building or equipment therein (including, without limitation, sanitary, electrical, heating, air conditioning or other systems), complying with all applicable laws, ordinances, rules, regulations, statutes, by-laws, court decisions and orders and requirements of all public authorities (collectively, "**Legal Requirements**"), or exercising any right reserved to Landlord under this Lease (including without limitation the right to take upon or through, or to keep and store within the Premises all necessary materials, tools and equipment); (b) permit Landlord and its agents and employees, at reasonable times, upon reasonable advance notice, to show the Premises during normal business hours (i.e. Monday – Friday 7 A.M. - 6 P.M., Saturday 7 A.M. – 12 P.M., excluding holidays) to any prospective Mortgagee or purchaser of the Building and/or the Property or of the interest of Landlord therein, and, during the last twelve (12) months of the Term or at any time after the occurrence of an Event of Default, prospective tenants; and (c) upon reasonable prior written notice from Landlord, permit Landlord and its agents, at Landlord's sole cost and expense, to perform environmental audits, environmental site investigations and environmental site assessments ("**Site Assessments**") in, on, under and at the Premises and the Land, it being understood that Landlord shall repair any damage arising as a result of the Site Assessments, and such Site Assessments may include both above and below the ground testing and such other tests as may be necessary or appropriate to conduct the Site Assessments. In addition, to the extent that it is necessary to enter the Premises in order to access any area that serves any portion of the Building outside the Premises, then Tenant shall, upon as much advance notice as is practical under the circumstances, and in any event at least twenty-four (24) hours' prior written notice (except that no notice shall

be required in emergency situations), permit contractors engaged by other occupants of the Building to pass through the Premises in order to access such areas but only if accompanied by a representative of Landlord. The parties agree and acknowledge that, despite commercially reasonable and customary precautions (which Landlord agrees it shall exercise), any property or equipment in the Premises of a delicate, fragile or vulnerable nature may nevertheless be damaged in the course of performing Landlord's obligations. Landlord and Tenant shall take commercially reasonable protective precautions with unusually fragile, vulnerable or sensitive property and equipment. Nonetheless, in the event any of Tenant's equipment is damaged Landlord shall, subject to Section 14.5, repair and/or replace same.

(b) Secure Areas within the Premises. Notwithstanding the foregoing, Tenant, at its own expense may, as hereinafter set forth, designate one or more areas of the Premises to be "**Secure Areas**" (i.e., portions of the Premises to which Landlord shall not have a right of entry or access for any reason whatsoever (except as otherwise provided below). Tenant may, from time to time, exercise its right to create Secure Areas by delivering to Landlord, for Landlord's written approval, which shall not be unreasonably withheld, conditioned or delayed, a plan showing the location of any such Secure Areas. If Landlord must gain access to a Secure Areas in a non-emergency situation, Landlord shall contact Tenant, and Landlord and Tenant shall arrange a mutually agreed upon time for Landlord to have such access. Landlord shall be accompanied by an employee of Tenant or a party designated by Tenant (the "**Escort**"). Tenant shall make an Escort available to Landlord during mutually agreed upon times within a reasonable period of time after request. At all times, Landlord shall comply with all reasonable security measures of the Tenant pertaining to the Secure Areas. If an emergency representing an imminent risk of injury to persons or material property damage in the Building or the Premises, including, without limitation, a suspected fire or flood, requires Landlord to gain access to the Secure Areas, Landlord may enter the Secure Areas without an Escort. If practicable under the emergency circumstances, Landlord shall immediately notify (which may be oral notification) and request that Tenant make an Escort available to Landlord if time permits, and if Tenant shall not make an Escort available to accompany Landlord, then Tenant hereby authorizes Landlord to enter the Secure Areas with a master key, and to enter without an Escort. In any such event, except (subject to Section 14.5 of this Lease) to the extent resulting from Landlord's negligence or willful misconduct, Landlord shall have no liability whatsoever to Tenant, and Tenant shall pay all reasonable expenses incurred by Landlord in repairing or reconstructing any entrance, corridor, door or other portions of the Premises damaged as a result of a forcible entry by Landlord. Landlord shall have no obligation to provide either janitorial service or cleaning in the Secure Areas unless Tenant shall make arrangements to have an Escort in the Secure Areas at the time such service or cleaning is provided to the remainder of the Premises.

2.5 Pipes, Ducts and Conduits. Tenant shall permit Landlord to erect, use, maintain and relocate pipes, ducts and conduits in and through the Premises, provided the same do not materially reduce the floor area or materially adversely affect the appearance thereof.

2.6 Minimize Interference. Except in the event of an emergency, Landlord shall use commercially reasonable efforts to minimize any interference with Tenant's business operations and use and occupancy of the Premises in connection with the exercise any of the foregoing rights under this Section 2.

3. CONDITION OF PREMISES; CONSTRUCTION.

3.1 Condition of Premises. Tenant acknowledges and agrees that Tenant is leasing the Premises in their "**AS IS**," "**WHERE IS**" condition and with all faults on the Execution Date, without representations or warranties, express or implied, in fact or by law, of any kind, and without recourse to Landlord, except that: (i) Landlord represents to Tenant that, as of the Term Commencement Date, the Building has the systems and capacities set forth on Exhibit 5 and (ii) Landlord shall perform Landlord's Work in accordance with the provisions of this Section 3 and Exhibit 4; provided, however, that Landlord and Tenant acknowledge and agree that the Vivarium Work (as hereinafter defined) will be performed by Landlord subsequent to the Term Commencement Date, as more particularly set forth in Section 3.2, below.

3.2 Landlord's Work.

(a) Subject to Force Majeure, as defined in Section 25.16 and any Tenant Delay, as hereinafter defined, Landlord shall perform Landlord's Work in order to prepare the Premises for Tenant's use and occupancy in accordance with Exhibit 4 attached hereto. Landlord shall use diligent efforts to substantially complete Landlord's Work, excluding the Vivarium Work, by April 1, 2020 (the "**Estimated Term Commencement Date**"), and to substantially complete the Vivarium Work by May 1, 2020 (the "**Estimated Vivarium Delivery Date**"). However, except to the extent that such failure constitutes a delay in the occurrence of the Term Commencement Date (as provided in the definition of the Term Commencement Date), and, except for Tenant's remedies set forth in Section 3.2 hereof: (i) Tenant's sole remedies shall be a delay in the Term Commencement Date, (ii) Tenant shall have no claim or rights against Landlord, and Landlord shall have no liability or obligation to Tenant in the event of delay in Landlord's Work, and (iii) no delay in Landlord's Work shall have any effect on the parties' rights or obligations under this Lease. Further, notwithstanding anything herein to the contrary, Tenant acknowledges that Landlord will be performing the Vivarium Work subsequent to the Term Commencement Date, and that so long as Landlord is using diligent efforts to complete the Vivarium Work in light of the circumstances (i.e., Tenant's occupancy of the Premises), Tenant shall have no claim or rights against Landlord, and Landlord shall have no liability or obligation to Tenant in the event of delay in the Vivarium Work, and no delay in the Vivarium Work shall have any effect on the parties' rights or obligations under this Lease.

(b) Definitions.

(i) "**Tenant Delay**" shall mean any act or omission by Tenant and/or Tenant's agents, employees or contractors (collectively with Tenant, the "**Tenant Parties**") which causes an actual delay in the performance of Landlord's Work, including, without limitation, any Changes to the Plans or the scope of Landlord's Work as shown on the Initial Plan (as such terms are hereinafter defined) that are requested by Tenant. Notwithstanding the foregoing, except where a Tenant Delay arises from Tenant's failure timely to act within on or before a date or time period expressly set forth in the Lease (in which event no Tenant Delay Notice shall be required): (x) in no event shall any act or omission be deemed to be a Tenant Delay until and unless Landlord has given Tenant written notice (the "**Tenant Delay Notice**") advising Tenant (a) that a Tenant Delay is occurring, and (b) of the basis on which Landlord has determined that a Tenant Delay is occurring, and (y) no period of time prior to the time that Tenant receives a Tenant Delay Notice

shall be included in the period of time charged to Tenant pursuant to such Tenant Delay Notice. The term "Tenant Parties" shall not include any of the following, to the extent hired by Landlord: contractors, subcontractors, architects, space planners, interior designers, facility managers, and other consultants.

(ii) "**Substantially Complete**" or "**Substantial Completion**," when referring to Landlord's Work shall mean that: (1) Landlord's Work is completed, other than minor work which does not materially affect Tenant's use of, or access to, the Premises, (2) the Premises and those portions of the Common Areas of the Building which affect Tenant's occupancy are in conformance with all applicable building codes, permits, laws and regulations, including without limitation, ADA, (3) all structural elements and subsystems of the Building, including but not limited to HVAC, mechanical, electrical, lighting, plumbing, and life safety systems, will be in good working condition and repair, (4) Landlord has delivered to Tenant a certificate of substantial completion from Landlord's architect stating that Landlord's Work is substantially complete, and (5) such evidence (the "**Town Approval**") as is customarily provided by the Town of Lexington to evidence its acceptance of Landlord's Work and Tenant's right to lawfully occupy the Premises (e.g., sign-offs on the Building permit by all applicable Town of Lexington departments or a certificate of occupancy, which may be a temporary certificate of occupancy) has been provided by the Town of Lexington; provided, however, that Substantial Completion shall be deemed to have occurred for purposes of clause (5) if (x) such required sign-offs are completed with respect to Landlord's Work but cannot be completed for the entire Premises due to Tenant's failure to complete installation or work to be performed by Tenant (including furniture, wiring and cabling) in a manner that allows such required inspections to be completed and a temporary certificate of occupancy to be issued, or (y) approval of applicable governmental authorities required to permit legal occupancy of the Premises for the Permitted Uses cannot be obtained for the entire Premises due to Tenant's failure to complete installation of installation or work to be performed by Tenant (including furniture, wiring and cabling) in a manner that allows such approval to be obtained. No costs incurred by Landlord in satisfying the definition of Substantial Completion shall be included in Operating Costs. Notwithstanding anything to the contrary herein contained, in the event that Landlord's Work is delayed by reason of a Tenant Delay, then Landlord shall be deemed to have achieved Substantial Completion of Landlord's Work on the date that Landlord would have achieved Substantial Completion of Landlord's Work, but for such Tenant Delay.

(iii) Punchlist. Promptly following Substantial Completion of Landlord's Work, Landlord shall provide Tenant with a punchlist prepared by Landlord's architect (the "**Punchlist**") incorporating those items jointly identified by Landlord and Tenant during their joint inspection of Landlord's Work, of outstanding items (the "**Punchlist Items**"). Promptly after Substantial Completion of Landlord's Work, Landlord and Tenant shall jointly inspect the Premises. Subject to Landlord's Force Majeure and Tenant Delays, Landlord shall complete all Punchlist Items within thirty (30) days of the date of the Punchlist (other than seasonal items, such as landscaping, requiring a longer period), provided that Tenant reasonably cooperates in connection with the completion of such Punchlist Items.

3.3 Tenant's Remedies in the Event of Delays in Term Commencement Date. If the Term Commencement Date does not occur on or before the Outside Termination Date, as hereinafter defined, then Tenant shall have the right to terminate the Lease, which shall be exercisable by a written thirty-(30)-day termination notice given on or after the Outside

Termination Date but before the date that the Term Commencement Date occurs. If the Term Commencement Date occurs on or before the thirtieth (30th) day after Landlord receives such termination notice, Tenant's termination notice shall be deemed to be void and of no force or effect. If the Term Commencement Date does not occur on or before such thirtieth (30th) day, this Lease shall terminate and shall be of no further force or effect, and, except for provisions of the Lease, which are intended to survive termination of the Lease (e.g., indemnification provisions), Landlord shall promptly refund to Tenant any Security Deposit paid by Tenant to Landlord and neither party shall have any further obligation to the other party. In such event, Tenant shall not be responsible for the payment of or reimbursement to Landlord for any expense associated with the design, construction, the preparations of plans and drawings to engage in the permitting process with local authorities or delivery of the Premises. For the purposes hereof, the "**Outside Termination Date**" shall be defined as October 1, 2020, provided however, that the Outside Termination Date shall be extended by the lesser of: (x) ninety (90) days, or (y) the length of any delays in Landlord's Work arising from Force Majeure.

4. USE OF PREMISES

4.1 Permitted Uses. During the Term, Tenant shall use the Premises only for the Permitted Uses and for no other purposes. Service and utility areas (whether or not a part of the Premises) shall be used only for the particular purpose for which they are designed. Tenant shall keep the Premises equipped with appropriate safety appliances to the extent required by applicable laws or insurance requirements.

4.2 Prohibited Uses.

(a) Notwithstanding any other provision of this Lease, Tenant shall not use the Premises or the Building, or any part thereof, or suffer or permit the use or occupancy of the Premises or the Building or any part thereof by any of the Tenant Parties (i) in a manner which would violate any of the covenants, agreements, terms, provisions and conditions of this Lease or otherwise applicable to or binding upon the Premises; (ii) for any unlawful purposes or in any unlawful manner; (iii) which, in the reasonable judgment of Landlord (taking into account the use of the Building as a combination laboratory, research and development and office building and the Permitted Uses) shall (a) impair the appearance or reputation of the Building; (b) impair, interfere with or otherwise diminish the quality of any of the Building services or the proper and economic heating, cleaning, ventilating, air conditioning or other servicing of the Building or Premises, or the use or occupancy of any of the Common Areas; (c) occasion discomfort, inconvenience or annoyance in any material respect (and Tenant shall not install or use any electrical or other equipment of any kind which, in the reasonable judgment of Landlord, will cause any such impairment, interference, discomfort, inconvenience, annoyance or injury), or cause any injury or damage to any occupants of the Premises or other tenants or occupants of the Building or their property; or (d) cause harmful air emissions, laboratory odors or noises or any unusual or other objectionable odors, noises or emissions to emanate from the Premises; (iv) in a manner which is inconsistent with the operation and/or maintenance of the Building as a first-class combination office, research, development and laboratory facility; (v) for any fermentation processes whatsoever; or (vi) in a manner which shall increase such insurance rates on the Building or on property located therein over that applicable when Tenant first took occupancy of the Premises hereunder.

(b) With respect to the use and occupancy of the Premises and the Common Areas, Tenant will not: (i) place or maintain any signage (except as set forth in Section 12.2 below), trash, refuse or other articles in any vestibule or entry of the Premises, on the footwalks or corridors adjacent thereto or elsewhere on the exterior of the Premises, nor obstruct any driveway, corridor, footwalk, parking area, mall or any other Common Areas; (ii) permit undue accumulations of or burn garbage, trash, rubbish or other refuse within or without the Premises; (iii) permit the parking of vehicles so as to interfere with (x) the ability of others, entitled thereto, to park in the common parking areas, or (y) the use of any driveway, corridor, footwalk, parking area, or other Common Areas; (iv) receive or ship articles of any kind outside of those areas reasonably designated by Landlord; (v) conduct or permit to be conducted any auction, going out of business sale, bankruptcy sale (unless directed by court order), or other similar type sale in or connected with the Premises; (vi) use the name of Landlord, or any of Landlord's affiliates in any publicity, promotion, trailer, press release, advertising, printed, or display materials without Landlord's prior written consent; or (vii) except in connection with Alterations (hereinafter defined) approved by Landlord, cause or permit any hole to be drilled or made in any part of the Building.

4.3 Transportation of Animals. No animals, animal waste, food or supplies relating to the animals maintained from time to time in the animal storage areas of the Premises shall be transported within the Building except as provided in this Section 4.3. All deliveries of animals or animal food or supplies to Tenant at the Building shall be made prior to 11:00 a.m. No transportation of animals, animal waste, food or supplies within the Building shall occur between the hours of 11:00 a.m. and 1:00 p.m. At all times that animals are transported within the Common Areas, they shall be transported in an appropriate cage or other container. At no time shall any animals, animal waste, food or supplies relating to the animals be brought into, transported through, or delivered to the lobby of the Building or be transported within the Building in elevators other than the freight elevator.

4.4 MWRA Permit. Tenant shall establish and maintain with respect to its use of wastewater facilities exclusively serving the Leased Premises, an MWRA waste water discharge program administered by a licensed, qualified individual (which individual may be (i) a third party contractor/consultant approved by Landlord, which approval shall not be unreasonably withheld, conditioned or delayed, or (ii) an employee of Tenant or Tenant's affiliate) in accordance with the requirements of the Massachusetts Water Resources Authority ("**MWRA**") and any other applicable governmental authority. Tenant shall be solely responsible for all costs incurred in connection with such MWRA waste water discharge, and Tenant shall provide Landlord with such documentation as Landlord may reasonably require evidencing Tenant's compliance with the requirements of (a) the MWRA and any other applicable governmental authority with respect to such chemical safety program and (b) this Section. Tenant shall obtain and maintain during the Term (i) any permit required by the MWRA ("**MWRA Permit**") and (ii) a wastewater treatment operator license from the Commonwealth of Massachusetts with respect to Tenant's use of any acid neutralization tank exclusively serving the Leased Premises in the Building. Tenant shall not introduce anything into the acid neutralization tank serving the Premises, if any (x) in violation of the terms of the MWRA Permit, (y) in violation of Legal Requirements or (z) that would interfere with the proper functioning of any such acid neutralization tank.

4.5 Parking and Traffic Demand Management Plan. The Property is subject to a Parking and Traffic Demand Management Plan with the Town of Lexington (the "**Initial PTDM**"). Tenant agrees to comply with the requirements of the Initial PTDM, only insofar as they apply to the Premises and/or Tenant's use and occupancy thereof. In the event that the Initial PTDM is ever modified, supplemented, amended or replaced ("**PTDM Modifications**"), Tenant agrees to comply with the requirements of the PTDM Modifications, only insofar as they apply to the Premises and/or Tenant's use and occupancy thereof. As of the date hereof, Landlord represents that, to Landlord's knowledge, the Premises currently comply with the Initial PTDM.

4.6 Vivarium. Tenant shall be responsible, at its sole expense, for the operations of its vivarium in accordance with all Legal Requirements and with best industry practices. Without limiting the general application of the foregoing, Tenant shall separately dispose of all waste products from the operation of Tenant's vivarium, including, without limitation, dead animals, strictly in accordance with Legal Requirements. Landlord shall have the right, from time to time by written notice to Tenant, to promulgate reasonable rules and regulations with respect to the operation of Tenant's vivarium so as to minimize any adverse effects that such operation may have on other occupants of the Building, including without limitation, regulations as to noise mitigation.

5. RENT; ADDITIONAL RENT

5.1 Base Rent. Commencing as of the Rent Commencement Date and continuing thereafter throughout the remainder of the Term, Tenant shall pay Base Rent to Landlord in equal monthly installments, in advance and without demand on the first day of each month for and with respect to such month. Unless otherwise expressly provided herein, the payment of Base Rent, Additional Rent and other charges reserved and covenanted to be paid under this Lease with respect to the Premises (collectively, "**Rent**") shall commence on the Rent Commencement Date and shall be prorated for any partial months. Rent shall be payable to Landlord or, if Landlord shall so direct in writing, to Landlord's agent or nominee, in lawful money of the United States which shall be legal tender for payment of all debts and dues, public and private, at the time of payment.

5.2 Operating Costs.

(a) "**Operating Costs**" shall mean all costs incurred and expenditures of whatever nature made by Landlord in the operation, management, repair, replacement, maintenance and insurance (including, without limitation, environmental liability insurance and property insurance on Landlord-supplied leasehold improvements for tenants, but not property insurance on tenants' equipment) of the Property or allocated to the Property, including without limitation all costs of labor (wages, salaries, fringe benefits, etc.) up to and including the Director of Property Management, any costs for utilities supplied to exterior areas and the Common Areas, and any costs for repair and replacements, cleaning and maintenance of exterior areas and the Common Areas, related equipment, facilities and appurtenances and HVAC equipment, security services, a management fee in the amount of four percent (4%) of gross Building revenues (increased, if applicable, in accordance with Section 5.2(f)), the costs, including, without limitation, a commercially reasonable rental factor, of Landlord's management office for the Property, which management office may be located outside the Property and which may serve other properties in addition to the Property (in which event such costs shall be equitably allocated

among the properties served by such office), the cost of operating any amenities in the Property available to all tenants of the Property and any subsidy provided by Landlord for or with respect to any such amenity, and the Annual Charge-Off (as hereinafter defined) with respect to a Permitted Capital Expenditure (as hereinafter defined), and all costs of applying and reporting for the Building or any part thereof to seek or maintain certification under the U.S. EPA's Energy Star® rating system, the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) rating system or a similar system or standard. For costs and expenditures made by Landlord in connection with the operation, management, repair, replacement, maintenance and insurance of the Building as a whole, Landlord shall make a reasonable allocation thereof between the retail and non-retail portions of the Building, if applicable. The allocation of Operating Costs relating to the Common Areas of the Campus shall be made in accordance with the Condominium Documents. Operating Costs shall not include Excluded Costs (hereinafter defined).

(b) **Capital Expenditures**. Permitted Capital Expenditures (as hereinafter defined) shall only be included in Operating Costs for each fiscal year during the Term to the extent of the Annual Charge-Off, as hereinafter defined, for such fiscal year with respect to such capital expenditure. Operating Costs shall not include any Annual Charge-Off with respect to Excluded Costs, as hereinafter defined. For the purposes hereof:

(i) "**Annual Charge-Off**" means the annual amount of principal and interest payments which would be required to repay a loan in equal monthly installments over the Useful Life, as defined below, of the capital item in question on a direct reduction basis at an annual interest rate equal to the Capital Interest Rate, as defined below, where the initial principal balance is the cost of the capital item in question.

(ii) "**Useful Life**" shall be reasonably determined by Landlord in accordance with generally accepted accounting principles and practices in effect at the time of acquisition of the capital item.

(iii) "**Capital Interest Rate**" shall be defined as an annual rate of either one percentage point over the AA bond rate (Standard & Poor's corporate composite or, if unavailable, its equivalent) as reported in the financial press at the time the capital expenditure is made or, if the capital item is acquired through third-party financing, then the actual (including fluctuating) rate paid by Landlord in financing the acquisition of such capital item.

(c) "**Excluded Costs**" shall be defined as (i) any fixed or percentage ground rent payable to any ground lessor, or any mortgage charges or other financing charges payable by Landlord (including but not limited to interest, principal, points and fees); (ii) brokerage commissions; (iii) salaries of executives and owners not directly employed in the management/operation of the Property; (iv) the cost of work done by Landlord for a particular tenant or prospective tenant; (v) the cost of items which, by generally accepted accounting principles, would be capitalized on the books of Landlord or are otherwise not properly chargeable against income, except to the extent such capital item is (A) required by any Legal Requirements, or (B) reasonably projected to reduce Operating Costs; (vi) the costs of Landlord's Work and any contributions made by Landlord to any tenant of the Property in connection with the build-out of its premises; (vii) franchise or income taxes imposed on Landlord; (viii) costs paid directly by individual tenants to suppliers, including tenant electricity, telephone and other utility costs; (ix)

increases in premiums for insurance when such increase is caused by the use of the Building by Landlord or any other tenant of the Building; (x) depreciation of the Building; (xi) costs relating to maintaining Landlord's existence as a corporation, partnership or other entity; (xii) advertising and other fees and costs incurred in procuring and negotiating leases with tenants; (xiii) the cost of any items for which Landlord is reimbursed by insurance, condemnation awards, refund, rebate or otherwise, and any expenses for repairs or maintenance to the extent covered by warranties, guaranties and service contracts; and (xiv) costs incurred in connection with any disputes between Landlord and its employees, between Landlord and Building management, or between Landlord and other tenants or occupants or contractors, (xv) Taxes, (xvi) costs associated with the operation of the Landlord entity, as distinguished from costs associated with the operation of the Building and Property, (xvii) costs associated with the sale or financing of the Building or Property, (xviii) the cost of remediating Hazardous Materials from the Building other than Included Hazardous Materials, as hereinafter defined; "**Included Hazardous Materials**" shall be defined as all Hazardous Materials, other than: (A) any material or substance located in the Building or the Property on the Execution Date which, as of the Execution Date, is not considered under then existing Legal Requirements, to be Hazardous Material, but which is subsequently determined to be a Hazardous Material by reason of a Legal Requirement which first becomes effective after the Execution Date of this Lease, and (B) any material or substance that is introduced to the Building or the Property after the Execution Date which, when introduced to the Building or the Property, is not then (i.e., at the time of introduction to the Building or the Property) considered, as a matter of any Legal Requirement, to be a Hazardous Material, but which is subsequently determined to be a Hazardous Material by reason of Legal Requirements which first becomes effective after the date of introduction of such material or substance to the Building or Property, (xix) interest and penalties incurred as a result of Landlord's late payment of Taxes or utility bills, (xx) fines and penalties incurred by Landlord in connection with any building code violation, to the extent the condition which gave rise to such building code violation existed prior to the Term Commencement Date, (xxi) costs incurred by Landlord in connection with a breach by Landlord or by another tenant of such tenant's lease, (xxii) charitable contributions and donations, (xxiii) costs incurred by Landlord in connection with the enforcement of the obligations or liabilities of other tenants in the Building or Property, (xxiv) income taxes paid by Landlord, and (xxv) all other items for which another party compensates Landlord so that Landlord shall not recover for any item more than once.

