
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 June 30, 2019

OR

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

Commission File Number: 001-36370

APPLIED GENETIC TECHNOLOGIES CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

59-3553710
(I.R.S. Employer
Identification No.)

14193 NW 119th Terrace, Suite 10, Alachua, Florida 32615
(Address of Principal Executive Offices, Including Zip Code)

(386) 462-2204

(Registrant's Telephone Number, Including Area Code)

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

Title of class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, \$0.001 par value	AGTC	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 Section 15(d) of the Act. Yes No

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 shares held by non-affiliates of the registrant was approximately \$44.9 million, computed by reference to the closing sale price of the common stock as reported by The Nasdaq Global Market on December 31, 2018, the last trading day of the registrant's most recently completed second fiscal quarter. The Company has no non-voting common shares.

The number of shares of the registrant's common stock outstanding as of September 24, 2019 was 18,218,402.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be provided in Part III of this Annual Report on Form 10-K will be provided by a definitive Proxy Statement for the registrant's Annual Meeting of Stockholders (the "Proxy Statement") to be filed with the Securities and Exchange Commission (the "SEC") on or before October 26, 2019.

APPLIED GENETIC TECHNOLOGIES CORPORATION
ANNUAL REPORT ON FORM 10-K
FOR FISCAL YEAR ENDED JUNE 30, 2019

TABLE OF CONTENTS

	Page
PART I	
Item 1. Business	1
Item 1A. Risk Factors	29
Item 1B. Unresolved Staff Comments	72
Item 2. Properties	72
Item 3. Legal Proceedings	72
Item 4. Mine Safety Disclosures	72
PART II	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	73
Item 6. Selected Financial Data	73
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	74
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	86
Item 8. Financial Statements and Supplementary Data	87
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	117
Item 9A. Controls and Procedures	117
Item 9B. Other Information	118
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	118
Item 11. Executive Compensation	118
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	118
Item 13. Certain Relationships and Related Transactions, and Director Independence	119
Item 14. Principal Accountant Fees and Services	119
PART IV	
Item 15. Exhibits and Financial Statement Schedules	119
Item 16. Form 10-K Summary	123
SIGNATURES	125

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections entitled “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements. These statements may relate to, but are not limited to, expectations of our future results of operations, business strategies and operations, financing plans, potential growth opportunities, potential market opportunities and the effects of competition, as well as assumptions relating to the foregoing. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. These risks and other factors include, but are not limited to, those listed under “Risk Factors.” In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “intend,” “potential,” “might,” “would,” “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

There may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Except as required by applicable law, including the securities laws of the United States and the rules and regulations of the SEC, we do not plan to publicly update or revise any forward-looking statements contained in this Annual Report on Form 10-K after we file it, whether as a result of any new information, future events or otherwise. Before you invest in our common stock, you should be aware that the occurrence of any of the events described in the “Risk Factors” section and elsewhere in this Annual Report on Form 10-K could harm our business, prospects, operating results and financial condition. 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.

As used herein, except as otherwise indicated by context, references to “we,” “us,” “our,” or the “Company” refer to Applied Genetic Technologies Corporation.

Item 1. Business

Applied Genetic Technologies Corporation (“AGTC”) is a clinical-stage biotechnology company that uses a proprietary gene therapy platform to develop transformational genetic therapies for patients suffering from rare and debilitating diseases. Our initial focus is in the field of ophthalmology, where we continue to progress clinical programs in X-linked retinitis pigmentosa (XLRP) and achromatopsia (ACHM). In addition, we have preclinical programs in optogenetics and adrenoleukodystrophy (ALD), which is a disease of the central nervous system (CNS), and several other ophthalmology, CNS and otology indications. With a number of important clinical milestones on the horizon, we believe we are well positioned to advance multiple programs towards pivotal studies. In addition to our product pipeline, we have also developed broad technological capabilities in the design, construction and manufacture of viral vectors using adeno-associated virus (AAV) technology. Finally, we have augmented these capabilities through multiple academic and commercial collaborations which provide us with additional expertise.

Our Strategy

Our objective is to become a leader in developing and commercializing gene therapy treatments for patients with severe diseases, with an initial focus in ophthalmology, and thereby provide a better life for patients with these diseases. Our strategy to accomplish this goal is to:

- **Develop and commercialize gene therapies in orphan ophthalmology.** Our lead product candidates are treatments for the severe orphan eye diseases XLRP and ACHM. Given the severity of these diseases and the current lack of treatment options, a one-time-treatment alternative that corrects the underlying genetic defect would provide long-term value for patients, their families and the healthcare system more broadly.