(d) **Payment of Operating Costs**. Commencing as of the Term Commencement Date and continuing thereafter throughout the remainder of the Term of the Lease, Tenant shall pay to Landlord, as Additional Rent, Tenant's Share of Operating Costs. Landlord may make a good faith estimate of Tenant's Share of Operating Costs for any fiscal year or part thereof during the Term, and Tenant shall pay to Landlord, on the Rent Commencement Date and on the first (1st) day of each calendar month thereafter, an amount equal to Tenant's Share of Operating Costs for such fiscal year and/or part thereof divided by the number of months therein. Landlord may estimate and re-estimate Tenant's Share of Operating Costs and deliver a copy of the estimate or re-estimate to Tenant. Thereafter, the monthly installments of Tenant's Share of Operating Costs shall be appropriately adjusted in accordance with the estimations so that, by the end of the fiscal year in question, Tenant shall have paid all of Tenant's Share of Operating Costs as estimated by Landlord. Any amounts paid based on such an estimate shall be subject to adjustment as herein provided when actual Operating Costs are available for each fiscal year. As of the Execution Date, the Property's fiscal year is January 1 – December 31.

(e) **Annual Reconciliation**. Landlord shall, within one hundred twenty (120) days after the end of each fiscal year, deliver to Tenant a reasonably detailed statement of the actual amount of Operating Costs for such fiscal year ("**Year End Statement**"). Failure of Landlord to provide the Year End Statement within the time prescribed shall not relieve Tenant from its obligations hereunder. If the total of such monthly remittances on account of any fiscal year is greater than Tenant's Share of Operating Costs actually incurred for such fiscal year, then, provided no Event of Default has occurred nor any event which, with the passage of time and/or the giving of notice would constitute an Event of Default, Tenant may credit the difference against the next installment of Additional Rent on account of Operating Costs due hereunder, except that if such difference is determined after the end of the Term, Landlord shall refund such difference to Tenant within thirty (30) days after such determination to the extent that such difference exceeds any amounts then due from Tenant to Landlord. If the total of such remittances is less than Tenant's Share of Operating Costs actually incurred for such fiscal year, Tenant shall pay the difference to Landlord, as Additional Rent hereunder, within thirty (30) days of Tenant's receipt of an invoice therefor. Landlord's estimate of Operating Costs for the next fiscal year shall be based upon the Operating Costs actually incurred for the prior fiscal year as reflected in the Year-End Statement plus a reasonable adjustment based upon estimated increases in Operating Costs. The provisions of this Section 5.2(d) shall survive the expiration or earlier termination of this Lease.

(f) **Part Years**. If the Rent Commencement Date or the Expiration Date occurs in the middle of a calendar year, Tenant shall be liable for only that portion of the Operating Costs with respect to such calendar year within the Term.

(g) **Gross-Up**. If, during any fiscal year, less than 95% of the Building is occupied by tenants or if Landlord was not supplying all tenants with the services being supplied to Tenant hereunder, actual Operating Costs incurred shall be reasonably extrapolated by Landlord on an item-by-item basis to the reasonable Operating Costs that would have been incurred if the Building was 95% occupied and such services were being supplied to all tenants, and such extrapolated Operating Costs shall, for all purposes hereof, be deemed to be the Operating Costs for such fiscal year. This "gross up" treatment shall be applied only with respect to variable Operating Costs arising from services provided to Common Areas or to space in the Building being occupied by tenants (which services are not provided to vacant space or may be provided only to some tenants) in order to allocate equitably such variable Operating Costs to the tenants receiving the benefits thereof.

(h) **Audit Right**. The Year End Statement shall be final and binding upon Tenant unless Tenant, within ninety (90) days after Tenant's receipt thereof, shall contest any item therein by giving written notice to Landlord, specifying each item contested and the reason therefor. Upon the timely delivery of such written notice by Tenant, and provided there is no Event of Default nor any event which, with the passage of time and/or the giving of notice would constitute an Event of Default, Landlord will provide Tenant with access to Landlord's books and records relating to Landlord's calculation of Operating Costs for any periods of time within the previous fiscal year before the audit or inspection. However, no audit or inspection shall extend to periods of time before the Rent Commencement Date. If Tenant fails to object to the calculation of Tenant's Share of Operating Costs on the Year-End Statement within ninety (90) days after such statement has been delivered to Tenant and/or fails to complete any such audit or inspection within ninety (90) days after receipt of the Year End Statement, then Tenant shall be deemed to

have waived its right to object to the calculation of Tenant's Share of Operating Costs for the year in question and the calculation thereof as set forth on such statement shall be final. Tenant's audit or inspection shall be conducted only at Landlord's offices or the offices of Landlord's property manager during business hours reasonably designated by Landlord. Tenant shall pay the cost of such audit or inspection. Tenant may not conduct an inspection or have an audit performed more than once during any fiscal year. If such inspection or audit reveals an underpayment by Tenant, then Tenant shall pay to Landlord, as Additional Rent hereunder, any underpayment of any such costs, as the case may be, within thirty (30) days after receipt of an invoice therefor. If such inspection and audit reveal that Landlord has overstated Operating Costs, then Landlord shall credit the discrepancy to Tenant against Tenant's next payment(s) of the applicable Additional Rent. In the event such inspection and audit reveal that Landlord has overstated Operating Costs by more than five (5) percent, then, in addition to a credit or refund to Tenant of the amount overcharged, Landlord shall reimburse Tenant for the reasonable out-of-pocket cost of said audit. In the event the Landlord disagrees in good faith with the results of the audit, Landlord shall notify Tenant within fifteen (15) days of the audit, and Landlord and Tenant shall mutually select a neutral third party to evaluate the charges for Tenant's Share of Operating Costs, and the results of such third party's evaluation shall bind Landlord and Tenant and shall be final. Costs charged by any such third party shall be shared equally by Landlord and Tenant. Tenant shall maintain the results of any such audit or inspection confidential and shall not be permitted to use any third party to perform such audit or inspection, other than an independent firm of certified public accountants (A) reasonably acceptable to Landlord, (B) which is not compensated on a contingency fee basis or in any other manner which is dependent upon the results of such audit or inspection, and (C) which executes Landlord's standard confidentiality agreement whereby it shall agree to maintain the results of such audit or inspection confidential. The provisions of this Section 5.2(h) shall survive the expiration or earlier termination of this Lease.

5.3 Taxes.

(a) "**Taxes**" shall mean the real estate taxes and other taxes, levies and assessments imposed upon the Unit of the Condominium in which the Building and the Land are located (the "**Unit**") and upon any personal property of Landlord used in the operation thereof, or on Landlord's interest therein or such personal property; charges, fees and assessments for transit, housing, police, fire or other services or purported benefits to the Building and the Land (including without limitation any community preservation assessments); service or user payments in lieu of taxes; and any and all other taxes, levies, betterments, assessments and charges arising from the ownership, leasing, operation, use or occupancy of the Building and the Land or based upon rentals derived therefrom, which are or shall be imposed by federal, state, county, municipal or other governmental authorities. Taxes shall not include any inheritance, estate, succession, gift, franchise, rental, income or profit tax, capital stock tax, capital levy or excise, or any income taxes arising out of or related to the ownership and operation of the Unit, provided, however, that any of the same and any other tax, excise, fee, levy, charge or assessment, however described, that may in the future be levied or assessed as a substitute for or an addition to, in whole or in part, any tax, levy or assessment which would otherwise constitute Taxes, whether or not now customary or in the contemplation of the parties on the Execution Date of this Lease, shall constitute Taxes, but only to the extent calculated as if the Unit were the only real estate owned by Landlord. "Taxes" shall also include reasonable expenses (including without limitation legal and consultant fees) of tax abatement or other proceedings contesting assessments or levies.

Landlord shall allocate Taxes which are incurred with respect to the Common Areas of the Campus on a reasonable basis. From and after substantial completion of any occupiable improvements constructed as part of a Future Development, if such improvements are not separately assessed, Landlord shall reasonably allocate Taxes between the Building and such improvements and the land area associated with the same. From and after the creation of the Condominium for the Campus, such allocation shall be effected based upon the Taxes payable by Landlord with respect to the unit in the Condominium in which the Property is located.

(b) "**Tax Period**" shall be any fiscal/tax period in respect of which Taxes are due and payable to the appropriate governmental taxing authority (i.e., as mandated by the governmental taxing authority), any portion of which period occurs during the Term of this Lease.

(c) **Payment of Taxes**. Commencing as of the Term Commencement Date and continuing thereafter throughout the remainder of the Term of the Lease, Tenant shall pay to Landlord, as Additional Rent, Tenant's Share of Taxes. Landlord may make a good faith estimate of the Taxes to be due by Tenant for any Tax Period or part thereof during the Term, and Tenant shall pay to Landlord, on the Rent Commencement Date and on the first (1st) day of each calendar month thereafter, an amount equal to Tenant's Share of Taxes for such Tax Period or part thereof divided by the number of months therein. Landlord may estimate and re-estimate Tenant's Share of Taxes and deliver a copy of the estimate or re-estimate to Tenant. Thereafter, the monthly installments of Tenant's Share of Taxes shall be appropriately adjusted in accordance with the estimations so that, by the end of the Tax Period in question, Tenant shall have paid all of Tenant's Share of Taxes as estimated by Landlord. Any amounts paid based on such an estimate shall be subject to adjustment as herein provided when actual Taxes are available for each Tax Period. If the total of such monthly remittances is greater than Tenant's Share of Taxes actually due for such Tax Period, then, provided no Event of Default has occurred nor any event which, with the passage of time and/or the giving of notice would constitute an Event of Default, Tenant may credit the difference against the next installment of Additional Rent on account of Taxes due hereunder, except that if such difference is determined after the end of the Term, Landlord shall refund such difference to Tenant within thirty (30) days after such determination to the extent that such difference exceeds any amounts then due from Tenant to Landlord. If the total of such remittances is less than Tenant's Share of Taxes actually due for such Tax Period, Tenant shall pay the difference to Landlord, as Additional Rent hereunder, within thirty (30) days of Tenant's receipt of an invoice therefor. Landlord's estimate for the next Tax Period shall be based upon actual Taxes for the prior Tax Period plus a reasonable adjustment based upon estimated increases in Taxes. The provisions of this Section 5.3(c) shall survive the expiration or earlier termination of this Lease.

(d) **Effect of Abatements**. Appropriate credit against Taxes shall be given for any refund obtained by reason of a reduction in any Taxes by the assessors or the administrative, judicial or other governmental agency responsible therefor after deduction of Landlord's expenditures for reasonable legal fees and for other reasonable expenses incurred in obtaining the Tax refund.

(e) **Part Years**. If the Rent Commencement Date or the Expiration Date occurs in the middle of a Tax Period, Tenant shall be liable for only that portion of the Taxes, as the case may be, with respect to such Tax Period within the Term.

5.4 Late Payments.

(a) Any payment of Rent due hereunder not paid when due shall bear interest for each month or fraction thereof from the due date until paid in full at the annual rate of twelve percent (12%), or at any applicable lesser maximum legally permissible rate for debts of this nature (the "**Default Rate**").

(b) Additionally, if Tenant fails to make any payment within five (5) days after the due date therefor, Landlord may charge Tenant a fee, which shall constitute liquidated damages, equal to three (3%) of any such late payment. Notwithstanding anything to the contrary in Section 5.4(a) and (b), the first late payment of Rent due in any twelve (12) month period shall not accrue interest at the Default Rate or liquidated damages so long as such payment is made within ten (10) days of notice from Landlord.

(c) For each Tenant payment check to Landlord that is returned by a bank for any reason, Tenant shall pay a returned check charge equal to the amount as shall be customarily charged by Landlord's bank at the time.

(d) Money paid by Tenant to Landlord shall be applied to Tenant's account in the following order: first, to any unpaid Additional Rent, including without limitation late charges, returned check charges, legal fees and/or court costs chargeable to Tenant hereunder; and then to unpaid Base Rent.

(e) The parties agree that the late charge referenced in Section 5.4(b) represents a fair and reasonable estimate of the costs that Landlord will incur by reason of any late payment by Tenant, and the payment of late charges and interest are distinct and separate in that the payment of interest is to compensate Landlord for the use of Landlord's money by Tenant, while the payment of late charges is to compensate Landlord for Landlord's processing, administrative and other costs incurred by Landlord as a result of Tenant's delinquent payments. Acceptance of a late charge or interest shall not constitute a waiver of Tenant's default with respect to the overdue amount or prevent Landlord from exercising any of the other rights and remedies available to Landlord under this Lease or at law or in equity now or hereafter in effect.

(f) If Tenant during any six (6) month period shall be more than five (5) days delinquent in the payment of any installment of Rent on three (3) or more occasions, then, notwithstanding anything herein to the contrary, Landlord may, by written notice to Tenant, elect to require Tenant to pay all Base Rent and Additional Rent on account of Operating Costs and Taxes quarterly in advance. Such right shall be in addition to and not in lieu of any other right or remedy available to Landlord hereunder or at law on account of Tenant's default hereunder.

5.5 No Offset; Independent Covenants; Waiver. Rent shall be paid without notice or demand, and without setoff, counterclaim, defense, abatement, suspension, deferment, reduction or deduction, except as expressly provided herein. **TENANT WAIVES ALL RIGHTS (I) TO ANY ABATEMENT, SUSPENSION, DEFERMENT, REDUCTION OR DEDUCTION OF OR FROM RENT, AND (II) TO QUIT, TERMINATE OR SURRENDER THIS LEASE OR THE PREMISES OR ANY PART THEREOF, EXCEPT AS EXPRESSLY PROVIDED HEREIN. TENANT HEREBY ACKNOWLEDGES AND**

AGREES THAT THE OBLIGATIONS OF TENANT HEREUNDER SHALL BE SEPARATE AND INDEPENDENT COVENANTS AND AGREEMENTS, THAT RENT SHALL CONTINUE TO BE PAYABLE IN ALL EVENTS AND THAT THE OBLIGATIONS OF TENANT HEREUNDER SHALL CONTINUE UNAFFECTED, UNLESS THE REQUIREMENT TO PAY OR PERFORM THE SAME SHALL HAVE BEEN TERMINATED PURSUANT TO AN EXPRESS PROVISION OF THIS LEASE. LANDLORD AND TENANT EACH ACKNOWLEDGES AND AGREES THAT THE INDEPENDENT NATURE OF THE OBLIGATIONS OF TENANT HEREUNDER REPRESENTS FAIR, REASONABLE, AND ACCEPTED COMMERCIAL PRACTICE WITH RESPECT TO THE TYPE OF PROPERTY SUBJECT TO THIS LEASE, AND THAT THIS AGREEMENT IS THE PRODUCT OF FREE AND INFORMED NEGOTIATION DURING WHICH BOTH LANDLORD AND TENANT WERE REPRESENTED BY COUNSEL SKILLED IN NEGOTIATING AND DRAFTING COMMERCIAL LEASES IN MASSACHUSETTS, AND THAT THE ACKNOWLEDGEMENTS AND AGREEMENTS CONTAINED HEREIN ARE MADE WITH FULL KNOWLEDGE OF THE HOLDING IN WESSON V. LEONE ENTERPRISES, INC., 437 MASS. 708 (2002). SUCH ACKNOWLEDGEMENTS, AGREEMENTS AND WAIVERS BY TENANT ARE A MATERIAL INDUCEMENT TO LANDLORD ENTERING INTO THIS LEASE.

5.6 Survival. Any obligations under this Section 5 which shall not have been paid at the expiration or earlier termination of the Term shall survive such expiration or earlier termination and shall be paid when and as the amount of same shall be determined and be due, subject to any applicable statute of limitations.

6. INTENTIONALLY OMITTED.

7. LETTER OF CREDIT

7.1 Amount. Contemporaneously with the execution of this Lease, Tenant shall deliver to Landlord either (i) cash in the amount specified in the Lease Summary Sheet (the "**Cash Security Deposit**"), which shall be held by Landlord in accordance with Section 7.5 below, or (ii) an irrevocable letter of credit (the "**Letter of Credit**") that shall (a) be in the initial amount of $622,421.90; (b) be issued on the form attached hereto as Exhibit 6; (c) name Landlord as its beneficiary; (d) be drawn on an FDIC insured financial institution reasonably satisfactory to Landlord that both (x) has an office in the greater Boston metropolitan area that will accept presentation of, and pay against, the Letter of Credit and (y) satisfies both the Minimum Rating Agency Threshold and the Minimum Capital Threshold (as those terms are defined below). The "**Minimum Rating Agency Threshold**" shall mean that the issuing bank has outstanding unsecured, uninsured and unguaranteed senior long-term indebtedness that is then rated (without regard to qualification of such rating by symbols such as "+" or "-" or numerical notation) "Baa" or better by Moody's Investors Service, Inc. and/or "BBB" or better by Standard & Poor's Rating Services, or a comparable rating by a comparable national rating agency designated by Landlord in its discretion. The "**Minimum Capital Threshold**" shall mean that the issuing bank has combined capital, surplus and undivided profits of not less than $10,000,000,000. The Letter of Credit (and any renewals or replacements thereof) shall be for a term of not less than one (1) year. If the issuer of the Letter of Credit gives notice of its election not to renew such Letter of Credit

for any additional period, Tenant shall be required to deliver a substitute Letter of Credit satisfying the conditions hereof at least thirty (30) days prior to the expiration of the term of such Letter of Credit. If the issuer of the Letter of Credit fails to satisfy either or both of the Minimum Rating Agency Threshold or the Minimum Capital Threshold, Tenant shall be required to deliver a substitute letter of credit from another issuer reasonably satisfactory to the Landlord and that satisfies both the Minimum Rating Agency Threshold and the Minimum Capital Threshold not later than ten (10) business days after Landlord notifies Tenant of such failure. Tenant agrees that it shall from time to time, as necessary, whether as a result of a draw on the Letter of Credit by Landlord pursuant to the terms hereof or as a result of the expiration of the Letter of Credit then in effect, renew or replace the original and any subsequent Letter of Credit so that a Letter of Credit, in the amount required hereunder, is in effect until a date which is at least ninety (90) days after the Expiration Date. If Tenant fails to furnish such renewal or replacement at least sixty (60) days prior to the stated expiration date of the Letter of Credit then held by Landlord, Landlord may draw upon such Letter of Credit and hold the proceeds thereof (and such proceeds need not be segregated) as a Security Deposit pursuant to the terms of this Article 7 until such time as a renewal or replacement Letter of Credit is furnished. Any renewal or replacement of the original or any subsequent Letter of Credit shall meet the requirements for the original Letter of Credit as set forth above, except that such replacement or renewal shall be issued by a national bank reasonably satisfactory to Landlord at the time of the issuance thereof.

7.2 Application of Proceeds of Letter of Credit. Upon an Event of Default, or if any proceeding shall be instituted by or against Tenant pursuant to any of the provisions of any Act of Congress or State law relating to bankruptcy, reorganizations, arrangements, compositions or other relief from creditors (and, in the case of any proceeding instituted against it, if Tenant shall fail to have such proceedings dismissed within thirty (30) days) or if Tenant is adjudged bankrupt or insolvent as a result of any such proceeding, Landlord at its sole option may draw down all or a part of the Letter of Credit. The balance of any Letter of Credit cash proceeds shall be held in accordance with Section 7.5 below. Should the entire Letter of Credit, or any portion thereof, be drawn down by Landlord, Tenant shall, upon the written demand of Landlord, deliver a replacement Letter of Credit in the amount drawn, and Tenant's failure to do so within ten (10) days after receipt of such written demand shall constitute an additional Event of Default hereunder. The application of all or any part of the cash proceeds of the Letter of Credit to any obligation or default of Tenant under this Lease shall not deprive Landlord of any other rights or remedies Landlord may have nor shall such application by Landlord constitute a waiver by Landlord.

7.3 Transfer of Letter of Credit. In the event that Landlord transfers its interest in the Premises, Tenant shall upon notice from and at no cost to Landlord, deliver to Landlord an amendment to the Letter of Credit or a replacement Letter of Credit naming Landlord's successor as the beneficiary thereof. If Tenant fails to deliver such amendment or replacement within ten (10) days after written notice from Landlord, Landlord shall have the right to draw down the entire amount of the Letter of Credit and hold the proceeds thereof in accordance with Section 7.5 below.

7.4 Cash Proceeds of Letter of Credit. Landlord shall hold the balance of proceeds remaining after a draw on the Letter of Credit (each hereinafter referred to as the "**Security Deposit**") as security for Tenant's performance of all its Lease obligations. After an Event of Default, Landlord may apply the Security Deposit, or any part thereof, to Landlord's damages without prejudice to any other Landlord remedy. Landlord has no obligation to pay interest on the

Security Deposit and may co-mingle the Security Deposit with Landlord's funds. If Landlord conveys its interest under this Lease, the Security Deposit, or any part not applied previously, may be turned over to the grantee in which case Tenant shall look solely to the grantee for the proper application and return of the Security Deposit.

7.5 Return of Security Deposit or Letter of Credit. Should Tenant comply with all of such terms, covenants and conditions and promptly pay all sums payable by Tenant to Landlord hereunder, the Security Deposit and/or Letter of Credit or the remaining proceeds therefrom, as applicable, shall (less any portion thereof which may have been utilized by Landlord to cure any default or applied to any actual damage suffered by Landlord) be returned to Tenant within ninety (90) days after the end of the Term.

8. INTENTIONALLY DELETED.

9. UTILITIES, LANDLORD'S SERVICES

9.1 Electricity. Landlord shall contract with the utility provider for electric service to the Property, including the Premises. Commencing on the Term Commencement Date, Tenant shall pay all charges for electricity furnished to the Premises and any equipment exclusively serving the Premises, as Additional Rent, based on the submeter(s) currently installed in the Premises. At Tenant's request, Landlord shall provide Tenant with reasonable back-up documentation regarding the total charges and the method of allocating the charges to Tenant. Tenant shall, at Tenant's sole cost and expense, maintain and keep in good order, condition and repair the metering equipment used to measure electricity furnished to the Premises and any equipment exclusively serving the same.

9.2 Water. Landlord shall contract with the utility provider for water service to the Property, including the Premises. Except as otherwise provided below, the cost of providing water service to the Premises and all other portions of the Building (including, without limitation, the premises of other tenants or occupants of the Building) shall be included in Operating Costs. Notwithstanding the foregoing, if Landlord determines that Tenant is using water in excess of its proportionate share (by floor area) of the total water usage in the Building, Landlord may elect, at Tenant's expense, to furnish and install in a location in or near the Premises metering equipment to measure water furnished to the Premises and any equipment exclusively serving the same. In such event, Tenant shall, within thirty (30) days after Landlord's written demand therefor from time to time, pay to Landlord, as Additional Rent, the full amount of any water service charges attributable to such meter.

9.3 Gas. Landlord shall contract with the utility provider for gas service to the Property, including the Premises. The cost of gas used to serve base building plumbing, mechanical and electrical systems shall be included in the costs reimbursed by Tenant pursuant to Section 9.6 below. If Tenant requires gas service for the operation of Tenant's laboratory equipment in the Premises, Tenant shall pay all charges for gas furnished to the Premises and/or any equipment exclusively serving the Premises as Additional Rent, based, at Landlord's election, (i) on Landlord's reasonable estimate of such gas usage or (ii) on metering or submetering equipment installed by Landlord at Tenant's expense.

9.4 Other Utilities. Subject to Landlord's reasonable rules and regulations governing the same, Tenant shall obtain and pay, as and when due, for all other utilities and services consumed in and/or furnished to the Premises, together with all taxes, penalties, surcharges and maintenance charges pertaining thereto.

9.5 Interruption or Curtailment of Utilities. When necessary by reason of accident or emergency, or for repairs, alterations, replacements or improvements which in the reasonable judgment of Landlord are desirable or necessary to be made, Landlord reserves the right, upon as much prior notice to Tenant as is practicable under the circumstances and no less than twenty-four (24) hours' notice except in the event of an emergency, to interrupt, curtail, or stop (i) the furnishing of hot and/or cold water, and (ii) the operation of the plumbing and electric systems. Landlord shall exercise reasonable diligence to eliminate the cause of any such interruption, curtailment, stoppage or suspension, but, except as set forth in Section 10.7, there shall be no diminution or abatement of Rent or other compensation due from Landlord to Tenant hereunder, nor shall this Lease be affected or any of Tenant's obligations hereunder reduced, and Landlord shall have no responsibility or liability for any such interruption, curtailment, stoppage, or suspension of services or systems.

9.6 Landlord's Services. Subject to reimbursement pursuant to Section 5.2 above, Landlord shall provide the services described in Exhibit 7 attached hereto and made a part hereof ("**Landlord's Services**"). Except for the cost of providing and maintaining supplemental HVAC equipment (which shall be Tenant's responsibility), all costs incurred in connection with the provision of Landlord's Services shall be included in Operating Costs. Landlord shall allocate to the Premises a portion of the total amount of such costs incurred with respect to the Building based upon the cubic footage of heated, chilled, and fresh air distributed in the Premises as indicated by the energy management system serving the Building as a percentage of the aggregate cubic footage of heated, chilled, and fresh air distributed in the entire Building for the applicable period. Tenant shall pay such costs monthly, together with monthly installments of Base Rent, on an estimated basis in amounts from time to time reasonably determined by Landlord. After the close of each fiscal year, Landlord shall determine the actual amount of such costs for such year and deliver to Tenant a reasonably detailed statement thereof, together with a statement of the amounts paid by Tenant on an estimated basis toward such costs as aforesaid. If such statement indicates that the estimated amounts paid by Tenant are less than Tenant's allocable share of the actual amount of such costs for such fiscal year, then Tenant shall pay the amount of such shortfall to Landlord within thirty (30) days after delivery of such statement. If such statement indicates that Tenant's estimated payments for such year exceed the actual amount of such costs for such year, then Landlord shall credit the excess against the next due installment(s) of Additional Rent payable under this Section 9.6.

9.7 Backup Generator. Reference is made to the fact the Building is served by a 400 kw 480/277 3 phase 4 wire ("**Existing Generator Capacity**") emergency generator (the "**Existing Generator**"). Tenant shall have the right, subject to obtaining Landlord's prior written approval, which approval shall not be unreasonably withheld, conditioned or delayed, to connect its equipment in the Premises to the Existing Generator, provided that the aggregate electrical demand of all equipment connected by Tenant to the Existing Generator at any time shall not exceed 80kW. Landlord's sole obligation to Tenant with respect to the Existing Generator shall be to contract with a reputable third party ("**Generator Servicer**") to maintain the Existing Generator as per the

manufacturer's standard maintenance guidelines. Landlord shall have no obligation to supervise, oversee or confirm that the Generator Servicer is maintaining the Existing Generator per the manufacturer's standard guidelines or otherwise, and Landlord shall have no obligation or liability to Tenant in the event that the Existing Generator is not operational.

10. MAINTENANCE AND REPAIRS

10.1 Maintenance and Repairs by Tenant. Tenant shall keep neat and clean and free of insects, rodents, vermin and other pests and in good repair, order and condition (reasonable wear and tear and damage by Casualty excepted): the Premises, including without limitation the entire interior of the Premises, all electronic, phone and data cabling and related equipment (other than building service equipment) that is installed by or for the exclusive benefit of the Tenant (whether located in the Premises or other portions of the Building), all fixtures, equipment and specialty lighting therein, any supplemental HVAC and humidification equipment exclusively serving the Premises, electrical equipment wiring, doors, non-structural walls, windows and floor coverings, and all laboratory specific systems and equipment that exclusively serve the Premises, including, without limitation, equipment critical to laboratory operations. Without limiting the foregoing, Tenant agrees that it shall maintain in the same repair, order, and condition as on the Term Commencement Date (reasonable wear and tear and damage by Casualty excepted) any equipment which is the responsibility for Tenant to maintain as set forth on Exhibit 4-3.

10.2 Maintenance and Repairs by Landlord. Except as otherwise provided in Section 15, and subject to Tenant's obligations in Section 10.1 above, Landlord shall maintain and keep in reasonable condition the Building foundation, the roof, Building structure, the common mechanical systems serving the Building, the structural floor slabs and columns in good repair, order and condition. In addition, Landlord shall operate and maintain the Common Areas in substantially the same manner as comparable combination office and laboratory facilities in the vicinity of the Premises. All costs incurred by Landlord under this Section 10.2 shall be included in Operating Costs, subject to, and in accordance with Section 5.2.

10.3 Accidents to Sanitary and Other Systems. Tenant shall give to Landlord prompt notice of any fire or accident in the Premises or in the Building and of any damage to, or defective condition in, any part or appurtenance of the Building including, without limitation, sanitary, electrical, ventilation, heating and air conditioning or other systems located in, or passing through, the Premises. Except as otherwise provided in Section 15, and subject to Tenant's obligations in Section 10.1 above, such damage or defective condition shall be remedied by Landlord with reasonable diligence, but, subject to Section 14.5 below, if such damage or defective condition was caused by any of the Tenant Parties, the cost to remedy the same shall be paid by Tenant.

10.4 Floor Load--Heavy Equipment. Tenant shall not place a load upon any floor of the Premises exceeding the floor load per square foot of area which such floor was designed to carry, and which is allowed by Legal Requirements. Landlord reserves the right to prescribe the weight and position of all safes, heavy machinery, heavy equipment, freight, bulky matter or fixtures (collectively, "**Heavy Equipment**"), which shall be placed so as to distribute the weight. Heavy Equipment shall be placed and maintained by Tenant at Tenant's expense in settings sufficient in Landlord's reasonable judgment to absorb and prevent vibration, noise and annoyance. Tenant shall not move any Heavy Equipment into or out of the Building without giving

Landlord prior written notice thereof and observing all of Landlord's Rules and Regulations with respect to the same. If such Heavy Equipment requires special handling, Tenant agrees to employ only persons holding a Master Rigger's License to do said work, and that all work in connection therewith shall comply with Legal Requirements. Any such moving shall be at the sole risk and hazard of Tenant and Tenant will defend, indemnify and save Landlord and Landlord's agents (including without limitation its property manager), contractors and employees (collectively with Landlord, the "**Landlord Parties**") harmless from and against any and all claims, damages, losses, penalties, costs, expenses and fees (including without limitation reasonable legal fees) (collectively, "**Claims**") resulting directly or indirectly from such moving, except if caused by Landlord's negligence. Proper placement of all Heavy Equipment in the Premises shall be Tenant's responsibility.

10.5 Premises Cleaning. Tenant shall be responsible, at its sole cost and expense, for janitorial and removing trash from the Premises to the common dumpster designated by Landlord and for providing biohazard disposal services for the Premises, including the laboratory areas thereof. Such services shall be performed by licensed (where required by law or governmental regulation), insured and qualified contractors approved in advance, in writing, by Landlord (which approval shall not be unreasonably withheld, delayed or conditioned) and on a sufficient basis to ensure that the Premises are at all times kept neat and clean. Landlord shall provide a dumpster and/or compactor at the Building loading dock for Tenant's disposal of non-hazardous and non-controlled substances.

10.6 Pest Control. Tenant, at Tenant's sole cost and expense, shall cause the Premises to be exterminated to Landlord's reasonable satisfaction and shall cause all portions of the Premises used for the storage, preparation, service or consumption of food or beverages to be cleaned daily in a manner reasonably satisfactory to Landlord, and to be treated against infestation by insects, rodents and other vermin and pests whenever there is evidence of any infestation. Tenant shall not permit any person to enter the Premises for the purpose of providing such extermination services, unless such persons have been approved by Landlord. If requested by Landlord, Tenant shall, at Tenant's sole cost and expense, store any refuse generated in the Premises by the consumption of food or beverages in a cold box or similar facility.

10.7 Service Interruptions.

(a) Abatement of Rent. In the event that: (i) there shall be an interruption, curtailment or suspension of any service or failure to perform any obligation required to be provided or performed by Landlord pursuant to Sections 9 and/or 10 (and no reasonably equivalent alternative service or supply is provided by Landlord) that shall materially interfere with Tenant's use and enjoyment of the Premises, or any portion thereof (any such event, a "**Service Interruption**"), and (ii) such Service Interruption shall continue for five (5) consecutive business days following receipt by Landlord of written notice (the "**Service Interruption Notice**") from Tenant describing such Service Interruption ("**Abatement Service Interruption Cure Period**"), and (iii) such Service Interruption shall not have been caused by a negligent act or negligent omission of Tenant or Tenant's agents, employees, contractors or invitees (an event that satisfies the foregoing conditions (i)-(iii) being referred to hereinafter as a "**Material Service Interruption**") then, Tenant, subject to the next following sentence, shall be entitled to an equitable abatement of Base Rent, Operating Costs and Taxes based on the nature and duration of

the Material Service Interruption and the area of the Premises affected, for any and all days following the Material Service Interruption Cure Period that both (x) the Material Service Interruption is continuing and (y) Tenant does not use such affected areas of the Premises for a bona fide business purpose. Any efforts by Tenant to respond or react to any Material Service Interruption, including, without limitation, any activities by Tenant to remove its personal property from the affected areas of the Premises, shall not constitute a use that precludes abatement pursuant to this Section 10.7(a). The Abatement Service Interruption Cure Period shall be extended by reason of any delays in Landlord's ability to cure the Service Interruption in question caused by Landlord's Force Majeure, provided however, that in no event shall the extension of the Abatement Service Interruption Cure Period resulting from Force Majeure with respect to any Service Interruption exceed fifteen (15) consecutive business days.

(b) The provisions of this Section 10.7 shall not apply in the event of a Service Interruption caused by Casualty or Taking (see Section 15 below).

(c) The provisions of this Section 10.7 set forth Tenant's sole rights and remedies, both in law and in equity, in the event of any Service Interruption.

11. ALTERATIONS AND IMPROVEMENTS BY TENANT

11.1 Landlord's Consent Required. Tenant shall not make any alterations, decorations, installations, removals, additions or improvements (collectively with Tenant's Work, "**Alterations**") in or to the Premises without Landlord's prior written approval of the contractor(s), written plans and specifications and a time schedule therefor. Landlord reserves the right to require that Tenant use Landlord's preferred vendor(s) for any Alterations that involve roof penetrations, alarm tie-ins, sprinklers, fire alarm and other life safety equipment. Tenant shall not make any amendments or additions to plans and specifications approved by Landlord without Landlord's prior written consent. Landlord's approval of non-structural Alterations shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, Landlord may withhold its consent in its sole discretion (a) to any Alteration to or affecting the fixed lab benches, fume hoods, roof and/or building systems, (b) with respect to matters of aesthetics relating to Alterations to or affecting the exterior of the Building, and (c) to any Alteration affecting the Building structure. Tenant shall be responsible for all elements of the design of Tenant's plans (including, without limitation, compliance with Legal Requirements, functionality of design, the structural integrity of the design, the configuration of the Premises and the placement of Tenant's furniture, appliances and equipment), and Landlord's approval of Tenant's plans shall in no event relieve Tenant of the responsibility for such design. In seeking Landlord's approval, Tenant shall provide Landlord, at least fourteen (14) business days in advance of any proposed construction, with plans, specifications, bid proposals, certified stamped engineering drawings and calculations by Tenant's engineer of record or architect of record (including connections to the Building's structural system, the Building's mechanical, electrical and plumbing systems, modifications to the Building's envelope, non-structural penetrations in slabs or walls, and modifications or tie-ins to life safety systems), work contracts, requests for laydown areas and such other information concerning the nature and cost of the Alterations as Landlord may reasonably request. Landlord shall have no liability or responsibility for any claim, injury or damage alleged to have been caused by the particular materials (whether building standard or non-building standard), appliances or equipment selected by Tenant in connection with any work performed by or on behalf of Tenant. Except as

otherwise expressly set forth herein, all Alterations shall be done at Tenant's sole cost and expense and at such times and in such manner as Landlord may from time to time reasonably designate. If Tenant shall make any Alterations, then Landlord shall advise Tenant contemporaneously with Landlord's approval of such Alterations whether Landlord will require said Alterations to be removed at the expiration or sooner termination of the Term, and whether Tenant will be required to restore the Premises to substantially the same condition as existed immediately prior to the Alterations in question, upon which Tenant will rely in determining whether to make said Alterations. Tenant shall provide Landlord with reproducible record drawings (in CAD format) of all Alterations within sixty (60) days after completion thereof.

11.2 After-Hours. Landlord and Tenant recognize that to the extent Tenant elects to perform some or all of the Alterations during times other than normal construction hours (i.e., Monday-Friday, 7:00 a.m. to 3:00 p.m., excluding holidays), Landlord may need to make arrangements to have supervisory personnel on site. Accordingly, Landlord and Tenant agree as follows: Tenant shall give Landlord at least two (2) business days' prior written notice of any time outside of normal construction hours when Tenant intends to perform any Alterations (the "**After-Hours Work**"). Tenant shall reimburse Landlord, within ten (10) days after demand therefor, for the out-of-pocket cost of Landlord's supervisory personnel overseeing the After-Hours Work. In addition, if construction during normal construction hours unreasonably disturbs other tenants of the Building, in Landlord's sole discretion, Landlord may require Tenant to stop the performance of Alterations during normal construction hours and to perform the same after hours, subject to the foregoing requirement to pay for the cost of Landlord's supervisory personnel.

11.3 Harmonious Relations. Tenant agrees that it will not, either directly or indirectly, use any contractors and/or materials if their use will create any difficulty, whether in the nature of a labor dispute or otherwise, with other contractors and/or labor engaged by Tenant or Landlord or others in the construction, maintenance and/or operation of the Building, the Property or any part thereof. In the event of any such difficulty, upon Landlord's reasonable request, Tenant shall cause all contractors, mechanics or laborers causing such difficulty to leave the Property within twenty-four (24) hours of its receipt of such request.

11.4 Liens. No Alterations shall be undertaken by Tenant until (i) Tenant has made provision for written waiver of liens from all contractors for such Alteration and taken other appropriate protective measures approved and/or required by Landlord; and (ii) Tenant has procured appropriate surety payment and performance bonds which shall name Landlord as an additional obligee and has filed lien bond(s) (in jurisdictions where available) on behalf of such contractors. Any mechanic's lien filed against the Premises or the Building for work claimed to have been done for, or materials claimed to have been furnished to, Tenant shall be discharged by Tenant within ten (10) days thereafter, at Tenant's expense by filing the bond required by law or otherwise.

11.5 General Requirements. Unless Landlord and Tenant otherwise agree in writing, Tenant shall (a) procure or cause others to procure on its behalf all necessary permits before undertaking any Alterations in the Premises (and provide copies thereof to Landlord); (b) perform all of such Alterations in a good and workmanlike manner, employing materials of good quality and in compliance with Landlord's construction rules and regulations, all insurance requirements of this Lease, and Legal Requirements; and (c) defend, indemnify and hold the Landlord Parties harmless from and against any and all Claims occasioned by or growing out of such Alterations.

12. SIGNAGE

12.1 Restrictions. Tenant shall have the right to install Building standard signage identifying Tenant's business at the entrance to the Premises, which signage shall be subject to Landlord's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed). Subject to the foregoing, and subject to Section 12.2 below, Tenant shall not place or suffer to be placed or maintained on the exterior of the Premises, or any part of the interior visible from the exterior thereof, any sign, banner, advertising matter or any other thing of any kind (including, without limitation, any hand-lettered advertising), and shall not place or maintain any decoration, letter or advertising matter on the glass of any window or door of the Premises without first obtaining Landlord's written approval. No signs may be put on or in any window or elsewhere if visible from the exterior of the Building.

12.2 Exterior Signage.

(a) Monument Signage. Subject to the provisions of this Section 12.2, for so long as: (x) there is no Event of Default of Tenant and (y) the Lease is in full force and effect (the "**Monument Signage Condition**"), then Tenant shall have the right to require Landlord (i) to list, at Landlord's initial cost and expense, Tenant's name ("**Tenant's Monument Signage**") on the existing exterior monument sign (the "**Monument Sign**") serving the Property during the initial Term of the Lease, and any extensions thereof, subject to the provisions of this Section 12.2. The parties hereby agree that the maintenance and removal of such Tenant's Monument Signage (including, without limitation, the repair and cleaning of the existing monument façade upon removal of Tenant's Monument Signage) shall be performed at Landlord's sole cost and expense, except that Tenant shall be responsible for the cost of any change in Tenant's Monument Signage during the initial Term of the lease.

12.3 Building Directory.

Landlord shall list Tenant within the directory in the Building lobby. The initial listing shall be at Landlord's cost and expense, and any changes to such directory listing shall be at Tenant's cost and expense.

13. ASSIGNMENT, MORTGAGING AND SUBLETTING

13.1 Landlord's Consent Required. Tenant shall not mortgage or encumber this Lease or in whole or in part whether at one time or at intervals, operation of law or otherwise. Except as expressly otherwise set forth herein, Tenant shall not, without Landlord's prior written consent, assign, sublet, license or transfer this Lease or the Premises in whole or in part whether by changes in the ownership or control of Tenant, or any direct or indirect owner of Tenant, whether at one

time or at intervals, by sale or transfer of stock, partnership or beneficial interests, operation of law or otherwise, or permit the occupancy of all or any portion of the Premises by any person or entity other than Tenant's employees (each of the foregoing, a "**Transfer**"). Any purported Transfer made without Landlord's consent, if required hereunder, shall be void and confer no rights upon any third person, provided that if there is a Transfer, Landlord may collect rent from the transferee without waiving the prohibition against Transfers, accepting the transferee, or releasing Tenant from full performance under this Lease. In the event of any Transfer in violation of this Section 13, Landlord shall have the right to terminate this Lease upon thirty (30) days' written notice to Tenant given within sixty (60) days after receipt of written notice from Tenant to Landlord of any completed Transfer, or within one (1) year after Landlord first learns of the completed Transfer if no notice is given. No Transfer shall relieve Tenant of its primary obligation as party Tenant hereunder, nor shall it reduce or increase Landlord's obligations under this Lease.

13.2 Landlord's Recapture Right.

Subject to Section 13.7 below, Tenant shall, prior to offering or advertising the Premises or any portion thereof for a Transfer, give a written notice (the "**Recapture Notice**") to Landlord which: (i) states that Tenant desires to make a Transfer, (ii) identifies the affected portion of the Premises (the "**Recapture Premises**"), (iii) identifies the period of time (the "**Recapture Period**") during which Tenant proposes to sublet the Recapture Premises, or indicates that Tenant proposes to assign its interest in this Lease, and (iv) offers to Landlord to terminate this Lease with respect to the Recapture Premises (in the case of a proposed assignment of Tenant's interest in this Lease or a subletting for the remainder of the Term of this Lease) or to suspend the Term for the Recapture Period (i.e. the Term with respect to the Recapture Premises shall be terminated during the Recapture Period and Tenant's rental obligations shall be proportionately reduced, or, if the Recapture Premises constitutes the entire Premises, fully abated during the Recapture Period). Landlord shall have fifteen (15) business days within which to respond to the Recapture Notice.

13.3 Standard of Consent to Transfer. If Landlord does not timely give written notice to Tenant accepting a Recapture Offer or declines to accept the same, then Landlord agrees that, subject to the provisions of this Section 13, Landlord shall not unreasonably withhold, condition or delay its consent to a Transfer on the terms contained in the Recapture Notice to an entity which will use the Premises for the Permitted Uses and, in Landlord's reasonable opinion: (a) has a tangible net worth not less than Tenant's net worth at the time of the transfer and other financial indicators sufficient to meet the Transferee's obligations under the Transfer instrument in question; (b) has a business reputation compatible with the operation of a first-class combination laboratory, research, development and office building; and (c) the intended use of such entity does not violate any restrictive use provisions then in effect with respect to space in the Building.

13.4 Listing Confers no Rights. The listing of any name other than that of Tenant, whether on the doors of the Premises or on the Building directory, or otherwise, shall not operate to vest in any such other person, firm or corporation any right or interest in this Lease or in the Premises or be deemed to effect or evidence any consent of Landlord, it being expressly understood that any such listing is a privilege extended by Landlord revocable at will by written notice to Tenant.

13.5 Profits in Connection with Transfers. Tenant shall, within thirty (30) days of receipt thereof, pay to Landlord fifty percent (50%) of any rent, sum or other consideration to be paid or given in connection with any Transfer (excluding payments or consideration paid or given for the sale merger or consolidation of Tenant's business in connection with a Permitted Transfer), either initially or over time, after deducting reasonable actual out-of-pocket legal, and brokerage expenses incurred by Tenant and unamortized improvements paid for by Tenant in connection therewith, in excess of Rent hereunder as if such amount were originally called for by the terms of this Lease as Additional Rent.

13.6 Prohibited Transfers. Notwithstanding any contrary provision of this Lease, Tenant shall have no right to make a Transfer unless on both (i) the date on which Tenant notifies Landlord of its intention to enter into a Transfer and (ii) the date on which such Transfer is to take effect, Tenant is not in default of any of its obligations under this Lease beyond the applicable notice and cure period. Notwithstanding anything to the contrary contained herein, Tenant agrees that in no event shall Tenant make a Transfer to (a) any government agency; (b) any tenant, subtenant or occupant of other space in the Building; or (c) any entity with whom Landlord shall have negotiated for space in the Property in the six (6) months immediately preceding such proposed Transfer.

13.7 Exceptions to Requirement for Consent. Notwithstanding anything to the contrary herein contained, Tenant shall have the right, without obtaining Landlord's consent and without giving Landlord a Recapture Notice, to (a) make a Transfer to an Affiliated Entity (hereinafter defined) so long as the transfer to such Affiliated Entity is for legitimate business purposes (and not for the purpose of avoiding the provisions of this Section 13), and (b) assign all of Tenant's interest in and to the Lease to a Successor, provided that prior to or simultaneously with any assignment pursuant to this **Section 13.7**, such Affiliated Entity or Successor, as the case may be, and Tenant execute and deliver to Landlord an assignment and assumption agreement in form and substance reasonably acceptable to Landlord whereby such Affiliated Entity or Successor, as the case may be, shall agree to be independently bound by and upon all the covenants, agreements, terms, provisions and conditions set forth in the Lease on the part of Tenant to be performed, and whereby such Affiliated Entity or Successor, as the case may be, shall expressly agree that the provisions of this **Article 13** shall, notwithstanding such Transfer, continue to be binding upon it with respect to all future Transfers. For the purposes hereof, an "**Affiliated Entity**" shall be defined as any entity which is controlled by, is under common control with, or which controls Tenant. For the purposes hereof, a "**Successor**" shall be defined as any entity into or with which Tenant is merged or with which Tenant is consolidated or reorganized or which acquires all or substantially all of Tenant's stock or assets, provided that the surviving entity shall have a net worth and other financial indicators sufficient to meet Tenant's obligations hereunder. Tenant shall give Landlord at least ten (10) days' prior written notice of ay Permitted Transfer, such notice to include evidence, reasonably satisfactory to Landlord, that the conditions to the Permitted Transfer in question have been satisfied. Transfers to Affiliated Entities and to Successor which are permitted pursuant to this Section 13.7, are referred to collectively herein as "**Permitted Transfers**", and such Affiliated Entities and Successors are referred to herein as "**Permitted Transferees**".

14. INSURANCE; INDEMNIFICATION; EXCULPATION

14.1 Tenant's Insurance.

(a) Tenant shall procure, pay for and keep in force throughout the Term (but in all events commencing on the date on which any Tenant Party first enters the Premises for the performance of any Tenant's Work, and for so long thereafter as Tenant remains in occupancy of the Premises) commercial general liability insurance insuring Tenant on an occurrence basis against all claims and demands for personal injury liability (including, without limitation, bodily injury, sickness, disease, and death) or damage to property which may be claimed to have occurred from and after the time any of the Tenant Parties shall first enter the Premises, of not less than One Million Dollars ($1,000,000) per occurrence and Two Million Dollars ($2,000,000) in the aggregate annually, and from time to time thereafter shall be not less than such higher amounts, if procurable, as may be reasonably required by Landlord. Tenant shall also carry umbrella liability coverage in an amount of no less than Five Million Dollars ($5,000,000). Such policy shall also include contractual liability coverage covering Tenant's liability assumed under this Lease, including without limitation Tenant's indemnification obligations. Such insurance policy(ies) shall name Landlord, Landlord's managing agent and persons claiming by, through or under them, if any, as additional insureds.

(b) Tenant shall take out and maintain throughout the Term a policy of fire, vandalism, malicious mischief, extended coverage and so-called "all risk" coverage insurance in an amount equal to one hundred percent (100%) of the replacement cost insuring (i) all items or components of Alterations (collectively, the "**Tenant-Insured Improvements**"), and (ii) all of Tenant's furniture, equipment, fixtures and property of every kind, nature and description related or arising out of Tenant's leasehold estate hereunder, which may be in or upon the Premises or the Building, including without limitation all of Tenant's animals (collectively, "**Tenant's Property**"). The insurance required to be maintained by Tenant pursuant to this Section 14.1(b) (referred to herein as "**Tenant Property Insurance**") shall insure the interests of both Landlord and Tenant as their respective interests may appear from time to time.

(c) Tenant shall take out and maintain a policy of business interruption insurance throughout the Term sufficient to cover at least twelve (12) months of Rent due hereunder and Tenant's business losses during such 12-month period.

(d) During periods when Tenant's Work and/or any Alterations are being performed, Tenant shall maintain, or cause to be maintained, so-called all risk or special cause of loss property insurance or its equivalent and/or builders risk insurance on 100% replacement cost coverage basis, including hard and soft costs coverages. Such insurance shall protect and insure Landlord, Landlord's agents, Tenant and Tenant's contractors, as their interests may appear, against loss or damage by fire, water damage, vandalism and malicious mischief, and such other risks as are customarily covered by so-called all risk or special cause of loss property / builders risk coverage or its equivalent.

(e) Tenant shall procure and maintain at its sole expense such additional insurance as may be necessary to comply with any Legal Requirements.

(f) Tenant shall cause all contractors and subcontractors to maintain during the performance of any Alterations the insurance described in Exhibit 10 attached hereto.

(g) The insurance required pursuant to Sections 14.1(a), (b), (c), (d) and (e) (collectively, "**Tenant's Insurance Policies**") shall be effected with insurers approved by Landlord, with a rating of not less than "A-XI" in the current *Best's Insurance Reports*, and authorized to do business in the Commonwealth of Massachusetts under valid and enforceable policies. Tenant's Insurance Policies shall each provide that it shall not be canceled or modified without at least thirty (30) days' prior written notice to each insured named therein. Tenant's Insurance Policies may include deductibles in an amount no greater than the greater of $25,000 or commercially reasonable amounts. On or before the date on which any of the Tenant Parties shall first enter the Premises and thereafter not less than fifteen (15) days prior to the expiration date of each expiring policy, Tenant shall deliver to Landlord binders of Tenant's Insurance Policies issued by the respective insurers setting forth in full the provisions thereof together with evidence satisfactory to Landlord of the payment of all premiums for such policies. In the event of any claim, and upon Landlord's request, Tenant shall deliver to Landlord complete copies of Tenant's Insurance Policies. Upon request of Landlord, Tenant shall deliver to any Mortgagee copies of the foregoing documents.