- **Expand our position in ophthalmology.**
 - **Continue our leadership position in orphan ophthalmology.** We have developed significant experience in the orphan ophthalmology space through our ongoing work on XLRP and ACHM, our previous experience in X-linked retinoschisis (XLRS) and Leber's Congenital Amaurosis Type 2 (LCA2) and in our preclinical ophthalmology programs. We are applying this knowledge to additional pre-clinical programs.
 - **Leverage capabilities into larger ocular market opportunities:** the insight and understanding gained in connection with our inherited retinal disease programs enhance the capabilities to apply our technology to larger ophthalmology indications such as our pre-clinical program in dry age-related macular degeneration (AMD).
 - **Seek opportunities for strategic partnerships and acquisitions in ophthalmology gene therapy.** In February 2017, we entered into a collaboration agreement with Bionic Sight to develop an optogenetic product candidate for patients with advanced retinal disease that leverages our deep experience in gene therapy and ophthalmology and Bionic Sight's innovative neuro-prosthetic device and algorithm for retinal coding. We believe there may be additional opportunities for us to partner with companies and academic groups in ophthalmology and more generally. We expect that our breadth of experience in research, manufacturing, clinical and regulatory matters will help us to identify and execute in-licenses, co-development agreements, intellectual property acquisitions or manufacturing agreements that could further extend our leadership position in ophthalmology gene therapy.
- **Extend our expertise in adeno-associated virus, or AAV, vector design, manufacturing and delivery.** We believe that our understanding of our target indications and our robust internal expertise in viral vector design gives us a significant competitive advantage. This understanding includes the identification of novel capsids and the optimization of genes and promoters, physical vector delivery, vector manufacturing, clinical trial design and clinical trial conduct. We intend to continue to devote substantial resources both internally and with others, such as our external research collaborations with Synpromics and the University of Florida, to identify next generation capsids and to develop optimized promoters. We are also expanding our discovery capabilities to further enhance our ability to develop next generation products.
- **Expand our manufacturing capabilities.** We continue to invest in the development and expansion of our internal manufacturing capabilities. We have a fully functional process development and pilot manufacturing facility used to manufacture early stage research materials, and as we advance further into clinical development, we plan to further develop our internal manufacturing capabilities. We have decreased our dependence on a single contract manufacturer by qualifying and contracting with multiple backup contractors. Further, we continue to invest in process and analytical improvements that have resulted in a ten-fold increase in manufacturing yields and robust quality control enhancements that are amenable to characterization of commercial products. We believe these investments will facilitate the more rapid advancement of our product candidates through regulatory approval while reducing risk and will enhance the therapeutic and commercial potential of our gene therapy platform.
- **Pursue indications outside of ophthalmology with high unmet medical need and strong probability of a streamlined clinical, regulatory and commercial pathway.** We will continue to focus on diseases for which the underlying genetic defect is well characterized and can be addressed by correcting or inserting a single gene, for which predictive animal models exist and for which clinical endpoints are objective and accepted by regulatory authorities. We believe that focusing on these types of indications will enable us to obtain data more rapidly and accelerate clinical studies and regulatory approval of our product candidates. Given the relatively low prevalence of patients who have these orphan diseases and the strong key opinion leader communities and patient advocacy groups that support them, we also believe these markets can be served with a small, targeted commercial infrastructure. Our research in otology and CNS are examples of this strategy.

[Table of Contents](#)

Our Focus in Ophthalmology

Sight is critical to the human experience. Many people fear blindness more than premature death. Consequently, we have initially decided to focus our expertise in gene therapy on orphan diseases in ophthalmology. These orphan indications have patient populations that are small enough to allow for clinical trials on a manageable scale but have a sufficient prevalence to provide substantial commercial opportunity. By focusing initially on orphan ophthalmology product candidates, we are also able to leverage our experience and develop strong relationships within the relevant scientific and medical communities. Our clinical trials are conducted mainly at academic test centers and by working with the principal investigators and surgeons at these test centers, we have realized a number of important synergies.

Our most advanced product candidates consist of three ophthalmology development programs across two targets: XLRP caused by mutations in the RPGR gene, and ACHM, caused by mutations in either the CNGB3 gene or the CNGA3 gene. These inherited orphan diseases of the eye are caused by mutations in single genes that significantly affect visual function and currently lack effective medical treatments.