14.2 Indemnification.

(a) Except to the extent caused by the negligence or willful misconduct of any of the Landlord Parties, Tenant shall defend, indemnify and save the Landlord Parties harmless from and against any and all Claims asserted by or on behalf of any person, firm, corporation or public authority arising from:

(i) Tenant's breach of any covenant or obligation under this Lease;

(ii) From and after the Term commencement Date, any injury to or death of any person, or loss of or damage to property, sustained or occurring in, upon, at or about the Premises;

(iii) Any injury to or death of any person, or loss of or damage to property arising out of the use or occupancy of the Premises by or the negligence or willful misconduct of any of the Tenant Parties; and

(iv) On account of or based upon any work or thing whatsoever done (other than by Landlord or any of the Landlord Parties) at the Premises during the Term and during the period of time, if any, prior to the Term Commencement Date that any of the Tenant Parties may have been given access to the Premises.

(b) Notwithstanding anything in this Lease to the contrary, the individual partners, members or shareholders directly or indirectly comprising Tenant (as opposed to Tenant itself) shall not have any personal liability for the performance of Tenant's obligations under this Lease.

(c) Except to the extent caused by the negligence or willful misconduct of any of the Tenant Parties, Landlord shall defend, indemnify and save the Tenant Parties harmless from and against any and all Claims asserted by or on behalf of third party which is unrelated to Tenant or any Tenant Party arising from any injury to or death of any person, or loss of or damage to property at the Property arising out the negligence or willful misconduct of any of the Landlord Parties.

14.3 Property of Tenant. Tenant covenants and agrees that, to the maximum extent permitted by Legal Requirements, all of Tenant's Property at the Premises shall be at the sole risk and hazard of Tenant, and that if the whole or any part thereof shall be damaged, destroyed, stolen or removed from any cause or reason whatsoever, no part of said damage or loss shall be charged to, or borne by, Landlord, except, subject to Section 14.5 hereof, to the extent such damage or loss is due to the negligence or willful misconduct of any of the Landlord Parties.

14.4 Limitation of Landlord's Liability for Damage or Injury. Landlord shall not be liable for any injury or damage to persons, animals or property resulting from fire, explosion, falling plaster, steam, gas, air contaminants or emissions, electricity, electrical or electronic emanations or disturbance, water, rain or snow or leaks from any part of the Building or from the pipes, appliances, equipment or plumbing works or from the roof, street or sub-surface or from any other place or caused by dampness, vandalism, malicious mischief or by any other cause of whatever nature, except, subject to Section 14.5, to the extent caused by or due to the negligence or willful misconduct of any of the Landlord Parties. Notwithstanding the foregoing, in no event shall any of the Landlord Parties be liable for any loss which is covered by insurance policies actually carried or required to be so carried by this Lease; nor shall any of the Landlord Parties be liable for any such damage caused by other tenants or persons in the Building or caused by operations in construction of any private, public, or quasi-public work; nor shall any of the Landlord Parties be liable for any latent defect in the Premises or in the Building.

14.5 Waiver of Subrogation; Mutual Release. Landlord and Tenant each hereby waives on behalf of itself and its property insurers (none of which shall ever be assigned any such claim or be entitled thereto due to subrogation or otherwise) any and all rights of recovery, claim, action, or cause of action against the other and its agents, officers, servants, partners, shareholders, or employees (collectively, the "**Related Parties**") for any loss or damage that may occur to or within the Premises or the Building or any improvements thereto, or any personal property of such party therein which is insured against under any Property Insurance (as defined in Section 14.7) policy actually being maintained by the waiving party from time to time, even if not required hereunder, or which would be insured against under the terms of any Property Insurance policy required to be carried or maintained by the waiving party hereunder, whether or not such insurance coverage is actually being maintained, including, in every instance, such loss or damage that may be caused by the negligence of the other party hereto and/or its Related Parties. Landlord and Tenant each agrees to cause appropriate clauses to be included in its Property Insurance policies necessary to implement the foregoing provisions.

14.6 Tenant's Acts--Effect on Insurance. Tenant shall not do or permit any Tenant Party to do any act or thing upon the Premises or elsewhere in the Building which will invalidate or be in conflict with any insurance policies covering the Building and the fixtures and property therein; and shall not do, or permit to be done, any act or thing upon the Premises which shall subject Landlord to any liability or responsibility for injury to any person or persons or to property by reason of any business or operation being carried on upon said Premises or for any other reason. If by reason of the failure of Tenant to comply with the provisions hereof the insurance rate applicable to any policy of insurance shall at any time thereafter be higher than it otherwise would be, Tenant shall, subject to the applicable notice and cure periods, reimburse Landlord upon demand for that part of any insurance premiums which shall have been charged because of such failure by Tenant, together with interest at the Default Rate until paid in full, within ten (10) days after receipt of an invoice therefor. In addition, Tenant shall reimburse Landlord for any increase in insurance premium arising as a result of Tenant's use and/or storage of any Hazardous Materials in the Premises.

14.7 Landlord's Insurance. Landlord shall carry at all times during the Term of this Lease: (i) commercial general liability insurance with respect to the Building, the Land and the Common Areas thereof in an amount not less than Five Million Dollars ($5,000,000) combined single limit per occurrence, (ii) with respect to the Building, excluding Tenant-Insured Improvements and improvements made by other tenants or occupants, insurance against loss or damage caused by any peril covered under fire, extended coverage and all risk insurance with coverage against vandalism, malicious mischief and such other insurable hazards and contingencies as are from time to time normally insured against by owners of similar first class offices/research/laboratory buildings/campuses in the Market Area or which are required by Landlord's mortgagee, in an amount equal to one hundred percent (100%) of the full replacement cost thereof above foundation walls ("**Landlord Property Insurance**"), and (iii) rent interruption insurance covering at least eighteen (18) months. Any and all such insurance: (x) may be maintained under a blanket policy affecting other properties of Landlord and/or its affiliated business organizations, and (y) may be written with commercially reasonable deductibles as determined by Landlord. The costs incurred by Landlord related to such insurance shall be included in Operating Costs. Tenant Property Insurance and Landlord Property Insurance are referred to collectively herein as "**Property Insurance**".

15. CASUALTY; TAKING

15.1 Damage. If the Premises are damaged in whole or part because of fire or other insured casualty ("**Casualty**"), or if the Premises are subject to a taking in connection with the exercise of any power of eminent domain, condemnation, or purchase under threat or in lieu thereof (any of the foregoing, a "**Taking**"), then unless this Lease is terminated in accordance with Section 15.2 below, Landlord shall restore the Building and/or the Premises to substantially the same condition as existed immediately following completion of Landlord's Work, or in the event of a partial Taking which affects the Building and the Premises, restore the remainder of the Building and the Premises not so Taken to substantially the same condition as is reasonably feasible. If, in Landlord's reasonable judgment, any element of the Tenant-Insured Improvements can more effectively be restored as an integral part of Landlord's restoration of the Building or the Premises, such restoration shall also be made by Landlord, but at Tenant's sole cost and expense. Subject to rights of Mortgagees, Tenant Delays, Legal Requirements then in existence and to delays for

adjustment of insurance proceeds or Taking awards, as the case may be, and instances of Force Majeure, Landlord shall substantially complete such restoration within one (1) year after Landlord's receipt of all required permits therefor with respect to substantial reconstruction of at least 50% of the Building, or, within one hundred eighty (180) days after Landlord's receipt of all required permits therefor in the case of restoration of less than 50% of the Building. Upon substantial completion of such restoration by Landlord, Tenant shall use diligent efforts to complete restoration of the Premises to substantially the same condition as existed immediately prior to such Casualty or Taking, as the case may be, as soon as reasonably possible. Tenant agrees to cooperate with Landlord in such manner as Landlord may reasonably request to assist Landlord in collecting insurance proceeds due in connection with any Casualty which affects the Premises or the Building. In no event shall Landlord be required to expend more than the Net (hereinafter defined) insurance proceeds Landlord receives for damage to the Premises and/or the Building or the Net Taking award attributable to the Premises and/or the Building. "**Net**" means the insurance proceeds or Taking award actually paid to Landlord (and not paid over to a Mortgagee) less all costs and expenses, including adjusters and attorney's fees, of obtaining the same. In the Operating Year in which a Casualty occurs, there shall be included in Operating Costs Landlord's deductible under its property insurance policy. Except as Landlord may elect pursuant to this Section 15.1, under no circumstances shall Landlord be required to repair any damage to, or make any repairs to or replacements of, any Tenant-Insured Improvements.

15.2 Termination Rights.

(a) Landlord's Termination Rights. Landlord may terminate this Lease upon thirty (30) days' prior written notice to Tenant if:

(i) any material portion of the Building or any material means of access thereto is taken;

(ii) more than thirty-five percent (35%) of the Building is damaged by Casualty; or

(iii) if the estimated time to complete restoration exceeds one (1) year from the date on which Landlord receives all required permits for such restoration.

(b) Tenant's Termination Right. If Landlord is so required but fails to complete restoration of the Premises within the time frames and subject to the conditions set forth in Section 15.1 above, then Tenant may terminate this Lease upon thirty (30) days' written notice to Landlord; provided, however, that if Landlord completes such restoration within thirty (30) days after receipt of any such termination notice, such termination notice shall be null and void and this Lease shall continue in full force and effect. The remedies set forth in this Section 15.2(b) and in Section 15.2(c) below are Tenant's sole and exclusive rights and remedies based upon Landlord's failure to complete the restoration of the Premises as set forth herein. Notwithstanding anything to the contrary contained herein, Tenant shall not have the right to terminate this Lease pursuant to this Section 15 if the Casualty was caused by the negligence or intentional misconduct of any Tenant Party.

(c) Either Party May Terminate. In the case of any Casualty or Taking affecting the Premises and occurring during the last twelve (12) months of the Term, then (i) if such Casualty or Taking results in more than twenty-five percent (25%) of the floor area of the Premises being unsuitable for the Permitted Uses, or (ii) the damage to the Premises costs more than $250,000 to restore, then either Landlord or Tenant shall have the option to terminate this Lease upon thirty (30) days' written notice to the other. In addition, if Landlord's Mortgagee does not release sufficient insurance proceeds to cover the cost of Landlord's restoration obligations, then Landlord shall (i) notify Tenant thereof, and (ii) have the right to terminate this Lease. If Landlord does not terminate this Lease pursuant to the previous sentence and such notice by Landlord does not include an agreement by Landlord to pay for the difference between the cost of such restoration and such released insurance proceeds, then Tenant may terminate this Lease by written notice to Landlord on or before the date that is thirty (30) days after such notice. Notwithstanding anything to the contrary contained in this Section 15, in no event may Tenant elect to terminate this Lease hereunder if the Casualty that would otherwise give rise to such right results from the gross negligence or willful misconduct of Tenant, its agents, contractors, or employees.

(d) Automatic Termination. In the case of a Taking of the entire Premises, then this Lease shall automatically terminate as of the date of possession by the Taking authority.

15.3 Rent Abatement. In the event of a Casualty affecting the Premises, there shall be an equitable adjustment of Base Rent, Operating Costs and Taxes based upon the degree to which Tenant's ability to conduct its business in the Premises is impaired by reason of such Casualty from and after the date of a Casualty, and continuing until the following portions of the repair and restoration work to be performed by Landlord, as set forth above, are substantially completed: (i) any repair and restoration work to be performed by Landlord within the Premises, and (ii) repair and restoration work with respect to the Common Areas to the extent that damage to the Common Areas caused by such Casualty materially adversely affects Tenant's use of, or access to, the Premises.

15.4 Taking for Temporary Use. If the Premises are Taken for temporary use, Tenant's obligations, including without limitation the payment of Rent, shall equitably abate. For purposes hereof, a "**Taking for temporary use**" shall mean a Taking of ninety (90) days or less.

15.5 Disposition of Awards. Except for any separate award for Tenant's movable trade fixtures, relocation expenses, and unamortized leasehold improvements paid for by Tenant (provided that the same may not reduce Landlord's award), all Taking awards to Landlord or Tenant shall be Landlord's property without Tenant's participation, and Tenant hereby assigns to Landlord Tenant's interest, if any, in such award. Tenant may pursue its own claim against the Taking authority.

16. ESTOPPEL CERTIFICATE.

Tenant shall at any time and from time to time upon not less than ten (10) days' prior notice from Landlord, execute, acknowledge and deliver to Landlord a statement in writing certifying that this Lease is unmodified and in full force and effect (or if there have been modifications, that the same is in full force and effect as modified and stating the modifications), and the dates to which Rent has been paid in advance, if any, stating whether or not Landlord is in default in

performance of any covenant, agreement, term, provision or condition contained in this Lease and, if so, specifying each such default, and such other facts as Landlord may reasonably request, it being intended that any such statement delivered pursuant hereto may be relied upon by Landlord, any prospective purchaser of the Building or of any interest of Landlord therein, any Mortgagee or prospective Mortgagee thereof, any lessor or prospective lessor thereof, any lessee or prospective lessee thereof, or any prospective assignee of any mortgage thereof. *Time is of the essence with respect to any such requested certificate*, Tenant hereby acknowledging the importance of such certificates in mortgage financing arrangements, prospective sales and the like. If Tenant shall fail to execute and deliver to Landlord any such statement within such ten-day period, Tenant hereby appoints Landlord as Tenant's attorney-in-fact in its name and behalf to execute such statement, such appointment being coupled with an interest.

17. HAZARDOUS MATERIALS

17.1 Prohibition. Tenant shall not, without the prior written consent of Landlord, bring or permit to be brought or kept in or on the Premises or elsewhere in the Building or the Property (i) any inflammable, combustible or explosive fluid, material, chemical or substance (except for standard office supplies stored in proper containers); and (ii) any Hazardous Material (hereinafter defined), other than the types and quantities of Hazardous Materials which are listed on Exhibit 8 attached hereto ("**Tenant's Hazardous Materials**"), provided that the same shall at all times be brought upon, kept or used in so-called 'control areas' (the number and size of which shall be reasonably determined by Landlord), as described in, and in accordance with, **Exhibit 11** attached hereto and in accordance with all applicable Environmental Laws (hereinafter defined) and prudent environmental practice and (with respect to medical waste and so-called "biohazard" materials) good scientific and medical practice. Tenant shall be responsible for assuring that all laboratory uses are adequately and properly vented. On or before each anniversary of the Rent Commencement Date, and on any earlier date during the 12-month period on which Tenant intends to add a new Hazardous Material or materially increase the quantity of any Hazardous Material to the list of Tenant's Hazardous Materials, Tenant shall submit to Landlord an updated list of Tenant's Hazardous Materials for Landlord's review and approval, which approval shall not be unreasonably withheld, conditioned or delayed. Landlord shall have the right, from time to time, to inspect the Premises for compliance with the terms of this Section 17.1. Notwithstanding the foregoing, with respect to any of Tenant's Hazardous Materials which Tenant does not properly handle, store or dispose of in compliance with all applicable Environmental Laws (hereinafter defined), prudent environmental practice and (with respect to medical waste and so-called "biohazard materials") good scientific and medical practice, Tenant shall, upon written notice from Landlord, no longer have the right to bring such material into the Building or the Property until Tenant has demonstrated, to Landlord's reasonable satisfaction, that Tenant has implemented programs to thereafter properly handle, store or dispose of such material. In order to induce Landlord to waive its otherwise applicable requirement that Tenant maintain insurance in favor of Landlord against liability arising from the presence of radioactive materials in the Premises, and without limiting the foregoing, Tenant hereby represents and warrants to Landlord that at no time during the Term will Tenant bring upon, or permit to be brought upon, the Premises any radioactive materials whatsoever.

17.2 Environmental Laws. For purposes hereof, "**Environmental Laws**" shall mean all laws, statutes, ordinances, rules and regulations of any local, state or federal governmental authority having jurisdiction concerning environmental, health and safety matters, including but not limited to any discharge by any of the Tenant Parties into the air, surface water, sewers, soil or groundwater of any Hazardous Material (hereinafter defined) whether within or outside the Premises, including, without limitation (a) the Federal Water Pollution Control Act, 33 U.S.C. Section 1251 et seq., (b) the Federal Resource Conservation and Recovery Act, 42 U.S.C. Section 6901 et seq., (c) the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. Section 9601 et seq., (d) the Toxic Substances Control Act of 1976, 15 U.S.C. Section 2601 et seq., and (e) Chapter 21E of the General Laws of Massachusetts. Tenant, at its sole cost and expense, shall comply with (i) Environmental Laws, and (ii) any rules, requirements and safety procedures of the Massachusetts Department of Environmental Protection, the Town of Lexington and any insurer of the Building or the Premises with respect to Tenant's use, storage and disposal of any Hazardous Materials.

17.3 Hazardous Material Defined. As used herein, the term "**Hazardous Material**" means asbestos, oil or any hazardous, radioactive or toxic substance, material or waste or petroleum derivative which is or becomes regulated by any Environmental Law, including without limitation live organisms, viruses and fungi, medical waste and any so-called "biohazard" materials. The term "**Hazardous Material**" includes, without limitation, oil and/or any material or substance which is (i) designated as a "hazardous substance," "hazardous material," "oil," "hazardous waste" or toxic substance under any Environmental Law.

17.4 Chemical Safety Program. Tenant shall establish and maintain a chemical safety program administered by a licensed, qualified individual in accordance with the requirements of any applicable governmental authority. Tenant shall be solely responsible for all costs incurred in connection with such chemical safety program, and Tenant shall provide Landlord with such documentation as Landlord may reasonably require evidencing Tenant's compliance with the requirements of (a) any applicable governmental authority with respect to such chemical safety program and (b) this Section. Tenant shall obtain and maintain during the Term any permit required by any such applicable governmental authority.

17.5 Testing. If any Mortgagee or governmental authority requires testing to determine whether there has been any release of Hazardous Materials and such testing is required as a result of the acts or omissions of any of the Tenant Parties, then Tenant shall reimburse Landlord upon demand, as Additional Rent, for the reasonable costs thereof, together with interest at the Default Rate until paid in full. Tenant shall execute affidavits, certifications and the like, as may be reasonably requested by Landlord from time to time concerning Tenant's best knowledge and belief concerning the presence of Hazardous Materials in or on the Premises, the Building or the Property. In addition to the foregoing, if Landlord reasonably believes that any Hazardous Materials have been released on the Premises in violation of this Lease or any Legal Requirement, Landlord shall have the right to conduct appropriate tests of the Premises or any portion thereof to demonstrate that Hazardous Materials are present or that contamination has occurred due to the acts or omissions of any of the Tenant Parties. Tenant shall pay all reasonable costs of such tests if such tests reveal that Hazardous Materials exist at the Premises in violation of this Lease or any Legal Requirement. Further, Landlord shall have the right to cause a third party consultant retained by Landlord, at Landlord's expense (provided, however, that such costs shall be included in

Operating Costs), to review, but not more than once in any calendar year, Tenant's lab operations, procedures and permits to ascertain whether or not Tenant is complying with law and adhering to best industry practices. Said consultant shall be accompanied by a designated representative of Tenant while in the Premises (provided that Tenant shall make a designated representative available at such times as Landlord may reasonably require for the purposes of accompanying said consultant), and Landlord agrees to cause said consultant to sign a reasonable non-disclosure agreement prior to entering the Premises; provided, however, that such non-disclosure agreement shall permit Landlord's consultant to disclose its findings to Landlord and Landlord's property manager, and, to the extent required by a Mortgage or applicable law, to any Mortgagee or governmental authority, respectively. Tenant agrees to cooperate in good faith with any such review and to provide to such consultant any information requested by such consultant and reasonably required in order for such consultant to perform such review, but nothing contained herein shall require Tenant to provide proprietary or confidential information to such consultant.

17.6 Indemnity; Remediation.

(a) Tenant hereby covenants and agrees to indemnify, defend and hold the Landlord Parties harmless from and against any and all Claims against any of the Landlord Parties arising out of contamination of any part of the Property or other adjacent property, which contamination arises as a result of: (i) the presence of Hazardous Material in the Premises, the presence of which is caused by any act or omission of any of the Tenant Parties, or (ii) from a breach by Tenant of its obligations under this Section 17. This indemnification of the Landlord Parties by Tenant includes, without limitation, reasonable costs incurred in connection with any investigation of site conditions or any cleanup, remedial, removal or restoration work or any other response actions required by any federal, state or local governmental agency or political subdivision because of Hazardous Material present in the soil, soil vapor or ground water on or under or any indoor air in the Building based upon the circumstances identified in the first sentence of this Section 17.6. The indemnification and hold harmless obligations of Tenant under this Section 17.6 shall survive the expiration or any earlier termination of this Lease, but are subject to any applicable statute of limitations. Without limiting the foregoing, if the presence of any Hazardous Material in the Building or otherwise in the Property is caused or permitted by any of the Tenant Parties and results in any contamination of any part of the Property or any adjacent property, Tenant shall promptly take all actions at Tenant's sole cost and expense as are necessary to return the Property and/or the Building or any adjacent property to their condition as of the date of this Lease, provided that Tenant shall first obtain Landlord's written approval of such actions, which approval shall not be unreasonably withheld, conditioned or delayed so long as such actions, in Landlord's reasonable discretion, would not potentially have any adverse effect on the Property, and, in any event, Landlord shall not withhold its approval of any proposed actions which are required by applicable Environmental Laws. Notwithstanding anything in this Lease to the contrary, Tenant shall not be liable for any Hazardous Materials existing on the Property (or any migration thereof) prior to the Term Commencement Date. The provisions of this Section 17.6 shall survive the expiration or earlier termination of the Lease, but are subject to any applicable statute of limitations.

(b) Without limiting the obligations set forth in Section 17.6(a) above, if any Hazardous Material is in, on, under, at or about the Building or the Property as a result of the acts or omissions of any of the Tenant Parties and results in any contamination of any part of the Property or any adjacent property that is in violation of any applicable Environmental Law or that requires the performance of any response action pursuant to any Environmental Law, Tenant shall promptly take all actions at Tenant's sole cost and expense as are necessary to reduce such Hazardous Material to amounts below any applicable Reportable Quantity, any applicable Reportable Concentration and any other applicable standard set forth in any Environmental Law such that no further response actions are required; provided that Tenant shall first obtain Landlord's written approval of such actions, which approval shall not be unreasonably withheld, conditioned or delayed so long as such actions would not be reasonably expected to have an adverse effect on the market value or utility of the Property for the Permitted Uses, and in any event, Landlord shall not withhold its approval of any proposed actions which are required by applicable Environmental Laws (such approved actions, "**Tenant's Remediation**").

(c) In the event that Tenant fails to complete Tenant's Remediation prior to the end of the Term, then:

(i) until the completion of Tenant's Remediation (as evidenced by the certification of Tenant's Licensed Site Professional (as such term is defined by applicable Environmental Laws), who shall be reasonably acceptable to Landlord) (the "**Remediation Completion Date**"), Tenant shall pay to Landlord, with respect to the portion of the Premises which reasonably cannot be occupied by a new tenant until completion of Tenant's Remediation, (A) Additional Rent on account of Operating Costs and Taxes and (B) Base Rent in an amount equal to the greater of (1) the fair market rental value of such portion of the Premises (determined in substantial accordance with the process described in Section 1.2 above), and (2) Base Rent attributable to such portion of the Premises in effect immediately prior to the end of the Term; and

(ii) Tenant shall maintain responsibility for Tenant's Remediation and Tenant shall complete Tenant's Remediation as soon as reasonably practicable in accordance with Environmental Laws. If Tenant does not diligently pursue completion of Tenant's Remediation, Landlord shall have the right to either (A) assume control for overseeing Tenant's Remediation, in which event Tenant shall pay all reasonable costs and expenses of Tenant's Remediation (it being understood and agreed that all costs and expenses of Tenant's Remediation incurred pursuant to contracts entered into by Tenant shall be deemed reasonable) within thirty (30) days of demand therefor (which demand shall be made no more often than monthly), and Landlord shall be substituted as the party identified on any governmental filings as the party responsible for the performance of such Tenant's Remediation or (B) require Tenant to maintain responsibility for Tenant's Remediation, in which event Tenant shall complete Tenant's Remediation as soon as reasonably practicable in accordance with Environmental Laws, it being understood that Tenant's Remediation shall not contain any requirement that Tenant remediate any contamination to levels or standards more stringent than those associated with the Property's current office, research and development, laboratory, and vivarium uses.

(d) The provisions of this Section 17.6 shall survive the expiration or earlier termination of this Lease, but are subject to any applicable statute of limitations.

17.7 Disclosures. Prior to bringing any Hazardous Material into any part of the Property, Tenant shall deliver to Landlord the following information with respect thereto: (a) a description of handling, storage, use and disposal procedures; (b) all plans or disclosures and/or emergency response plans which Tenant has prepared, including without limitation Tenant's Spill Response Plan, and all plans which Tenant is required to supply to any governmental agency or authority pursuant to any Environmental Laws; (c) copies of all Required Permits relating thereto; and (d) other information reasonably requested by Landlord.

17.8 Removal. Tenant shall be responsible, at its sole cost and expense, for Hazardous Material and other biohazard disposal services for the Premises. Such services shall be performed by contractors reasonably acceptable to Landlord and on a sufficient basis to ensure that the Premises are at all times kept neat, clean and free of Hazardous Materials and biohazards except in appropriate, specially marked containers reasonably approved by Landlord.

18. RULES AND REGULATIONS.

18.1 Rules and Regulations. Tenant will faithfully observe and comply with the Rules and Regulations attached hereto as Exhibit 9 ("**Current Rules and Regulations**") and reasonable rules and regulations as may be promulgated, from time to time, with respect to the Building, the Property and construction within the Property (collectively, the "**Rules and Regulations**"). The Current Rules and Regulations consist of the Building Rules and Regulations attached hereto as Exhibit 9-1 and the Construction Rules and Regulations attached hereto as Exhibit 9-2. In the case of any conflict between the provisions of this Lease and any future rules and regulations, the provisions of this Lease shall control. Nothing contained in this Lease shall be construed to impose upon Landlord any duty or obligation to enforce the Rules and Regulations or the terms, covenants or conditions in any other lease as against any other tenant and Landlord shall not be liable to Tenant for violation of the same by any other tenant, its servants, employees, agents, contractors, visitors, invitees or licensees.

18.2 Energy Conservation. Landlord may institute upon written notice to Tenant such policies, programs and measures as may be necessary, required, or expedient for the conservation and/or preservation of energy or energy services (collectively, the "**Conservation Program**"), provided however, that the Conservation Program does not, by reason of such policies, programs and measures, materially adversely affect Tenant's ability to maintain its normal business operations in the Premises, or reduce the level of energy or energy services being provided to the Premises below the level of energy or energy services then being provided in comparable combination laboratory, research and development and office buildings in the vicinity of the Premises, or as may be necessary or required to comply with Legal Requirements or standards or the other provisions of this Lease. Upon receipt of such notice, Tenant shall comply with the Conservation Program.

18.3 Recycling. Upon written notice, Landlord may establish policies, programs and measures for the recycling of paper, products, plastic, tin and other materials (a "**Recycling Program**"). Upon receipt of such notice, Tenant will comply with the Recycling Program at Tenant's sole cost and expense.

19. LAWS AND PERMITS.

19.1 Legal Requirements. Tenant shall not cause or permit the Premises, or cause the Property or the Building to be used in any way that violates any Legal Requirement, order, permit, approval, variance, covenant or restrictions of record or any provisions of this Lease, interferes with the rights of tenants of the Building, or constitutes a nuisance or waste. Tenant shall obtain, maintain and pay for all permits and approvals needed for the operation of Tenant's business and/or Tenant's Rooftop Equipment, as soon as reasonably possible, and in any event shall not undertake any operations or use of Tenant's Rooftop Equipment unless all applicable permits and approvals are in place and shall, promptly take all actions necessary to comply with all Legal Requirements, including, without limitation, the Occupational Safety and Health Act, applicable to Tenant's use of the Premises, the Property or the Building. Tenant shall maintain in full force and effect all certifications or permissions required by any authority having jurisdiction to authorize, franchise or regulate Tenant's use of the Premises. Tenant shall be solely responsible for procuring and complying at all times with any and all necessary permits and approvals directly or indirectly relating or incident to: the conduct of its activities on the Premises; its scientific experimentation, transportation, storage, handling, use and disposal of any chemical or radioactive or bacteriological or pathological substances or organisms or other hazardous wastes or environmentally dangerous substances or materials or medical waste or animals or laboratory specimens. Within ten (10) days of a request by Landlord, which request shall be made not more than once during each period of twelve (12) consecutive months during the Term hereof, unless otherwise requested by any mortgagee of Landlord or unless Landlord reasonably suspects that Tenant has violated the provisions of this Section 19.1, Tenant shall furnish Landlord with copies of all such permits and approvals that Tenant possesses or has obtained together with a certificate certifying that such permits are all of the permits that Tenant possesses or has obtained with respect to the Premises. Tenant shall promptly give written notice to Landlord of any warnings or violations relative to the above received from any federal, state or municipal agency or by any court of law and shall promptly cure the conditions causing any such violations. Tenant shall not be deemed to be in default of its obligations under the preceding sentence to promptly cure any condition causing any such violation in the event that, in lieu of such cure, Tenant shall contest the validity of such violation by appellate or other proceedings permitted under applicable law, provided that: (i) any such contest is made reasonably and in good faith, (ii) Tenant makes provisions, including, without limitation, posting bond(s) or giving other security, reasonably acceptable to Landlord to protect Landlord, the Building and the Property from any liability, costs, damages or expenses arising in connection with such alleged violation and failure to cure, (iii) Tenant shall agree to indemnify, defend (with counsel reasonably acceptable to Landlord) and hold Landlord harmless from and against any and all liability, costs, damages, or expenses arising in connection with such condition and/or violation, (iv) Tenant shall promptly cure any violation in the event that its appeal of such violation is overruled or rejected, and (v) Tenant's decision to delay such cure shall not, in Landlord's good faith determination, be likely to result in any actual or threatened bodily injury, property damage, or any civil or criminal liability to Landlord, any tenant or occupant of the Building or the Property, or any other person or entity. Nothing contained in this Section 19.1 shall be construed to expand the uses permitted hereunder beyond the Permitted Uses. Landlord shall comply with any Legal Requirements and with any direction of any public office or officer relating to the maintenance or operation of the structural elements of the Building and the Common Areas, and the costs so incurred by Landlord shall be included in Operating Costs in accordance with the provisions of Section 5.2.

20. DEFAULT

20.1 Events of Default. The occurrence of any one or more of the following events shall constitute an "**Event of Default**" hereunder by Tenant:

(a) If Tenant fails to make any payment of Rent or any other payment required hereunder, as and when due, and such failure shall continue for a period of five (5) days after notice thereof from Landlord to Tenant; provided, however, an Event of Default shall occur hereunder without any obligation of Landlord to give any notice if (i) Tenant fails to make any payment within five (5) days after the due date therefor, and (ii) Landlord has given Tenant written notice under this Section 20.1(a) on more than one (1) occasion during the twelve (12) month interval preceding such failure by Tenant;

(b) If Tenant shall abandon the Premises (meaning that Tenant has ceased operating for normal business purposes in the Premises for a period of thirty (30) consecutive calendar days) (whether or not the keys shall have been surrendered or the Rent shall have been paid);

(c) If Tenant shall fail to execute and deliver to Landlord an estoppel certificate pursuant to Section 16 above or a subordination and attornment agreement pursuant to Section 22 below, within the timeframes set forth therein;

(d) If Tenant shall fail to maintain any insurance required hereunder, and, in the event of the lapse of any of Tenant's insurance policies required hereunder, Tenant fails to provide Landlord with proof of insurance satisfying the requirements of this Lease within five (5) days after delivery of notice thereof by Landlord;

(e) If Tenant shall fail to restore the Security Deposit to its original amount or deliver a replacement Letter of Credit as required under Section 7 above;

(f) If Tenant causes or suffers any release of Hazardous Materials in or near the Property;

(g) If Tenant shall make a Transfer in violation of the provisions of Section 13 above, or if any event shall occur or any contingency shall arise whereby this Lease, or the Term and estate thereby created, would (by operation of law or otherwise) devolve upon or pass to any person, firm or corporation other than Tenant, except as expressly permitted under Section 13 hereof;

(h) If Tenant shall fail to perform its obligations under Section 3 hereof and such failure continues for more than thirty (30) days after delivery of notice thereof from Landlord;

(i) The failure by Tenant to observe or perform any of the covenants or provisions of this Lease to be observed or performed by Tenant, other than as specified above, and such failure continues for more than thirty (30) days after delivery of notice thereof from Landlord; provided, further, that if the nature of Tenant's default is such that more than thirty (30) days are reasonably required for its cure, then Tenant shall not be deemed to be in default if Tenant shall commence such cure within said thirty (30) day period and thereafter diligently prosecute such cure to completion, which completion shall occur not later than ninety (90) days from the date of such notice from Landlord;

(j) Tenant shall be involved in financial difficulties as evidenced by an admission in writing by Tenant of Tenant's inability to pay its debts generally as they become due, or by the making or offering to make a composition of its debts with its creditors;

(k) Tenant shall make an assignment or trust mortgage, or other conveyance or transfer of like nature, of all or a substantial part of its property for the benefit of its creditors,

(l) an attachment on mesne process, on execution or otherwise, or other legal process shall issue against Tenant or its property and a sale of any of its assets shall be held thereunder;

(m) [intentionally deleted];

(n) the leasehold hereby created shall be taken on execution or by other process of law and shall not be revested in Tenant within thirty (30) days thereafter;

(o) a receiver, sequesterer, trustee or similar officer shall be appointed by a court of competent jurisdiction to take charge of all or any part of Tenant's Property and such appointment shall not be vacated within thirty (30) days; or

(p) any proceeding shall be instituted by or against Tenant pursuant to any of the provisions of any Act of Congress or State law relating to bankruptcy, reorganizations, arrangements, compositions or other relief from creditors, and, in the case of any proceeding instituted against it, if Tenant shall fail to have such proceedings dismissed within thirty (30) days or if Tenant is adjudged bankrupt or insolvent as a result of any such proceeding; or

20.2 Remedies. Upon an Event of Default, Landlord may, by notice to Tenant, elect to terminate this Lease; and thereupon (and without prejudice to any remedies which might otherwise be available for arrears of Rent or preceding breach of covenant or agreement and without prejudice to Tenant's liability for damages as hereinafter stated), upon the giving of such notice, this Lease shall terminate as of the date specified therein as though that were the Expiration Date. Upon such termination, Landlord shall have the right to utilize the Security Deposit or draw down the entire Letter of Credit, as applicable, and apply the proceeds thereof to its damages hereunder. Without being taken or deemed to be guilty of any manner of trespass or conversion, and without being liable to indictment, prosecution or damages therefor, Landlord may, by lawful process, enter into and upon the Premises (or any part thereof in the name of the whole); repossess the same, as of its former estate; and expel Tenant and those claiming under Tenant. The words "re-entry" and "re-enter" as used in this Lease are not restricted to their technical legal meanings.

20.3 Damages - Termination.

(a) Upon the termination of this Lease under the provisions of this Section 20, Tenant shall pay to Landlord Rent up to the time of such termination, shall continue to be liable for any preceding breach of covenant, and in addition, shall pay to Landlord as damages, at the election of Landlord, either:

(i) the amount (discounted to present value at the rate of five percent (5%) per annum) by which, at the time of the termination of this Lease (or at any time thereafter if Landlord shall have initially elected damages under Section 20.3(a)(ii) below), (x) the aggregate of Rent projected over the period commencing with such termination and ending on the Expiration Date, exceeds (y) the aggregate projected rental value of the Premises for such period, taking into account a reasonable time period during which the Premises shall be unoccupied, plus all Reletting Costs (hereinafter defined); or

(ii) amounts equal to Rent which would have been payable by Tenant had this Lease not been so terminated, payable upon the due dates therefor specified herein following such termination and until the Expiration Date, *provided*, *however*, if Landlord shall re-let the Premises during such period, that Landlord shall credit Tenant with the net rents received by Landlord from such re-letting, such net rents to be determined by first deducting from the gross rents as and when received by Landlord from such re-letting the expenses incurred or paid by Landlord in terminating this Lease, as well as the expenses of re-letting, including altering and preparing the Premises for new tenants, brokers' commissions, and all other similar and dissimilar expenses properly chargeable against the Premises and the rental therefrom (collectively, "**Reletting Costs**"), it being understood that any such re-letting may be for a period equal to or shorter or longer than the remaining Term; and *provided*, *further*, that (x) in no event shall Tenant be entitled to receive any excess of such net rents over the sums payable by Tenant to Landlord hereunder and (y) in no event shall Tenant be entitled in any suit for the collection of damages pursuant to this Section 20.3(a)(ii) to a credit in respect of any net rents from a re-letting except to the extent that such net rents are actually received by Landlord prior to the commencement of such suit. If the Premises or any part thereof should be re-let in combination with other space, then proper apportionment on a square foot area basis shall be made of the rent received from such re-letting and of the expenses of re-letting.

(b) In calculating the amount due under Section 20.3(a)(i), above, there shall be included, in addition to the Base Rent, all other considerations agreed to be paid or performed by Tenant, including without limitation Tenant's Share of Operating Costs and Taxes, on the assumption that all such amounts and considerations would have increased at the rate of three percent (3%) per annum for the balance of the full term hereby granted.

(c) Suit or suits for the recovery of such damages, or any installments thereof, may be brought by Landlord from time to time at its election, and nothing contained herein shall be deemed to require Landlord to postpone suit until the date when the Term would have expired if it had not been terminated hereunder.

(d) Nothing herein contained shall be construed as limiting or precluding the recovery by Landlord against Tenant of any sums or damages to which, in addition to the damages particularly provided above, Landlord may lawfully be entitled by reason of any Event of Default hereunder.

(e) In lieu of any other damages or indemnity and in lieu of full recovery by Landlord of all sums payable under all the foregoing provisions of this Section 20.3, Landlord may, by written notice to Tenant, at any time after this Lease is terminated as a result of an Event of Default, elect to recover, and Tenant shall thereupon pay, as liquidated damages, an amount

equal to the aggregate of (x) an amount equal to the lesser of (1) Rent accrued under this Lease in the twelve (12) months immediately prior to such termination, or (2) Rent payable during the remaining months of the Term if this Lease had not been terminated, plus (y) the amount of Rent accrued and unpaid at the time of termination, less (z) the amount of any recovery by Landlord under the foregoing provisions of this Section 20.3 up to the time of payment of such liquidated damages.

20.4 Landlord's Self-Help; Fees and Expenses. If Tenant shall default in the performance of any covenant on Tenant's part to be performed in this Lease contained, including without limitation the obligation to maintain the Premises in the required condition pursuant to Section 10.1 above, Landlord may, upon reasonable advance notice, except that no notice shall be required in an emergency, immediately, or at any time thereafter, perform the same for the account of Tenant. Tenant shall pay to Landlord upon demand therefor any costs incurred by Landlord in connection therewith, together with interest at the Default Rate until paid in full. In addition, Tenant shall pay all of Landlord's costs and expenses, including without limitation reasonable attorneys' fees, incurred (i) in enforcing any obligation of Tenant under this Lease or (ii) as a result of Landlord or any of the Landlord Parties, without its fault, being made party to any litigation pending by or against any of the Tenant Parties.

20.5 Waiver of Redemption, Statutory Notice and Grace Periods. Tenant does hereby waive and surrender all rights and privileges which it might have under or by reason of any present or future Legal Requirements to redeem the Premises or to have a continuance of this Lease for the Term hereby demised after being dispossessed or ejected therefrom by process of law or under the terms of this Lease or after the termination of this Lease as herein provided. Except to the extent prohibited by Legal Requirements, any statutory notice and grace periods provided to Tenant by law are hereby expressly waived by Tenant.

20.6 Remedies Not Exclusive. The specified remedies to which Landlord and Tenant may respectively resort hereunder are cumulative and are not intended to be exclusive of any remedies or means of redress to which either such party may at any time be lawfully entitled. Landlord may invoke any remedy (including the remedy of specific performance) allowed at law or in equity as if specific remedies were not herein provided for.

20.7 No Waiver. Landlord's failure to seek redress for violation, or to insist upon the strict performance, of any covenant or condition of this Lease, or any of the Rules and Regulations promulgated hereunder, shall not prevent a subsequent act, which would have originally constituted a violation, from having all the force and effect of an original violation. The receipt by Landlord of Rent with knowledge of the breach of any covenant of this Lease shall not be deemed a waiver of such breach. The failure of Landlord to enforce any of such Rules and Regulations against Tenant and/or any other tenant in the Building shall not be deemed a waiver of any such Rules and Regulations. No provisions of this Lease shall be deemed to have been waived by either party unless such waiver be in writing signed by such party. No payment by Tenant or receipt by Landlord of a lesser amount than the Rent herein stipulated shall be deemed to be other than on account of the stipulated Rent, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as Rent be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or pursue any other remedy in this Lease provided.

20.8 [Intentionally Deleted].

20.9 Landlord Default. Notwithstanding anything to the contrary contained in the Lease, Landlord shall in no event be in default in the performance of any of Landlord's obligations under this Lease unless Landlord shall have failed to perform such obligations within thirty (30) days (or such additional time as is reasonably required to correct any such default, provided Landlord commences cure within 30 days) after notice by Tenant to Landlord properly specifying wherein Landlord has failed to perform any such obligation. Except as expressly set forth in this Lease, Tenant shall not have the right to terminate or cancel this Lease or to withhold rent or to set-off or deduct any claim or damages against rent as a result of any default by Landlord or breach by Landlord of its covenants or any warranties or promises hereunder, except in the case of a wrongful eviction of Tenant from the Premises (constructive or actual) by Landlord, and then only if the same continues after notice to Landlord thereof and an opportunity for Landlord to cure the same as set forth above. In addition, Tenant shall not assert any right to deduct the cost of repairs or any monetary claim against Landlord from rent thereafter due and payable under this Lease, except in the case of a wrongful eviction of Tenant from the Premises (constructive or actual) by Landlord, and then only if the same continues after notice to Landlord thereof and an opportunity for Landlord to cure the same as set forth above.

21. SURRENDER; ABANDONED PROPERTY; HOLD-OVER

21.1 Surrender

(a) Upon the expiration or earlier termination of the Term, Tenant shall (i) peaceably quit and surrender to Landlord the Premises (including without limitation all fixed lab benches, fume hoods, electric, plumbing, heating and sprinkling systems, fixtures and outlets, vaults, paneling, molding, shelving, radiator enclosures, cork, rubber, linoleum and composition floors, ventilating, silencing, air conditioning and cooling equipment therein and all other furniture, fixtures, and equipment that was either provided by Landlord or paid for in whole or in part by any allowance provided to Tenant by Landlord under this Lease) broom clean, in good order, repair and condition excepting only ordinary wear and tear and damage by fire or other insured Casualty; (ii) remove all of Tenant's Property, all autoclaves and cage washers and, to the extent specified by Landlord, Alterations made by Tenant, including without limitation Tenant's vivarium; and (iii) repair any damages to the Premises or the Building caused by Tenant's installation or Tenant's removal of Tenant's Property and/or such Alterations. Tenant's obligations under this Section 21.1(a) shall survive the expiration or earlier termination of this Lease, subject to any applicable statute of limitations.

(b) Prior to the expiration of this Lease (or within thirty (30) days after any earlier termination), Tenant shall clean and otherwise decommission all interior surfaces (including floors, walls, ceilings, and counters), piping, supply lines, waste lines, acid neutralization systems and plumbing in and/or exclusively serving the Premises, and all exhaust or other ductwork in and/or exclusively serving the Premises, in each case which has carried or released or been contacted by any Hazardous Materials or other chemical or biological materials used in the operation of the Premises, and shall otherwise clean the Premises so as to permit the Surrender Plan (defined below) to be issued. At least thirty (30) days prior to the expiration of the Term (or, if applicable, within five (5) business days after any earlier termination of this Lease),

Tenant shall deliver to Landlord a reasonably detailed narrative description of the actions proposed (or required by any Legal Requirements) to be taken by Tenant in order to render the Premises (including any Alterations permitted or required by Landlord to remain therein) free of Hazardous Materials and otherwise released for unrestricted use and occupancy including without limitation causing the Premises to be decommissioned in accordance with the regulations of the U.S. Nuclear Regulatory Commission and/or the Massachusetts Department of Public health (the "**MDPH**") for the control of radiation, and cause the Premises to be released for unrestricted use by the Radiation Control Program of the MDPH (the "**Surrender Plan**"). The Surrender Plan (i) shall be accompanied by a current list of (A) all Required Permits held by or on behalf of any Tenant Party with respect to Hazardous Materials in, on, under, at or about the Premises, and (B) Tenant's Hazardous Materials, and (ii) shall be subject to the review and approval of Landlord's environmental consultant. In connection with review and approval of the Surrender Plan, upon request of Landlord, Tenant shall deliver to Landlord or its consultant such additional non-proprietary information concerning the use of and operations within the Premises as Landlord shall request. On or before the expiration of the Term (or within thirty (30) days after any earlier termination of this Lease, during which period Tenant's use and occupancy of the Premises shall be governed by Section 21.3 below), Tenant shall (i) perform or cause to be performed all actions described in the approved Surrender Plan, and (ii) deliver to Landlord a certification from a third party certified industrial hygienist reasonably acceptable to Landlord certifying that the Premises do not contain any Hazardous Materials and evidence that the approved Surrender Plan shall have been satisfactorily completed by a contractor acceptable to Landlord, and Landlord shall have the right, subject to reimbursement at Tenant's expense as set forth below, to cause Landlord's environmental consultant to inspect the Premises and perform such additional procedures as may be deemed reasonably necessary to confirm that the Premises are, as of the expiration of the Term (or, if applicable, the date which is thirty (30) days after any earlier termination of this Lease), free of Hazardous Materials and otherwise available for unrestricted use and occupancy as aforesaid. Landlord shall have the unrestricted right to deliver the Surrender Plan and any report by Landlord's environmental consultant with respect to the surrender of the Premises to third parties. Such third parties and the Landlord Parties shall be entitled to rely on the Surrender Report. If Tenant shall fail to prepare or submit a Surrender Plan approved by Landlord, or if Tenant shall fail to complete the approved Surrender Plan, or if such Surrender Plan, whether or not approved by Landlord, shall fail to adequately address the use of Hazardous Materials by any of the Tenant Parties in, on, at, under or about the Premises, Landlord shall have the right to take any such actions as Landlord may deem reasonable or appropriate to assure that the Premises and the Property are surrendered in the condition required hereunder, the cost of which actions shall be reimbursed by Tenant as Additional Rent upon demand. Tenant's obligations under this Section 21.1(b) shall survive the expiration or earlier termination of the Term.

(c) No act or thing done by Landlord during the Term shall be deemed an acceptance of a surrender of the Premises, and no agreement to accept such surrender shall be valid, unless in writing signed by Landlord. Unless otherwise agreed by the parties in writing, no employee of Landlord or of Landlord's agents shall have any power to accept the keys of the Premises prior to the expiration or earlier termination of this Lease. The delivery of keys to any employee of Landlord or of Landlord's agents shall not operate as a termination of this Lease or a surrender of the Premises.

(d) Notwithstanding anything to the contrary contained herein, Tenant shall, at its sole cost and expense, remove from the Premises, prior to the end of the Term, any item installed by or for Tenant and which, pursuant to Legal Requirements, must be removed therefrom before the Premises may be used by a subsequent tenant.

21.2 Abandoned Property. Subject to the Consent to Removal of Personal Property attached hereto as Exhibit 12 ("**Consent to Removal**"), after the expiration or earlier termination hereof, if Tenant fails to remove any property from the Building or the Premises which Tenant is obligated by the terms of this Lease to remove within five (5) business days after written notice from Landlord, such property (the "**Abandoned Property**") shall be conclusively deemed to have been abandoned, and may either be retained by Landlord as its property or sold or otherwise disposed of in such manner as Landlord may see fit, except as otherwise set forth in said Consent to Removal. If any item of Abandoned Property shall be sold, Tenant hereby agrees that Landlord may receive and retain the proceeds of such sale and apply the same, at its option, to the expenses of the sale, the cost of moving and storage, any damages to which Landlord may be entitled under Section 20 hereof or pursuant to law, and to any arrears of Rent.

21.3 Holdover. If any of the Tenant Parties holds over (which term shall include, without limitation, the failure of Tenant or any Tenant Party to perform all of its obligations under Section 21.1 above) after the end of the Term, Tenant shall be deemed a tenant-at-sufferance subject to the provisions of this Lease; provided that whether or not Landlord has previously accepted payments of Rent from Tenant, (i) for the first sixty (60) days of any such holding over, Tenant shall pay Base Rent at 150% of the highest rate of Base Rent payable during the Term, and thereafter, Tenant shall pay Base Rent at 200% of the highest rate of Base Rent payable during the Term, (ii) Tenant shall continue to pay to Landlord all Additional Rent, and (iii) Tenant shall be liable for all damages, including without limitation lost business and consequential damages, incurred by Landlord as a result of such holding over, Tenant hereby acknowledging that Landlord may need the Premises after the end of the Term for other tenants and that the damages which Landlord may suffer as the result of Tenant's holding over cannot be determined as of the Execution Date. Nothing contained herein shall grant Tenant the right to holdover after the expiration or earlier termination of the Term.

21.4 Warranties. Tenant hereby assigns to Landlord any warranties in effect on the last day of the Term with respect to any fixtures and Alterations installed in the Premises. Tenant shall provide Landlord with copies of any such warranties prior to the expiration of the Term (or, if the Lease is earlier terminated, within five (5) days thereafter).

22. MORTGAGEE RIGHTS

22.1 Subordination. Tenant's rights and interests under this Lease shall be (i) subject and subordinate to any ground lease, overleases, mortgage, deed of trust, or similar instrument covering the Premises, the Building and/or the Land and to all advances, modifications, renewals, replacements, and extensions thereof (each of the foregoing, a "**Mortgage**"), or (ii) if any Mortgagee elects, prior to the lien of any present or future Mortgage. Tenant further shall attorn to and recognize any successor landlord, whether through foreclosure or otherwise, as if the successor landlord were the originally named landlord. The provisions of this Section 22.1 shall be self-operative and no further instrument shall be required to effect such subordination or attornment; however, Tenant agrees to execute, acknowledge and deliver such instruments, confirming such subordination and attornment in such form as shall be requested by any such holder within fifteen (15) days of request therefor.

22.2 **Notices**. Tenant shall give each Mortgagee the same notices given to Landlord concurrently with the notice to Landlord, and each Mortgagee shall have a reasonable opportunity thereafter to cure a Landlord default, and Mortgagee's curing of any of Landlord's default shall be treated as performance by Landlord.

22.3 **Mortgagee Consent**. Tenant acknowledges that, where applicable, any consent or approval hereafter given by Landlord may be subject to the further consent or approval of a Mortgagee; and the failure or refusal of such Mortgagee to give such consent or approval shall, notwithstanding anything to the contrary in this Lease contained, constitute reasonable justification for Landlord's withholding its consent or approval.

22.4 **Mortgagee Liability**. Tenant acknowledges and agrees that if any Mortgage shall be foreclosed, (a) the liability of the Mortgagee and its successors and assigns shall exist only so long as such Mortgagee or purchaser is the owner of the Premises, and such liability shall not continue or survive after further transfer of ownership; and (b) such Mortgagee and its successors or assigns shall not be (i) liable for any act or omission of any prior lessor under this Lease; (ii) liable for the performance of Landlord's covenants pursuant to the provisions of this Lease which arise and accrue prior to such entity succeeding to the interest of Landlord under this Lease or acquiring such right to possession; (iii) subject to any offsets or defense which Tenant may have at any time against Landlord; (iv) bound by any base rent or other sum which Tenant may have paid previously for more than one (1) month; or (v) liable for the performance of any covenant of Landlord under this Lease which is capable of performance only by the original Landlord.

23. QUIET ENJOYMENT.

Landlord covenants that so long as Tenant keeps and performs each and every covenant, agreement, term, provision and condition herein contained on the part and on behalf of Tenant to be kept and performed, Tenant shall peaceably and quietly hold, occupy and enjoy the Premises during the Term from and against the claims of all persons lawfully claiming by, through or under Landlord subject, nevertheless, to the covenants, agreements, terms, provisions and conditions of this Lease, any matters of record or of which Tenant has knowledge and to any Mortgage to which this Lease is subject and subordinate, as hereinabove set forth.

24. NOTICES.

Any notice, consent, request, bill, demand or statement hereunder (each, a "**Notice**") by either party to the other party shall be in writing and shall be deemed to have been duly given when either delivered by hand or by nationally recognized overnight courier (in either case with evidence of delivery or refusal thereof) addressed as follows:

If to Landlord:	HCP/King Hayden Campus LLC. c/o King Street Properties 800 Boylston Street, Suite 1570 Boston, MA 02199 Attention: Stephen D. Lynch
With a copy to:	Goulston & Storrs PC 400 Atlantic Avenue Boston, MA 02110 Attention: King Street
if to Tenant:	Prior to the Term Commencement Date: Matthias Jaffé | CFO LogicBio Therapeutics 99 Erie Street Cambridge, MA 02139 From and after the Term Commencement Date: Matthias Jaffé | CFO LogicBio Therapeutics 65 Hayden Avenue Lexington, MA 02421
With a copy to:	James Duberman, Esq. Outside GC LLC 501 Boylston Street, 10th Floor Boston, MA 02116

Notwithstanding the foregoing, any notice from Landlord to Tenant regarding ordinary business operations (e.g., exercise of a right of access to the Premises, maintenance activities, invoices, etc.) may also be given by written notice delivered by electronic mail or facsimile to Tenant's designated representative in lieu of delivering copies as specified above, Tenant hereby designating Matthias Jaffé (e-mail: mjaffe@logicbio.com) as its designated representative for the purposes of this Section 24. Either party may at any time change the address or specify an additional address for such Notices by delivering or mailing, as aforesaid, to the other party a notice stating the change and setting forth the changed or additional address, provided such changed or additional address is within the United States. Notices shall be effective upon the date of receipt or refusal thereof.

25. MISCELLANEOUS

25.1 Separability. If any provision of this Lease or portion of such provision or the application thereof to any person or circumstance is for any reason held invalid or unenforceable, the remainder of this Lease (or the remainder of such provision) and the application thereof to other persons or circumstances shall not be affected thereby.

25.2 Captions. The captions are inserted only as a matter of convenience and for reference, and in no way define, limit or describe the scope of this Lease nor the intent of any provisions thereof.

25.3 Broker. Tenant and Landlord each warrants and represents that it has dealt with no broker in connection with the consummation of this Lease other than Jones Lang LaSalle and Newmark Knight Frank (collectively, "**Broker**"). Tenant and Landlord each agrees to defend, indemnify and save the other harmless from and against any Claims arising in breach of the representation and warranty set forth in the immediately preceding sentence. Landlord shall be solely responsible for the payment of any brokerage commissions to Broker.

25.4 Entire Agreement. This Lease, Lease Summary Sheet and Exhibits 1-12 attached hereto and incorporated herein contain the entire and only agreement between the parties and any and all statements and representations, written and oral, including previous correspondence and agreements between the parties hereto, are merged herein. Tenant acknowledges that all representations and statements upon which it relied in executing this Lease are contained herein and that Tenant in no way relied upon any other statements or representations, written or oral. This Lease may not be modified orally or in any manner other than by written agreement signed by the parties hereto.

25.5 Governing Law. This Lease is made pursuant to, and shall be governed by, and construed in accordance with, the laws of the Commonwealth of Massachusetts and any applicable local municipal rules, regulations, by-laws, ordinances and the like.

25.6 Representation of Authority. By his or her execution hereof, each of the signatories on behalf of the respective parties hereby warrants and represents to the other that he or she is duly authorized to execute this Lease on behalf of such party. Upon Landlord's request, Tenant shall provide Landlord with evidence that any requisite resolution, corporate authority and any other necessary consents have been duly adopted and obtained.

25.7 Expenses Incurred by Landlord Upon Tenant Requests. Tenant shall, upon demand, reimburse Landlord for all reasonable expenses, including, without limitation, legal fees, incurred by Landlord in connection with all requests by Tenant for consents or approvals related to this Lease, including, without limitation, costs incurred by Landlord in the review and approval of Tenant's plans and specifications in connection with proposed Alterations to be made by Tenant to the Premises or in connection with requests by Tenant for Landlord's consent to make a Transfer. Such costs shall be deemed to be Additional Rent under this Lease.

25.8 Survival. Without limiting any other obligation of Tenant which may survive the expiration or prior termination of the Term, all obligations on the part of Tenant to indemnify, defend, or hold Landlord harmless, as set forth in this Lease shall survive the expiration or prior termination of the Term.

25.9 Limitation of Liability. Tenant shall neither assert nor seek to enforce any claim against Landlord or any of the Landlord Parties, or the assets of any of the Landlord Parties, for breach of this Lease or otherwise, other than against Landlord's interest in the Building and in the uncollected rents, issues and profits thereof, and Tenant agrees to look solely to such interest for the satisfaction of any liability of Landlord under this Lease. This Section 25.9 shall not limit any right that Tenant might otherwise have to obtain injunctive relief against Landlord. **Landlord and Tenant specifically agree that in no event shall any officer, director, trustee, employee or representative of Landlord or any of the other Landlord Parties ever be personally liable for any obligation under this Lease, nor shall Landlord or any of the other Landlord Parties be liable for consequential or incidental damages or for lost profits whatsoever in connection with this Lease.**

25.10 Binding Effect. The covenants, agreements, terms, provisions and conditions of this Lease shall bind and benefit the successors and assigns of the parties hereto with the same effect as if mentioned in each instance where a party hereto is named or referred to, except that no violation of the provisions of Section 13 hereof shall operate to vest any rights in any successor or assignee of Tenant.

25.11 Landlord Obligations upon Transfer. Upon any sale, transfer or other disposition of the Building, Landlord shall be entirely freed and relieved from the performance and observance thereafter of all covenants and obligations hereunder on the part of Landlord to be performed and observed, it being understood and agreed in such event (and it shall be deemed and construed as a covenant running with the land) that the person succeeding to Landlord's ownership of said reversionary interest shall thereupon and thereafter assume, and perform and observe, any and all of such covenants and obligations of Landlord, except as otherwise agreed in writing.

25.12 No Grant of Interest. Tenant shall not grant any interest whatsoever in any fixtures within the Premises or any item paid in whole or in part by Landlord's Contribution or by Landlord.

25.13 Financial Information. Tenant shall deliver to Landlord, within thirty (30) days after Landlord's reasonable request, Tenant's most recently completed balance sheet and related statements of income, shareholder's equity and cash flows statements (audited if available) reviewed by an independent certified public accountant and certified by an officer of Tenant as being true and correct in all material respects for the sole purposes of the sale or refinance of this Property. Any such financial information may be relied upon by any actual or potential ground lessor, purchaser, or mortgagee of the Property or any portion thereof.

25.14 OFAC Certificate and Indemnity. Executive Order No. 13224 on Terrorist Financing, effective September 24, 2001 (the "**Executive Order**"), and the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (Public Law 10756, the "**Patriot Act**") prohibit certain property transfers. Tenant hereby represents and warrants to Landlord (which representations and warranties shall be

deemed to be continuing and re-made at all times during the Term) that neither Tenant nor any stockholder, manager, beneficiary, partner, or principal of Tenant is subject to the Executive Order, that none of them is listed on the United States Department of the Treasury Office of Foreign Assets Control ("OFAC") list of "Specially Designated Nationals and Blocked Persons" as modified from time to time, and that none of them is otherwise subject to the provisions of the Executive Order or the Patriot Act. The most current list of "**Specially Designated Nationals and Blocked Persons**" can be found at http://www.treas.gov/offices/eotffc/ofac/sdn/index.html. Tenant shall from time to time, within ten days after request by Landlord, deliver to Landlord any certification or other evidence requested from time to time by Landlord in its reasonable discretion, confirming Tenant's compliance with these provisions. No assignment or subletting shall be effective unless and until the assignee or subtenant thereunder delivers to Landlord written confirmation of such party's compliance with the provisions of this subsection, in form and content satisfactory to Landlord. If for any reason the representations and warranties set forth in this subsection, or any certificate or other evidence of compliance delivered to Landlord hereunder, is untrue in any respect when made or delivered, or thereafter becomes untrue in any respect, then an Event of Default hereunder shall be deemed to occur immediately, and there shall be no opportunity to cure. Tenant shall indemnify, defend with counsel reasonably acceptable to Landlord, and hold Landlord harmless from and against, any and all liabilities, losses claims, damages, penalties, fines, and costs (including attorneys' fees and costs) arising from or related to the breach of any of the foregoing representations, warranties, and duties of Tenant. The provisions of this subsection shall survive the expiration or earlier termination of this Lease for the longest period permitted by law.

25.15 Confidentiality. Tenant acknowledges and agrees that the terms of this Lease are confidential. Disclosure of the terms hereof could adversely affect the ability of Landlord to negotiate other leases with respect to the Building and may impair Landlord's relationship with other tenants of the Building. Tenant agrees that it and its partners, officers, directors, employees, brokers, and attorneys, if any, shall not disclose the terms and conditions of this Lease to any other person or entity without the prior written consent of Landlord which may be given or withheld by Landlord, in Landlord's sole discretion, except as required for financial disclosures or securities filings, as required by the order of any court or public body with authority over Tenant, or in connection with any litigation between Landlord and Tenant with respect this Lease. It is understood and agreed that damages alone would be an inadequate remedy for the breach of this provision by Tenant, and Landlord shall also have the right to seek specific performance of this provision and to seek injunctive relief to prevent its breach or continued breach.

25.16 Force Majeure. Other than for Tenant's obligations under this Lease that can be performed by the payment of money (e.g., payment of Rent and maintenance of insurance), whenever a period of time is herein prescribed for action to be taken by either party hereto, such party shall not be liable or responsible for, and there shall be excluded from the computation of any such period of time, any delays due to strikes, riots, acts of God, shortages of labor or materials, war, acts of terrorism, governmental laws, regulations, or restrictions, or any other causes of any kind whatsoever which are beyond the control of such party (collectively "**Force Majeure**"). In no event shall financial inability of a party be deemed to be Force Majeure.

[SIGNATURES ON FOLLOWING PAGE]

IN WITNESS WHEREOF the parties hereto have executed this Lease as a sealed instrument as of the Execution Date.

LANDLORD

HCP/KING HAYDEN CAMPUS LLC,
a Delaware limited liability company

By: King Mattingly LLC, a Massachusetts limited liability company, its Manager

By: King Street Properties Investments LLC, a Massachusetts limited liability company, its Manager

By: _____

Name: _____
Its Manager

TENANT

LOGICBIO THERAPEUTICS, INC.,
a Delaware corporation

By: _____
Name: _____
Title: _____

EXHIBIT 1A

LEASE PLAN – PRIME PREMISES

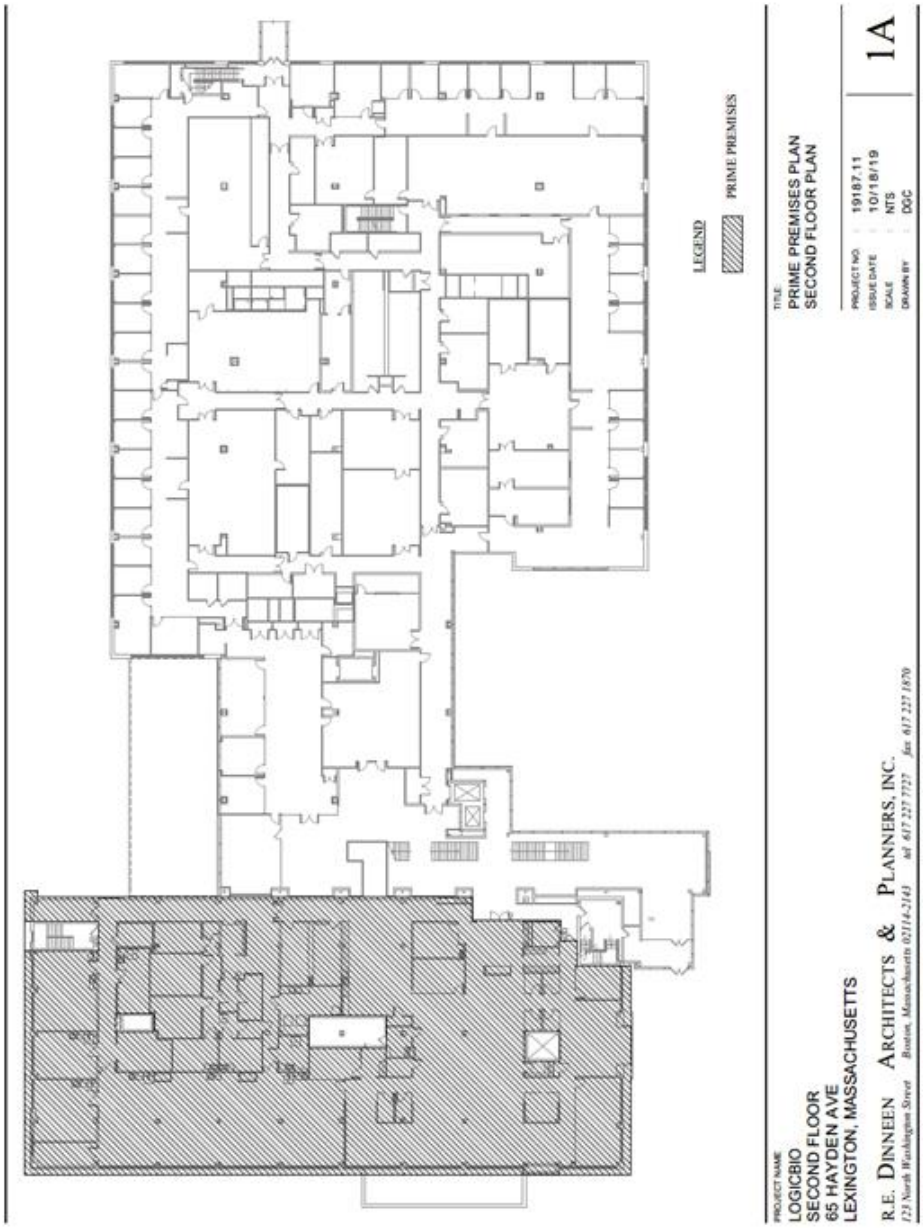

EXHIBIT 1B

LEASE PLAN – PH SYSTEM PREMISES

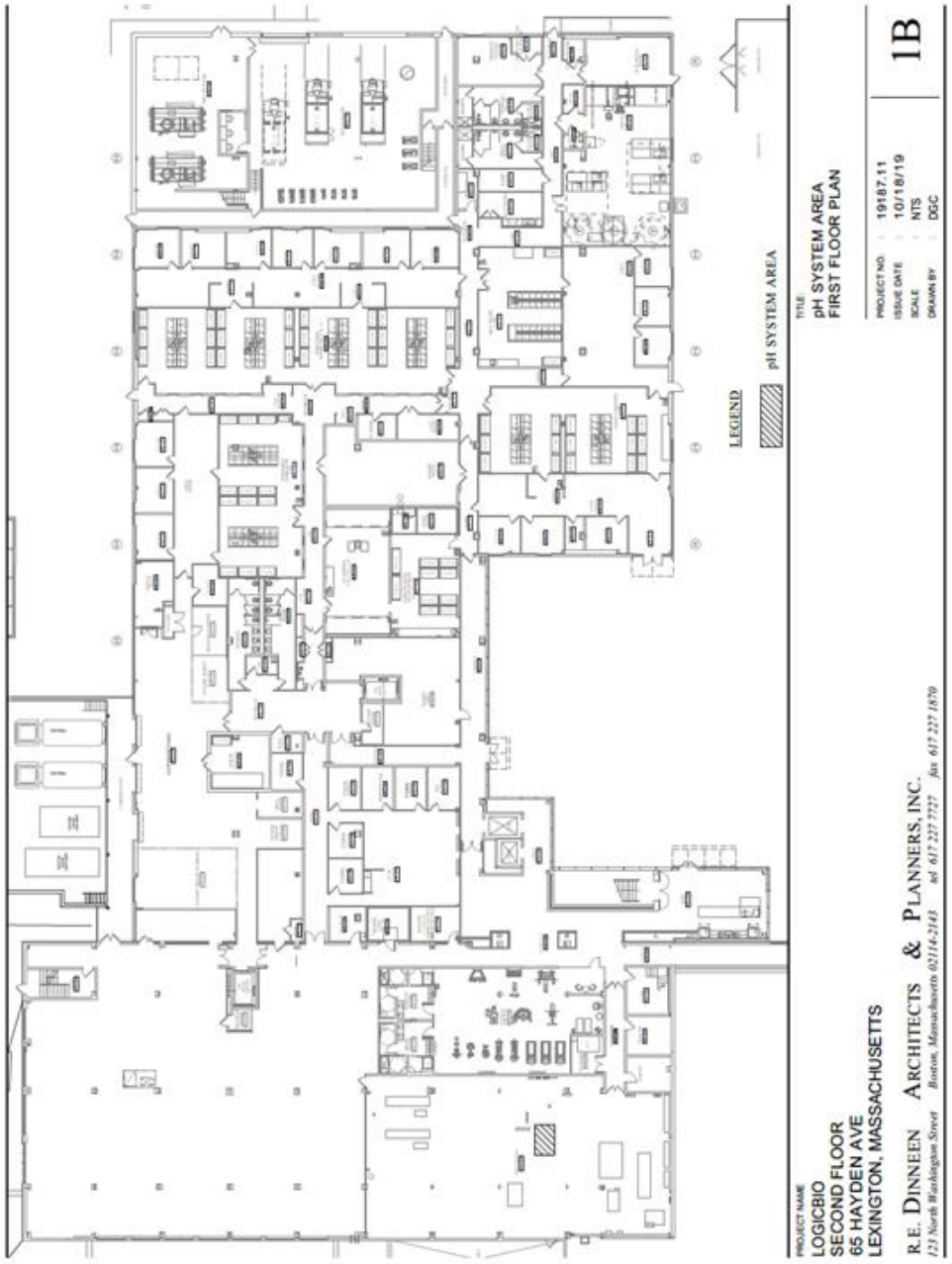

EXHIBIT 1C

TENANT'S ROOFTOP PREMISES

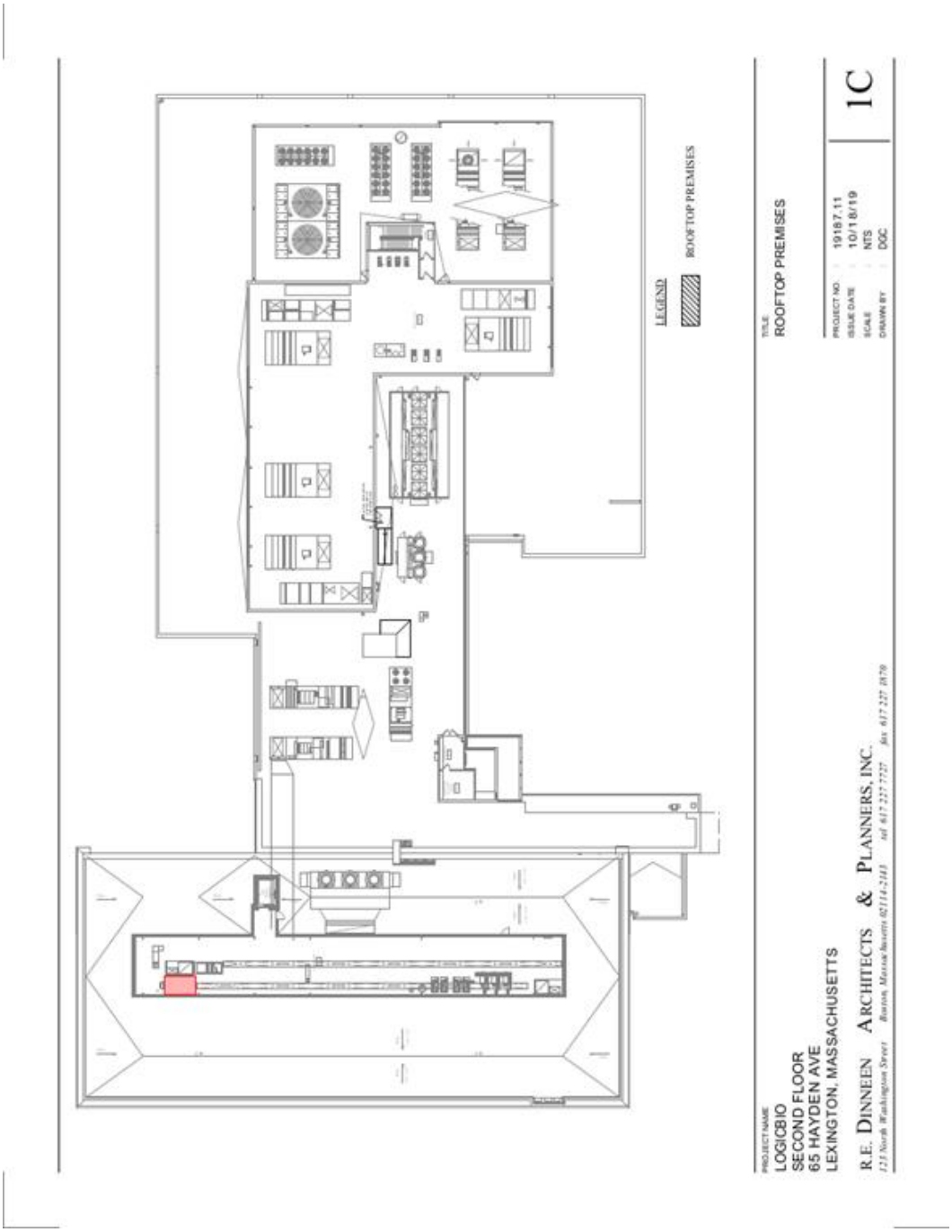

EXHIBIT 2

LEGAL DESCRIPTION - LAND

Real property in the Town of Lexington, County of Middlesex, Commonwealth of Massachusetts, described as follows:

Parcel One (45 & 55 Hayden Avenue):

A certain parcel of land in the Commonwealth of Massachusetts, County of Middlesex, Town of Lexington, and shown as Lot 2 on a plan entitled “Plan of Land in Lexington, Mass. (Middlesex County),” dated March 27, 1998, recorded October 6, 1998, with Middlesex South Registry of Deeds as Plan No. 1088 of 1998 in Book 29190, Page 447, prepared by Beals and Thomas, Inc., more particularly bounded and described as follows:

Beginning at the most southwesterly corner of the premises, at the southeasterly corner of Lot 1 as shown on said plan, then running:

N 02° 20’ 56” E 180.68 feet to a point, thence turning and running;

N 87° 39” 04” W 40.00 feet to a point, thence turning and running;

N 02° 20’ 56” E 122.19 feet to a point, thence turning and running;

N 87° 39’ 04” E 40.00 feet to a point, thence turning and running;

N 02° 20’ 56” E 547.13 feet to a point, thence turning and running, said last five courses being bounded by Lot 1, as shown on said plan, thence turning and running;

S 87° 36’ 20” E 1,330.04 feet to a point of curvature, thence running;

Northeasterly to a curve to the left having a radius of 135.00 feet and a length of 58.90 feet to a point of tangency, thence running;

N 67° 23’ 52” E 146.89 feet to a point, thence turning and running;

S 03° 52’ 06” E 111.25 feet to a point, said last four courses being bounded by land now or formerly of the Town of Lexington, thence turning and running;

S 44° 07’ 54 W 561.19 feet to a point, thence turning and running;

S 22° 29’ 38” E 435.76 feet to a point, said last two courses are bounded in part by land now or formerly the Town of Lexington and, in part now or formerly of Hayden Office Trust, thence running;

Southwesterly by a curve to the right, having a radius of 985.00 feet and a length of 12.11 feet to a point of tangency, thence turning and running;

N 87° 36’ 20” W 1,329.27 feet to the point of beginning, said last two courses being bounded by the northerly sideline of Hayden Avenue.

Containing 1,123,722 square feet more or less, or 25.797 acres, more or less.

A portion of said Lot 2 is registered land, described as follows:

Lot 293 on Land Court Plan 19485 N as approved by the Land Court and filed in the Land Registration Office; and

Lots 10 and 11 on Land Court Plan 16660 O as approved by the Land Court and filed with the Land Registration Office.

Parcel Two (Appurtenant Easements - 45 & 55 Hayden Avenue):

A. There is appurtenant to the above described Lot 11 the right and easement to use the drainage ditch running from west to east across the northerly portion of Lot 10, shown on said plan, as set forth in Registered Document No. 517903.

B. There is appurtenant to the above described Lot 11 rights and easements for sewer purposes as set forth in Registered Document No. 479201.

C. There is appurtenant to said Lot 293 the benefits of the agreement and reservation as to trunk sewer more particularly set forth in deed filed as Document No. 479738.

D. Lot 10 has the benefit of a reservation in the strip of land marked sewer easement as shown on said plan, set forth in Document 517903 and the rights and easements for sewer purposes as set forth in Registered Document No. 479201, insofar as applicable.

E. Together with the benefit of the appurtenant easements over Lot B shown on plan entitled “A Compiled Plan of Land in Lexington, Mass.” Dated August 27, 1970, by John J. McSweeney, recorded with Middlesex South District Deeds in Book 11928, Page 614, as shown on said plan, as reserved in a taking by the Town of Lexington dated November 30, 1970, recorded with said Deeds in Book 11928, Page 611, and in a deed from George H. Crawford to the Town of Lexington of the said Lot B dated December 7, 1970, recorded with said Deeds in Book 11928, Page 614.

F. Together with the benefit of the appurtenant easements set forth in Declaration of Covenants and Easements dated September 18, 1998 filed as Document No. 1084070 and recorded in Book 29287, Page 189; as affected by Amended and Restated Declaration of Covenants and Easements dated November 8, 1999, filed as Document No. 1123738, and recorded in Book 30855, Page 323; as affected by First Amendment to Amended and Restated Declaration of Covenants and Easements dated March 26, 2002, filed as Document No. 1261521, recorded in Book 37256, Page 364.

Parcel Three (65 Hayden Avenue):

That certain parcel of land situate in Lexington in the County of Middlesex and Commonwealth of Massachusetts shown as Lot 292 on Land Court Plan No. 19485-N.

All of said boundaries are determined by the Court to be located as shown on a subdivision plan, as approved by the Court, filed in the Land Registration Office, a copy of which is filed in the Registry of Deeds for the South Registry District of Middlesex County in Registration Book 1178 Page 11.

Parcel Four (Appurtenant Easements - 65 Hayden Avenue):

There is appurtenant to said Lot 292 the right to use the whole of Grassland Street and Valleyfield Street as shown on the plan Registered in the Registration Book 383 Page 149 in common with others entitled thereto; the right to use all streets or roads as shown on the plan Registered in Registration Book 506 Page 153, in common with all others legally entitled thereto; the benefit of the agreement and reservation as to trunk sewer more particularly set forth in the deed Registered as Document No. 479738; and the benefit of the appurtenant easements set forth in Declaration of Covenants and Easements dated September 18, 1998 filed as Document No. 1084070 and recorded in Book 29287, Page 189; as affected by Amended and Restated Declaration of Covenants and Easements dated November 8, 1999, filed as Document No. 1123738, and recorded in Book 30855, Page 323; as affected by First Amendment to Amended and Restated Declaration of Covenants and Easements dated March 26, 2002, filed as Document No. 1261521, recorded in Book 37256, Page 364

EXHIBIT 3

Intentionally Deleted

EXHIBIT 4

WORK LETTER

This Exhibit is attached to and made a part of the Lease (the "**Lease**") by and between **HCP/KING HAYDEN CAMPUS LLC**, a Delaware limited liability company ("**Landlord**"), and **LOGICBIO THERAPEUTICS, INC.**, a Delaware corporation ("**Tenant**"), for space located at 65 Hayden Avenue, Lexington, Massachusetts. Capitalized terms used but not defined herein shall have the meanings given in the Lease.

This Work Letter shall set forth the obligations of Landlord and Tenant with respect to the improvements to be performed in preparing the Premises for Tenant's use. This Exhibit shall not be deemed applicable to any additional space added to the Premises at any time or from time to time, whether by any options under the Lease or otherwise, or to any portion of the original Premises or any additions to the Premises in the event of a renewal or extension of the original Term of the Lease, whether by any options under the Lease or otherwise, unless expressly so provided in the Lease or any amendment or supplement to the Lease.

1. Definitions. This Work Letter shall set forth the obligations of Landlord and Tenant with respect to the improvements to be performed in the Premises for Tenant's use. For the purposes of this Lease, "**Landlord's Work**" consists of: (i) the Base Building Work described on Exhibit 4-1, and (ii) the Tenant Improvement Work, as hereinafter defined. The "**Tenant Improvement Work**" shall mean all of the work to be performed by Landlord in preparing the Premises for Tenant's occupancy as shown on the Construction Documents (as hereinafter defined), excluding any Base Building Work, and shall also consist of the construction of the Tenant's vivarium in accordance with the Construction Documents (the "**Vivarium Work**"). The parties intend that Tenant Improvement Work will be in accordance with construction documents (the "**Construction Documents**") prepared by Landlord and approved by Tenant in accordance with this Exhibit 4, and the Construction Documents will be based upon the schematic plan ("**Initial Plan**") attached hereto as Exhibit 4-2, and the equipment list ("**Equipment List**") attached hereto as Exhibit 4-3. The "**Cost of Tenant Improvement Work**" shall be defined as all hard costs ("**Hard Costs**") incurred by Landlord relating to the performance of the Tenant Improvement Work (including, without limitation, the cost of obtaining permits and any applicable state sales and use taxes) and soft costs ("**Soft Costs**") incurred by Landlord in connection with the Tenant Improvement Work (including, without limitation, the cost of preparing Construction Documents). Landlord will charge Tenant a construction management fee equal to 3% of all Hard Costs payable by Tenant in connection with the Tenant Improvement Work. The items listed on Exhibit 4-1 as "Tenant Responsibility" ("**Tenant's Work**") shall be performed by Tenant, at Tenant's sole cost and expense.

2. Contractor; GMP. Landlord shall enter into a contract ("**Contract**") for the Tenant Improvement Work with BW Kennedy ("**Contractor**"). The Contract may be on the basis of a guaranteed maximum price ("**GMP**").

3. Preparation of Construction Documents. The Contractor and/or Landlord shall engage RE Dineen as subconsultants to prepare the Construction Documents for Tenant's approval, which approval shall not be unreasonably withheld, conditioned, or delayed.

4. Tenant Responses. Tenant shall respond, in writing, to any requests from Landlord or the Contractor for information, consents, or authorizations to proceed, within two (2) business days of Tenant's receipt of such request. Tenant shall respond within any designated period of time set forth in the estimated construction schedule attached hereto as Exhibit 4-4 and otherwise cooperate with Landlord to achieve such construction schedule. Any failure by Tenant to respond within such time period may be the basis of a Tenant Delay.

5. Tenant shall have the right to hire a mutually approved Tenant Construction Representative to oversee all required construction relative to the Tenant Premises.

6. Bid Process. Tenant hereby acknowledges that:

(i) the Contractor will receive a single bid for each of the following portions of Landlord's Work from the designated subcontractors ("**Designated Subcontractors**") listed below who will perform such portions of Landlord's Work:

- Mechanical/HVAC: Environmental Systems, Inc.
- Plumbing: North Shore Mechanical Contractors, Inc.
- Fire Protection: Legacy Fire Protection, Inc.
- Electrical: Nappa Electric, Inc.

(ii) Landlord will cause the Contractor to use reasonable efforts to obtain at least three (3) bidders for other portions of Landlord's Work; however, given the current market, it may not be possible to obtain more than one or two bidders with respect to portions of Landlord's Work.

Tenant shall have the right to review the revised GMP within three (3) business days after receipt thereof.

7. Changes. If Tenant shall request any change, addition or alteration to the scope of work set forth on the Initial Plan and in Exhibit 4-1 or in any of the Plans after approval by Landlord ("**Changes**"), Landlord shall have such revisions to the drawings prepared. Promptly upon completion of the revisions, Landlord shall notify Tenant in writing of the increased cost, if any, which will be chargeable to Tenant by reason of such change, addition or deletion. Tenant, within three (3) business days, shall notify Landlord in writing whether it desires to proceed with such Change. In the absence of such written authorization, Landlord shall have the option to continue design of and work on the Premises disregarding the requested Change. Tenant shall reimburse Landlord for the Cost of Tenant Improvement Work associated with such Changes and for the design cost associated with the preparation of the revised Plans or Construction Documents within thirty (30) days of upon Billing, as such Change Work is being performed. In addition, to the extent any Tenant Delay result in an increase in the Cost of Tenant Improvement Work, if any, Tenant shall reimburse Landlord for such increased cost within thirty (30) days of upon Billing. "**Billing**" shall be defined as any invoice from Landlord setting forth, reasonable detail, the amount due from Tenant, and shall include invoices from vendors and service providers, and, if applicable, applications for payment from the Contractor for work completed through the date of Billing, as certified by the Contractor. Billing may not be submitted to Tenant more than one time per calendar month. The amounts payable by Tenant hereunder constitute Rent payable pursuant to the Lease, and the failure to timely pay same constitutes an event of default under the Lease.

8. Claims. To the extent that any claims ("**Claims**") by the Contractor cause an increase in the Cost of Tenant Improvement Work, Tenant shall pay for such excess within thirty (30) days of Billing. Claims shall include any amounts properly due to the Contractor under the Contract based upon the claims of the Contractor under the Contract, provided however, that the Claims shall not include any amounts arising from the default or negligence of Landlord, or Landlord's agents or employees, under the Contract.

9. Performance of Landlord's Work. Following approval of the Construction Documents and Tenant's written authorization to proceed with Tenant Improvement Work, Landlord shall cause the Tenant Improvement Work to be constructed in all material respects in accordance with the approved Construction Documents and at Landlord's sole cost and expense, except as otherwise expressly set forth herein.

10. Miscellaneous

(a) **Tenant's Authorized Representative**. Tenant designates Matthias Jaffé (email: mjaffe@logicbio.com, telephone 617-959-7425; "**Tenant's Representative**") as the only person authorized to act for Tenant pursuant to this Work Letter. Landlord shall not be obligated to respond to or act upon any request, approval, inquiry or other communication ("**Communication**") from or on behalf of Tenant in connection with this Work Letter unless such Communication is in writing from Tenant's Representative. Tenant may change either Tenant's Representative at any time upon not less than five (5) business days advance written notice to Landlord.

(b) **Landlord's Authorized Representative**. Landlord designates Brian Grisaru (email: bgrisaru@ks-prop.com, telephone 617-910-5033; "**Landlord's Representative**") as the only person authorized to act for Landlord pursuant to this Work Letter. Tenant shall not be obligated to respond to or act upon any request, approval, inquiry or other Communication from or on behalf of Landlord in connection with this Work Letter unless such Communication is in writing from Landlord's Representative. Landlord may change either Landlord's Representative at any time upon not less than five (5) business days advance written notice to Tenant.

(c) Tenant shall have the right, during the performance of Landlord's Work, to have Tenant's Representative participate in weekly construction meetings with Landlord and the Contractor as to the status of the performance of Tenant Improvement Work.

(d) Tenant shall have access to the Premises prior to the Commencement Date in accordance with the provisions of Section 1.4 of the Lease.

11. Disputes.

Any disputes relating to provisions or obligations in this Lease in connection with Landlord's Work or Tenant's Work or this Exhibit 4 shall be submitted to arbitration in accordance with the provisions of applicable state law, as from time to time amended. Arbitration proceedings, including the selection of an arbitrator, shall be conducted pursuant to the rules, regulations and procedures from time to time in effect as promulgated by the American Arbitration Association. Notwithstanding the foregoing, the parties hereby agree that the arbitrator for any disputes relating to Landlord's Work or Tenant's Work shall be a construction consultant, experienced in the

construction of offices/research/laboratory buildings/campuses in the Route 128/Route 2/Alewife corridor real estate market, as mutually agreed upon by the parties, or, if not then designated by the parties, within ten (10) days after either party makes a request for arbitration hereunder, or (if the parties do not mutually agree upon such arbitrator) as designated by the Boston office of the American Arbitration Association upon request by either party. Prior written notice of application by either party for arbitration shall be given to the other at least ten (10) days before submission of the application to the said Association's office in Boston, Massachusetts. The arbitrator shall hear the parties and their evidence. The decision of the arbitrator shall be binding and conclusive, and judgment upon the award or decision of the arbitrator may be entered in the appropriate court of law; and the parties consent to the jurisdiction of such court and further agree that any process or notice of motion or other application to the Court or a Judge thereof may be served outside the Commonwealth of Massachusetts by registered mail or by personal service, provided a reasonable time for appearance is allowed. The costs and expenses of each arbitration hereunder and their apportionment between the parties shall be determined by the arbitrator in his award or decision. Except where a specified period is referenced in this Lease, no arbitrable dispute shall be deemed to have arisen under this Lease prior to the expiration of the period of twenty (20) days after the date of the giving of written notice by the party asserting the existence of the dispute together with a description thereof sufficient for an understanding thereof. In connection with the foregoing, it is expressly understood and agreed that the parties shall continue to perform their respective obligations under the Lease during the pendency of any such arbitration proceeding hereunder (with any adjustments or reallocations to be made on account of such continued performance as determined by the arbitrator in his or her award).

EXHIBIT 4-1

Landlord/Tenant Responsibilities Matrix

65 Hayden Avenue *updated: 10/28/2019*
LogicBio Therapeutics

Landlord/Tenant Responsibilities Matrix

Scope Description	Landlord Responsibility	Tenant Responsibility
Scope of Work		
Finishes: The lab areas shall have latex painted walls with a 4" vinyl base and Armstrong Excelon VCT flooring throughout with Armstrong Meditech sheet vinyl flooring in the specialty lab. The lab areas ceiling shall be 2'x4 USG Climaplus 3270 sheetrock lay-in with 15/16" prelude XL 7300 exposed tee white on white. The office areas shall have latex painted walls with a 4" vinyl base and Milliken Nordic series carpet tile throughout. TBD specified walls in office will be painted with tenant selected accent color. The office areas ceiling shall be 2'x2' mineral fiber Armstrong Dune 1775 beveled tegular with Armstrong 9/16" silhouette XL 76008. Walls between offices and conference rooms will extend to the deck. Aluminum door frames and wood doors with 1/2" storefront glass at offices, conference and meeting room.	X	
Furniture: Furnish and install cubicles, work stations, break area furniture, and other office furniture		X
Break Area / Kitchen: Furnish and install upper and lower plastic laminate cabinets and solid surface countertop with sink. (2) refrigerators, (1) microwave and (1) dishwasher. Sink and dishwasher to have HWS and CWS.	X	
Lighting: The lab areas shall have 2'x2' Metalux 22FP LED panel and 2'x4' Metalux 24FP LED panel. The office areas shall have 2'x2' Metalux 22RTC LED troffer, 2'x4' Metalux 24RTC LED troffer, and 4" Portfolio LED square recessed downlight. The conference rooms will contain a linear A3 light fixture with dimmable ballast.	X	
HVAC: Furnish and install all branch supply, return, and exhaust duct work from riser, VAV terminals and hot water/chilled water fan coil units for space with associated piping, DDC controls and wiring tied into base building BMS, ductwork and piping insulation, registers, grilles, and diffusers.	X	
Fume Hoods: LL to provide two reused 6' fume hoods per Premises plan. Fume hoods to have compressed air and vacuum services.	X	
Plumbing: pH neutralization and branch piping to lab sinks. Five (5) total RO/DI drops included at lab sinks in Biology Lab and Tissue Culture Labs. RO/DI loop available in the building for tenant's use.	X	
Electrical: Provide power to offices, copy room, general convenience outlets for non specific areas, and Tenant provided furniture. Stand by generator power connections at areas in locations TBD (maximum connected load 80 kW).	X	
Lab case work: Furnish and install lab casework tables and benches with reagent shelving per Final Schematic Plan.	X	
Lab equipment: All lab equipment shown on Tenant Equipment List including but not limited to Bio Safety Cabinets, water purifications systems, nitrogen generator manifolds, CO2 manifolds, bulk storage tanks and associated distribution piping.		X
Plumbing and lab utilities: Furnish and install one compressed air and one vacuum drop to each ceiling panel for equipment. Furnish and install drains and tie-ins for Tenant equipment as TBD. Furnish and install pH neutralization tank. Furnish and install all lab sinks and drain piping (including pH branch lines to Tenant pH neutralization tank). Furnish and install emergency eyewash stations and emergency showers. HWS and CWS to be provided to lab sinks and kitchenette sink.	X	
Existing Equipment for Tenant's Use: Landlord to make available for Tenant's use a cold room, autoclave, and glasswash system in their "as-is" condition (the "Existing Equipment"). The Existing Equipment will be located within the space per the Final Schematic Plan.	X	
ACF Assumptions: - Approximately 1,500 sf located on the 2nd floor - Mice, Rat, Guinea pig sized animals **Included Scope:** - (1) scullery sink loacted in ACF - One air lock for entry and exit of suite - Provide tables within ACF per plan - Lighting controls provided with day/night settings. Red night time lamp switch incorporated into controls - Air pressure detection system to visually display pressurizations - Backup air circulation provided through dedicated emergency fans (dedicated backup air handler not included) - Epoxy floors - Epoxy painted walls - Vinyl coated lab grade ACT or drywall ceilings - HEPA filtration provided through Tenant supplied caging systems	X	
ACF - Excluded from Landlord's Scope: - Cage and bottle washers - Separate autoclave or glasswash		X
Security, card access, tele-data, and A/V for Premises and Tenant Equipment		X

EXHIBIT 4-2

Initial Plan

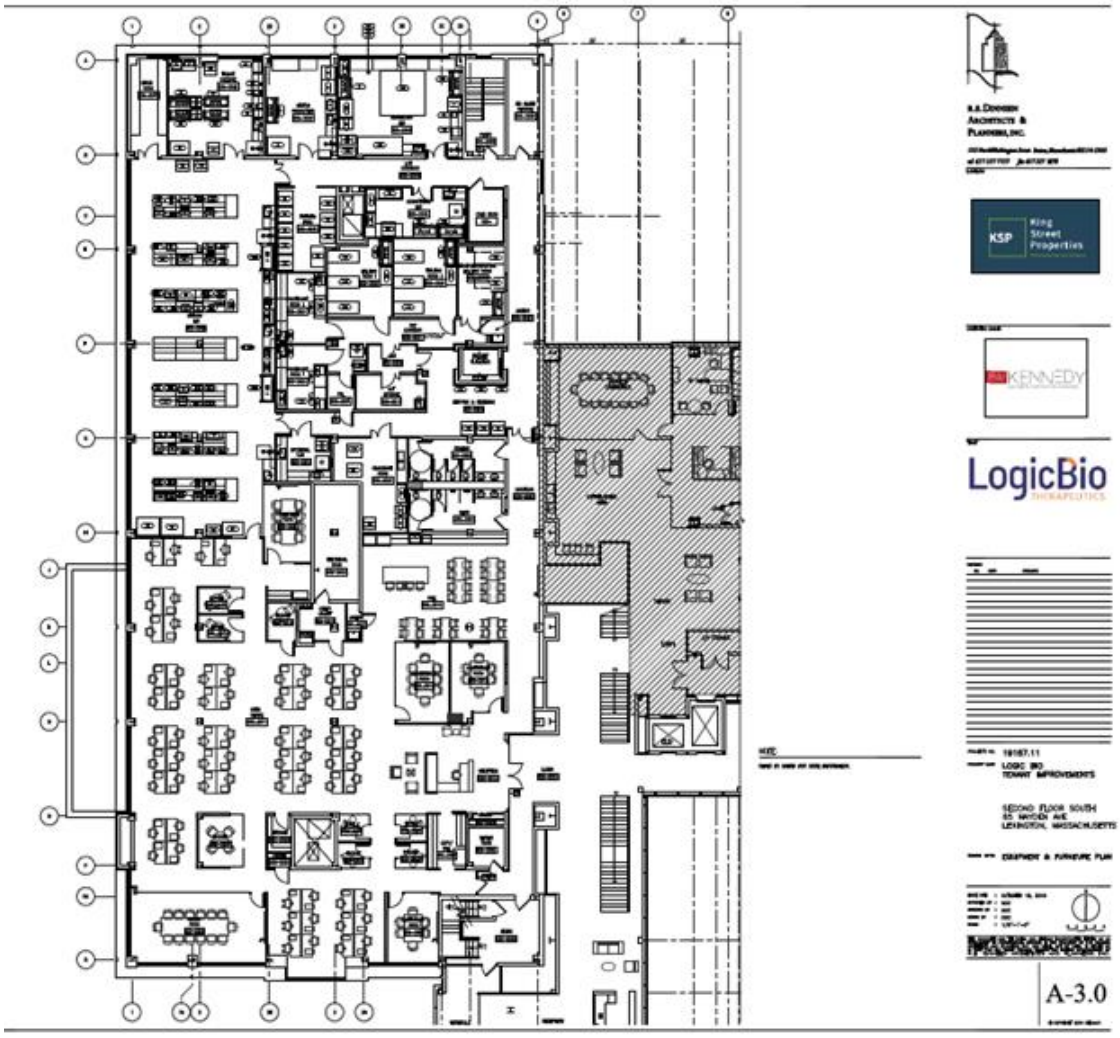

EXHIBIT 4-3

Equipment List

[see attached]

EXHIBIT 4-3

Construction Schedule

[see attached]

EXHIBIT 5

Base Building Capacities

Tenant Maximum Capacity:

Base Building Generator: 80 kilowatts

RODI Water: 18 megohm water with a flow rate of 42 gallons per minute

EXHIBIT 6

FORM OF LETTER OF CREDIT

[To be attached]

EXHIBIT 7

LANDLORD'S SERVICES

1. Hot and cold water to the common area lavatories
2. Electricity for building common areas
3. HVAC services to the Building common areas and the Premises (but excepting those areas served by supplemental HVAC solely dedicated to any tenant).
4. Maintenance and repair of the Property as described in Section 10.2
5. Elevator service
6. Trash removal
7. Snow removal
8. Exterior grounds and parking maintenance
9. Management services
10. Building security systems and services
11. Maintenance of life safety systems (fire alarm and sprinkler)
12. Access to the following shared laboratory systems:
    - Vacuum
    - Compressed air
    - RO/DI water
13. Such other services as Landlord reasonably determines are necessary or appropriate for the Property.

EXHIBIT 8

TENANT'S HAZARDOUS MATERIALS

Product Name	Physical State	Flammability Class	Storage Location	Qty	Volume
Agarose I	Solid	N/A	Bench	1	25 g
Anti-HEK 293:HRP Conjugate	Liquid	N/A	4°C Refrigerator	4	12ml
ASSB 20X	Liquid	N/A	4°C Refrigerator	12	20ml
B1 Antibody	Liquid	N/A	-20°C Freezer	1	0.5 mg
Bolt™ MES SDS Running Buffer (20X)	Liquid	N/A	Bench	1	500ml
Buffer RDD	Liquid	N/A	4°C Refrigerator	10	2ml
Cesium Chloride	Cubic Crystals	N/A	Bench	1	50g
Cesium Chloride	Solid		Bench	1	500 g
Dextrose (50%)	Liquid	N/A	Bench	1	1L
Dexycholic acid Sodium Salt	Solid	N/A	Bench	1	500g
DNase I Buffer (10X)	Liquid	N/A	-20°C Freezer	10	1ml
Dnase I Qiagen	Lyophilized	N/A	4°C Refrigerator	5	N/A
EDTA (0.5M, pH 8.0)	Liquid	N/A	Bench	1	500ml
Ethanol	Liquid		Bench	1	6 Gallons
Ethylene glycol (2-amino ethylether) tetraacetic acid, EGTA	Solid		Bench	1	25g
fludarabine, C10H13FN5O7P	Solid	not combustible	4°C Refrigerator	2	1g
GlutaMax	Liquid		Bench	2	1 L
HEK 293 HCP Stds. A-F	Liquid	N/A	4°C Refrigerator	18	1ml
HEPES Buffer	Liquid		Bench	1	250 mL
hydroxyurea	Solid	not combustible	-20C	2	5g
Imperial™ Protein Stain	Liquid	HMIS 1	Bench	1	1000ml
Intercept Odyssey Blocking Buffer	Liquid	N/A	4°C Refrigerator	4	1 L
Licot Goat anti-Mouse Antibody	Solid	N/A	4°C Refrigerator	1	0.5 mg
Magnesium Chloride	Liquid		Bench	3	125ml
Morpholino propanesulfonic acid (MOPS)	Solid		Bench	1	100g
NaOH (10N)	Liquid	N/A	Base Cabinet	1	1 L
NuPAGE™ LDS Sample Buffer (4X)	Liquid	N/A	Bench	1	10ml
NuPAGE™ Sample Reducing Agent (10X)	Liquid	N/A	4°C Refrigerator	1	10ml
OptiPro	Liquid		Bench	1	1L
paraformaldehyde 4%, Polyoxymethylene, OH(CH2O)nH(n=8-100)	Liquid	H228 Flammable solid	4°C Refrigerator	1	1 L
PBS - Tween	Liquid		Bench	1	500 mL
phenol red	Liquid		Bench	1	100 mL
phosphate buffered saline (1X)	Liquid	N/A	Bench	1	1 L
phosphate buffered saline (20X)	Liquid		Bench	24	1L
Pluronic F-68	Liquid	N/A	Bench	2	100ml
Potassium Chloride	Liquid		Bench	2	100ml
Proteinase K Solution (20 mg/mL)	Liquid	N/A	-20°C Freezer	10	1.25ml
Qiagen Proteinase K	Liquid		Bench	1	10mL
RLT Buffer	Liquid	N/A	Bench	2	220ml
RNA later Solution	Liquid		Bench	1	100 mL
RNase AWAY®	Liquid	N/A	Bench	10	475ml
RPE Buffer	Liquid	N/A	Bench	2	65ml
RW1 Buffer	Liquid	GHS Category 3	Bench	2	220ml
Salmon Sperm DNA, sheared (10 mg/mL)	Liquid	N/A	-20°C Freezer	10	1ml
SeeBlue™ Plus2 Pre-stained Protein Standard	Liquid	N/A	4°C Refrigerator	1	0.5ml
SimplyBlue™ SafeStain	Liquid	HMIS 2	Bench	1	1000ml
sodium chloride	Solid		Bench	1	500 g
Sodium Citrate	Liquid		Bench	1	1 L
sodium deoxycholate			Bench	1	100 mL
Sodium dodecyl sulfate	Solid	N/A	Bench	1	100mL
Sodium dodecyl sulfate (10%)	Liquid	N/A	Bench	1	500ml
Sodium hypochlorite (NaClO) / Bleach	Liquid	not combustible	Lab bench	12	1 gallon

sodium phosphate monobasic	Solid		Bench	1	500g
STOP	Liquid	N/A	4°C Refrigerator	4	13ml
Stop Solution	Liquid	N/A	4°C Refrigerator	4	12ml
SYBR Gold Nucleic Acid Gel Stain	Liquid	WHMIS 3	-20°C Freezer	1	500 ul
TAE 50X	Liquid	N/A	Bench	1	1L
TaqMan™ Fast Advanced Master Mix	Liquid	N/A	-20°C Freezer	3	5ml
TBS Wash Concentrate, 20X	Liquid	N/A	4°C Refrigerator	1	50ml
TBS-T (20X)	Liquid	N/A	Bench	1	1 L
TE, pH 8.0	Liquid	N/A	Bench	100	2ml
TMB	Liquid	HMIS 1	4°C Refrigerator	4	12ml
TMB Substrate for ELISA	Liquid	N/A	4°C Refrigerator	4	12ml
Tris-Buffer pH 7.4	Liquid		Bench	6	1 L
Tris-HCl Buffer 7.5	Liquid		Bench	2	500 mL
Tris-HCl pH 8.0	Liquid	N/A	Bench	3	500ml
Tris-HCl pH 8.5	Liquid		Bench	3	500 mL
Triton X-100	Liqid	N/A	Lab Bench	1	500 mL
Trizma base	Solid		Lab Bench	1	250g
Tween 20	Liquid	N/A	Bench	1	1 L
Tween 20	Liqid	N/A	Lab Bench	2	1L

EXHIBIT 9-1

BUILDING RULES AND REGULATIONS

65 HAYDEN AVENUE, LEXINGTON, MA

A. General

1. Tenant and its employees shall not in any way obstruct the sidewalks, halls, stairways, or exterior vestibules of the Building, and shall use the same only as a means of passage to and from their respective offices. At no time shall Tenants permit its employees, contractors, or other representatives to loiter in Common Areas or elsewhere in and about the Property.

2. Corridor doors, when not in use, shall be kept closed.

3. Areas used in common by tenants shall be subject to such regulations as are posted therein.

4. Any Tenant or vendor sponsored activity or event in the Common Area must be approved and scheduled through Landlord's representative, which approval shall not be unreasonably withheld.

5 No animals, except Seeing Eye dogs, shall be brought into or kept in, on or about the Premises or Common Areas, except as approved by Landlord.

6. Alcoholic beverages (without Landlord's prior written consent), illegal drugs or other illegal controlled substances are not permitted in the Common Areas, nor will any person under the influence of the same be permitted in the Common Areas. Landlord reserves the right to exclude or expel from the Building any persons who, in the judgment of the Landlord, is under the influence of alcohol or drugs, or shall do any act in violation of the rules and regulations of the Building.

7. No firearms or other weapons are permitted in the Common Areas.

8. No fighting or "horseplay" will be tolerated at any time in the Common Areas.

9. Tenant shall not cause any unnecessary janitorial labor or services in the Common Areas by reason of Tenant's carelessness or indifference in the preservation of good order and cleanliness.

10. Smoking and discarding of smoking materials by Tenant and/or any Tenant Party is permitted only in exterior locations designated by Landlord. Tenant will instruct and notify its employees and visitors of such policy.

11. Bicycles and other vehicles are not permitted inside or on the walkways outside the Building, except in those areas specifically designated by Landlord for such purposes

12. Tenant shall not operate or permit to be operated on the Premises any coin or token operated vending machine or similar device (including, without limitation, telephones, lockers, toilets, scales, amusement devices and machines for sale of beverages food, candy, cigarettes or other goods), except for those vending machines or similar devices which are for the sole and exclusive use of tenant's employees and located within the Tenant Premises.

13. Canvassing, soliciting, and peddling in or about the Building is prohibited. Tenant, its employees, agents and contractors shall cooperate with said policy, and Tenant shall cooperate and use best efforts to prevent the same by Tenant's invitees.

14. Fire protection and prevention practices implemented by the Landlord from time to time in the Common Areas, including participation in fire drills, must be observed by Tenant at all times.

15. Except as provided for in the Lease, no signs, advertisements or notices shall be painted or affixed on or to any windows, doors or other parts of the Building that are visible from the exterior of the Building unless approved in writing by the Landlord.

16. The restroom fixtures shall be used only for the purpose for which they were constructed and no rubbish, ashes, or other substances of any kind shall be thrown into them. Tenant will bear the expense of any damage resulting from misuse.

17. Tenant will not interfere with or obstruct any building central HVAC, electrical, or plumbing systems.

18. Tenant shall utilize the pest control service designated by Landlord to control pests in the Premises. Except as included in Landlord's Services, tenants shall bear the cost and expense of such pest control services.

19. Tenant shall not install, operate or maintain in the Premises or in any other area of the Building, any electrical equipment which does not bear the U/L (Underwriters Laboratories) seal of approval, or which would overload the electrical system or any part thereof beyond its capacity for proper, efficient and safe operation as determined by Landlord, taking into consideration the overall electrical system and the present and future requirements of the Building.

20. Tenants shall not use more than its proportionate share of telephone lines available to service the Building.

21. Tenants shall not perform improvements or alterations within the Building or their Premises, if the work has the potential of disturbing the fireproofing which has been applied on the surfaces of structural steel members, without the prior written consent of Landlord, subject to the provisions of the Lease.

22. Tenant shall manage its waste removal and janitorial program, at its sole cost and expense, keeping any recyclables, garbage, trash, rubbish and refuse in vermin proof containers for Tenants sole use within the Landlord designated area until removed with all work to be performed during non-business hours.

23. Lab operators who travel outside lab space must abide by the one glove rule and remove lab coats where predetermined.

24. Chemical lists and MSDS sheets must be readily available at the entrance to each lab area. In the event of an emergency, first responders will require this information in order to properly evaluate the situation.

25. Tenant shall provide Landlord, in writing, the names and contact information of two (2) representatives authorized by Tenant to request Landlord services, either billable or non-billable and to act as a liaison for matters related to the Premises.

26. Parking of any trailers, trucks, motor homes, or unregistered vehicles in the parking lots is prohibited.

27. Tenants shall not use more than its proportionate share of Base Building Central HVAC or electrical capacity, subject to the provisions of the lease.

B. Access & Security

1. Landlord reserves the right to close and keep locked all entrance and exit doors of the Building during the hours Landlord may deem advisable for the adequate protection of the Property. Use of the Building and the leased Premises before 8 AM or after 6 PM, or any time during Saturdays, Sundays or legal holidays shall be allowed only to persons with a key/card key to the Building or guests accompanied by such persons. Any persons found in the Building after hours without such keys/card keys are subject to the surveillance of building staff.

2. Tenant shall not place any additional lock or locks on any exterior door in the Premises or Building or on any door in the Building core within the Premises, including doors providing access to the telephone and electric closets and the slop sink, without Landlord's prior written consent. A reasonable number of keys to the locks on the doors in the Premises shall be furnished by Landlord to Tenant at the cost of Tenant, and Tenant shall not have any duplicate keys made. All keys shall be returned to landlord at the expiration or earlier termination of this Lease.

3. Landlord may from time to time adopt appropriate systems and procedures for the security or safety of the Building, its occupants, entry and use, or its contents, provided that Tenant shall have access to the Building 24 hours per day, 7 days a week. Tenant, Tenant's agents, employees, contractors, guests and invitees shall comply with Landlord's reasonable requirements relative thereto.

4. Tenant acknowledges that Property security problems may occur which may require the employment of extreme security measures in the day-to-day operation of the Common Areas. Accordingly, Tenant agrees to cooperate and cause its employees, contractors, and other representatives to cooperate fully with Landlord in the implementation of any reasonable security procedures concerning the Common Areas.

5. Tenant and its employees, agents, contractors, invitees and licensees are limited to the Premises and the Common Areas. Tenants and its employees, agents, contractors, invitees and licensees may not enter other areas of the Project (other than the Common Areas) except when accompanied by an escort from the Landlord.

C. Shipping/Receiving

1. Dock areas for the Building shall not be used for storage or staging by Tenant except in the Loading Dock Premises as permitted in the Lease.

2. In no case shall any truck or trailer be permitted to remain in a loading dock area for more than 60 minutes, except with prior written notice to Landlord, which notice may be given via email, provided that, in any event Landlord shall have the right, in good faith, to require Tenant to adjust its schedule for the use of the dock areas based upon the needs of the other tenants of the Building and Building operations.

3. There shall not be used in any Common Area, either by Tenant or by delivery personnel or others, in the delivery or receipt of merchandise, any hand trucks, except those equipped with rubber tires and sole guards.

4. Lab operators carrying any lab related materials may only travel within the Premises. At no time should any lab materials travel in the Common Areas, except at the Loading Dock and Freight Elevator.

5. Any dry ice brought into the building must be delivered through the loading dock.

6. All nitrogen tanks must travel through the loading dock and should never be left unattended outside of the Premises.

EXHIBIT 9-2

TENANT CONSTRUCTION

BUILDING RULES AND REGULATIONS

LINCOLN PROPERTY COMPANY
TENANT CONSTRUCTION
BUILDING RULES AND REGULATIONS

THE RULES MUST BE POSTED AT THE JOB SITE AT ALL TIMES!

1. Parking. Parking areas are designated by the Management Office and are subject to change at any time. Construction personnel are required to park in the parking areas designated by the Management Office. Failure to adhere to this regulation will result in the towing of the vehicle in violation at the owner's expense.

2. Access. Building entrances; lobbies, passages, corridors, public elevators, stairways, and other common areas may not be encumbered, or obstructed by the contractor, or contractor's agents during construction of the tenant's lease premises. Material deliveries must be scheduled in advance through the Management Office and coordinated with the Lincoln Property Company representative. Contractors are not to use Tenant phones, or Restrooms under any circumstances. Construction personnel found using phones, or restrooms located in the tenant's suite will be asked to immediately leave the premises and will not be allowed to return.

3. Each contractor is responsible for their subcontractor(s), and for the actions of their personnel including clean-up of work and construction traffic. No alcoholic beverages, glass containers, or "controlled substances" are allowed on the premises. All work must be scheduled through the Management Office and include a list of contractors performing work prior to the start of the work. After-hours work must be scheduled through the Management Office 24 hours before the activity will occur. Weekend activity must be scheduled by Friday at 9 a.m. Contractors will not be allowed to work in the Building after hours, or on weekends unless the procedures outlined above have been followed.

All after-hours work must be supervised by the general contractor. There will be no exceptions to this rule.

Prior to the commencement and upon completion of each job, a walk-through of public areas will be made, i.e. restrooms, etc., and any subsequent damages will be the responsibility of the contractor. The contractor shall be responsible for cleaning the assigned restrooms each day at his own expense.

4. Noise and Vapor Restrictions. Any work that would cause inconvenience to other tenants in the Building, or that must be done in an occupied space must be done after hours or on the weekend. Structural modifications, floor penetrations created with the use of core drilling machines, pneumatic hammers, etc., shall be performed before 7:30 a.m. or after 7:00 p.m. Likewise, any construction operations causing excessive noise, dust, vapors must be conducted during these hours.

When construction is on an occupied multi-tenant floor, noise, i.e., radios, loud talking, noise from equipment, etc., must be kept to a minimum. On these multi-tenant floors, public restrooms are not to be used by contractors.

A Lincoln Property Company superintendent, or the Property Manager will have the sole authority to determine if an operation is causing excessive noise, dust, or vapors.

5. Lincoln Property Company has the right to inspect work at any time and may reject work that does not conform to code, tenant's plans, or work that may affect the exterior appearance, structural components, or service system of the building.

6. Mechanical and electrical shop drawings must be reviewed and approved by Landlord's approved engineer. Prior to starting work, the general, mechanical, and electrical contractors must review the work with the Facilities Manager and Facilities Supervisor.

All panels and transformers are to match the building standard systems and all materials and methods used to connect panels and transformers must be approved by Landlord.

Unscheduled outages of any utility, or building service is strictly prohibited.

7. Dust and air contamination are to be controlled with temporary partitions which are sealed adequately to prevent dust from entering leased areas or mechanical equipment. Floor sweep or a comparable material will be used when sweeping concrete or tile floors.

8. Clean-up of Common and Lease Areas. Premises must be kept in a clean, orderly fashion at all times and free of potential safety and fire hazards. A general clean-up of the space under construction is to be performed on a daily basis. Final clean-up will be the responsibility of the contractor, which is to include all vacuuming and dusting as required. Failure to adequately keep the work area clean and accessible will result in Lincoln Property Company using its own forces to achieve this through whatever means determined necessary, and the total cost will be deducted from the contract.

9. Trash Removal. Contractor is responsible for removing all construction debris and trash from the construction site. UNDER NO circumstances shall trash, or construction debris be allowed to accumulate. Trash removal must be coordinated through the Lincoln Property Company Management Office. No vehicles, or dumpsters will be allowed to remain stationary on the site.

Under no circumstances is the Landlord's dumpster to be used.

10. If any fire sprinkler work, or modification to the fire sprinkler system is required, the system must be back in operation at the end of the work day. Under no circumstances shall the fire sprinkler system be left inoperative overnight. The facilities manager must be notified each morning of the location of and type of sprinkler work to be performed. The engineer hourly rate of $75.00 will be charged for routine work and/or extended regular hour work.

11. Existing pull stations and horns and strobes located throughout the Building will remain live during construction.

12. It shall be the responsibility of the general contractor to complete all punch list items before the tenant move-in date or the stipulated completion date.

13. All construction staging, storage, and temporary contractor facilities will be located in specific areas assigned by the Lincoln Property Company. Contractors will be responsible for the maintenance, housekeeping, and demolition of all temporary facilities.

14. Any removal, replacement, or repair work to a base building system to accommodate work directed by the tenant, or unforeseen interference (i.e., sprinkler head conflicts) which is not part of the Work, will be performed by the tenant's contractor at tenant's sole expense.

15. No firearms or weapons are permitted on the property.

16. Insurance. Contractors will be required to carry standard requirements incorporating both the owner and LPC Commercial Services, Inc. as additionally insured parties.

17. At no time is any welding or cutting with a torch to be used in the building without prior approval and coordination from the Management Office. Hot work permits may be required depending on the status of the project for all hot work including welding, soldering, and torch cutting. All hot work requires a fire extinguisher supplied by the contractor and must be in the immediate vicinity and easily accessible. Fire extinguishers must be inspected at least monthly.

18. A copy of these regulations shall be posted on the job site for all parties to observe. Contractor is responsible for instructing all of his personnel, subcontractors and supplies to comply with these regulations.

19. ALL PASSENGER ELEVATORS AND PUBLIC AREAS SHALL BE RESTRICTED AND OFF LIMITS TO ALL CONSTRUCTION PERSONNEL. Under no circumstances shall the exit stairwells be used for access to/from the first floor. All construction personnel for this project shall only use the freight elevator from the first-floor back lobby. Under no circumstances shall the main entrance to the Building or the garage passenger elevators be used for access.

All deliveries of materials and equipment must be scheduled at least twenty-four (24) hours prior to their delivery through the Lincoln Property Company Management Office. The contractor will be provided access to the freight elevator to be used in the "independent mode" for after-hours deliveries. The Contractor shall provide an operator during work hours to ensure correct and safe usage. Contractor shall keep the elevator cab and door tracks clean and free of all debris. Contractor shall be responsible for repair costs incurred due to misuse or damage caused by his forces. All major deliveries must be made between the hours of 11:00 p.m. to 7:00 a.m. Monday through Friday and all day long on Saturday and Sunday. Contractor will be charged for having an engineer on duty to assist with deliveries when the loading dock is closed. Additional charges incurred due to non-standard elevator use (i.e., moving freight on top of elevator cab) shall be paid by the General Contractor.

Your signature below signifies that you have read the rules above and agree to abide by all of them.

Signature	Date	Firm Name

Effective Date: _____

EXHIBIT 10

TENANT'S WORK INSURANCE SCHEDULE

Tenant shall, at its own expense, maintain and keep in force, or cause to be maintained and kept in force by any general contractors, sub-contractors or other third party entities where required by contract, throughout any period of alterations to the Premises or the Building by Tenant, the following insurance coverages:

(1) Property Insurance. "All-Risk" or "Special" Form property insurance, and/or Builders Risk coverage for major renovation projects, including, without limitation, coverage for fire, earthquake and flood; boiler and machinery (if applicable); sprinkler damage; vandalism; malicious mischief coverage on all equipment, furniture, fixtures, fittings, tenants work, improvements and betterments, business income, extra expense, merchandise, inventory/stock, contents, and personal property located on or in the Premises. Such insurance shall be in an amount equal to the full replacement cost of the aggregate of the foregoing and shall provide coverage comparable to the coverage in the standard ISO "All-Risk" or "Special" form, when such coverage is supplemented with the coverages required above. Property policy shall also include coverage for Plate Glass, where required by written contract.

Builders Risk insurance coverage may be provided by the general contractor on a blanket builders' risk policy with limits adequate for the project and evidencing the additional insureds as required in the Lease.

(2) Liability Insurance. General Liability, Umbrella/Excess Liability, Workers Compensation and Auto Liability coverage as follows:

(a)	General Liability	$1,000,000 per occurrence $1,000,000 personal & advertising injury $2,000,000 products/completed operations aggregate

The General Contractor is required to maintain, during the construction period and up to 3 years after project completion, a General Liability insurance policy, covering bodily injury, personal injury, property damage, completed operations, with limits to include a $1,000,000 limit for blanket contractual liability coverage and adding Landlord as additional insured as respects the project during construction and for completed operations up to 3 years after the end of the project. Landlord requires a copy of the ISO 20 10 11 85 Additional Insured endorsement, showing Landlord as an additional insured to the GC's policy.

(b)	Auto Liability	$1,000,000 combined single limit (Any Auto) for bodily injury and property damage, hired and non-owned cover.
(c)	Workers Compensation Employers Liability	Statutory Limits $1,000,000 each accident* $1,000,000 each employee* $1,000,000 policy limit* * or such amounts as are customarily obtained by operators of comparable businesses

General Contractor shall ensure that any and all sub-contractors shall maintain equal limits of coverage for Workers Compensation/EL and collect insurance certificates verifying same.

(d)	Umbrella/Excess Liability	$5,000,000 per occurrence
(e)	Environmental Insurance	To the extent required by Landlord Contractors' commercial general liability/umbrella insurance policy(ies) shall include Landlord and Landlord's designees as additional insureds' and shall include a primary non-contributory provision. Liability policy shall contain a clause that the insurer may not cancel or materially change coverage without first giving Landlord thirty (30) days prior written notice, except cancellation for non-payment of premium, in which ten (10) days prior written notice shall be required.

(3) Deductibles. If any of the above insurances have deductibles or self-insured retentions, the Tenant and/or contractor (policy Named Insured) shall be responsible for the deductible amount.

All of the insurance policies required in this Exhibit 10 shall be written by insurance companies which are licensed to do business in the State where the property is located, or obtained through a duly authorized surplus lines insurance agent or otherwise in conformity with the laws of such state, with an A.M. Best rating of at least A and a financial size category of not less than VII. Tenant shall provide Landlord with certificates of insurance upon request, prior to commencement of the Tenant/contractor work, or within thirty (30) days of coverage inception and subsequent renewals or rewrites/replacements of any cancelled/non-renewed policies.

EXHIBIT 11

TENANT CONTROL AREAS

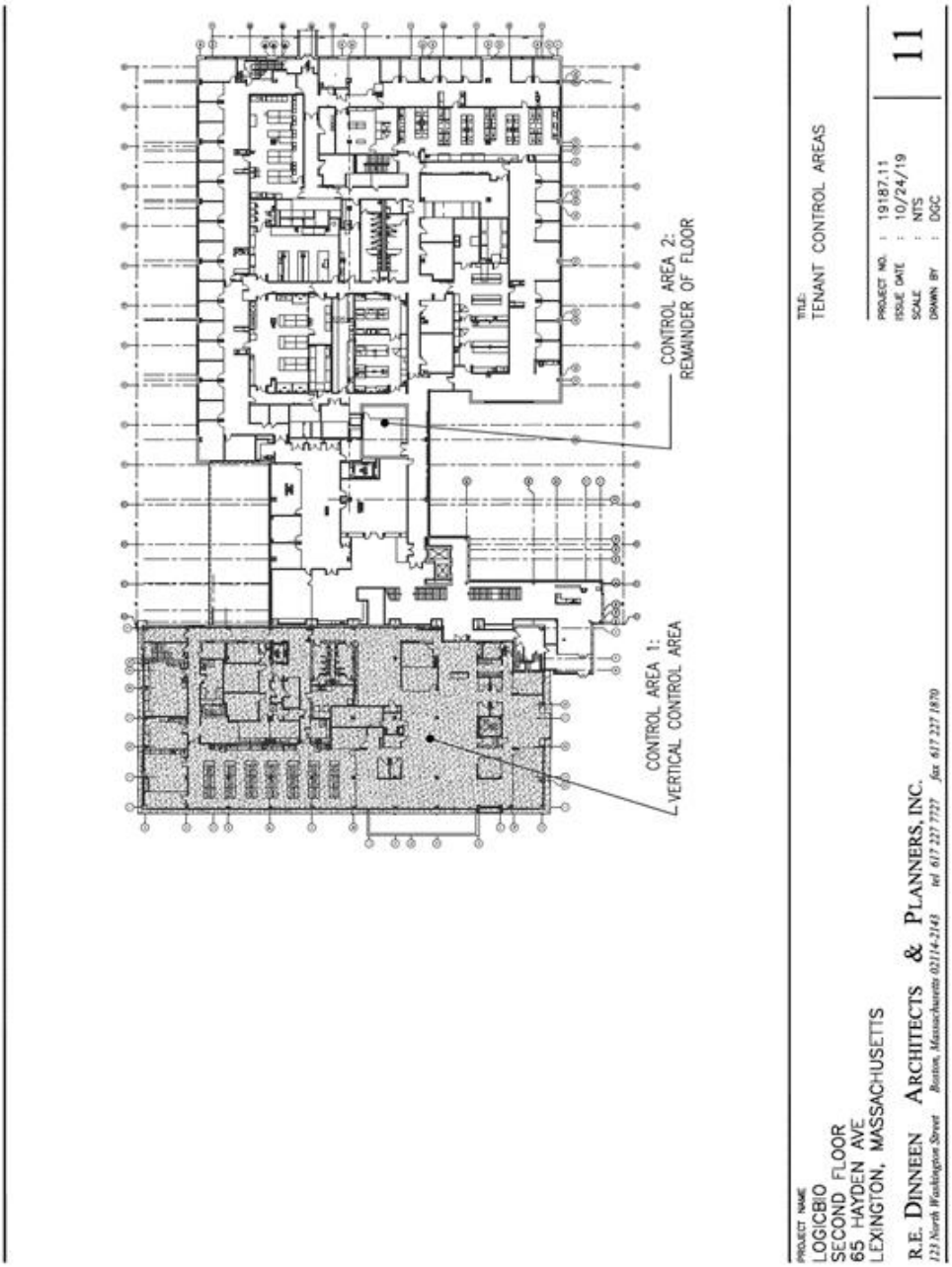

Exhibit 21.1

Subsidiaries of the Registrant

Name	Ownership Percentage	Jurisdiction of Organization
LOGICBIO AUSTRALIA PTY LIMITED	100%	Australia
LOGICBIO SECURITIES CORPORATION	100%	Delaware

Exhibit23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-234735 on Form S-3 and Registration Statement No. 333-230698 on Form S-8 of our report dated March 16, 2020, relating to the financial statements of LogicBio Therapeutics, Inc. appearing in this Annual Report on Form 10-K of LogicBio Therapeutics, Inc. for the year ended December 31, 2019.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 16, 2020

Exhibit 31.1

CERTIFICATIONS

I, Frederic Chereau, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 16, 2020

By: /s/ Frederic Chereau
Frederic Chereau
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Matthias Jaffé, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 16, 2020

By: /s/ Matthias Jaffé
Matthias Jaffé
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of LogicBio Therapeutics, Inc. (the "Company") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that to the best of his knowledge:

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

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

Date: March 16, 2020

By: /s/ Frederic Chereau
Frederic Chereau
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 16, 2020

By: /s/ Matthias Jaffé
Matthias Jaffé
Chief Financial Officer
(Principal Financial Officer)