- XLRP is a disease of the rod and cone photoreceptors characterized by progressive degeneration of the retina, which can lead to total blindness in adult men. According to a published study, the incidence rate for retinitis pigmentosa is about one in 4,000 people and we estimate that there are about 200,000 patients in the United States and Europe combined. It is estimated that about ten percent, or 20,000, of these people have XLRP. We are currently enrolling patients in Phase 1/2 clinical trials for our XLRP product candidate.
- ACHM is characterized by the absence of cone photoreceptor function, resulting in extremely poor visual acuity, extreme light sensitivity, day blindness and complete loss of color discrimination. According to a published study, the incidence rate for ACHM is approximately one in 30,000 people, and we therefore estimate that there are about 27,000 patients in the United States and Europe combined. Of these patients, about 75% have the form of disease caused by mutations in the CNGB3 gene or the CNGA3 gene. We are currently enrolling patients in Phase 1/2 clinical trials for both our ACHM CNGB3 product candidate and our ACHM CNGA3 product candidate.

In addition to these clinical-stage ophthalmology programs, we have a pre-clinical program in collaboration with Bionic Sight to develop an optogenetic product candidate for patients with advanced retinal disease.

Recent Corporate Milestones

In July 2019, we announced we completed enrollment of the third dose group in the phase 1/2 clinical trial for our ACHM CNGA3 product candidate.

In June 2019, we announced that Dr. Theresa G.H. Heah, M.D., M.B.A and Brian Krex, J.D. joined the Company as Chief Medical Officer and General Counsel, respectively.

In April 2019, we completed enrollment of the fourth dosing group of the phase 1/2 clinical trial for our ACHM CNGB3 product candidate and the expansion group (including pediatric patients) of the phase 1/2 clinical trial for our XLRP product candidate.

In March 2019, in connection with the termination of our collaboration with Biogen MA Inc. (Biogen), we received back the exclusive license rights to develop, manufacture and commercialize the product candidates for all of our previously partnered programs including our XLRP program, XLRS program and three discovery programs.

In December 2018, we reported the topline interim six-month data from our phase 1/2 clinical trial for our XLRS product candidate, that demonstrated the safety and tolerability of our gene delivery platform but did not demonstrate signs of clinical activity at six months.

[Table of Contents](#)

Our Strengths

We believe the combination of our technology expertise and product development know-how positions us well to be leaders in the gene therapy field. We believe our strengths include:

- Product candidates in clinical development, including three ongoing Phase 1/2 clinical trials with sufficient capital to complete enrollment and initial data analysis on all of these trials;
- Significant relationships with key opinion leaders in the fields of ophthalmology, otology, CNS, and AAV production;
- Robust preclinical product development pipeline including ophthalmology, otology and CNS disorders;
- A collaboration with Bionic Sight for the development of an optogenetic gene therapy and a neuro-prosthetic device with an algorithm for advanced retinal coding;
- Proprietary gene therapy manufacturing system, capable of making significant quantities of high quality viral vectors in accordance with Good Manufacturing Practice (GMP) standards as successfully demonstrated in seven different clinical trials, and has recently demonstrated a 10-fold increase in productivity as a result of our internal development efforts;
- Product candidates which, to date, use recombinant AAV vector technology, a well-studied, versatile and efficient gene therapy approach;
- Topline interim six-month and 12- month data from our phase 1/2 clinical trial for our XLRS product candidate demonstrating the safety and tolerability of our gene delivery platform (though it did not demonstrate signs of clinical activity);
- Technical expertise in analytical techniques, synthetic promoter development, engineered capsids, optimized capsids and specialized formulation and delivery techniques; and
- Capabilities in clinical operations and medical affairs to power our multiple clinical programs forward.

Our Gene Therapy Platform

Although the concept of gene therapy is relatively straightforward, the process of developing and manufacturing vectors capable of delivering genetic material safely into a patient's own cells is highly technical and demands significant expertise, experience and know-how. Our approach to gene therapy product development is built on our core competencies in four key areas: vector selection, design, manufacturing and delivery, each of which is described in further detail below. One of our key capabilities is our depth of understanding of the complex interplay between the clinical disease, the cells in the patient's body that need treatment, the selection of a capsid and a promoter, the design of the gene construct and the physical administration method. We have spent more than 18 years conducting research on the best combinations of these elements with the aim of developing safe and effective product candidates.

Vector Selection

The success of a gene therapy platform is highly dependent on the vector selected. Our platform is based on the use of a modified version of the non-replicating AAV to deliver the correct DNA directly to the nucleus of the cells affected by the disease. As an underlying platform, we believe that AAV vectors are particularly well suited for treating our target diseases and have advantages over other viral vectors, such as adenovirus, herpes virus and lentivirus. These advantages include:

- AAV is a small, simple non-enveloped virus with only two native genes, which makes the virus easy to engineer as an effective vector;
- AAV is inherently stable and resistant to degradation;

[Table of Contents](#)

- AAV vectors are capable of delivering functional genes in a manner that supports long-term production of protein, leading to sustained therapeutic effect, without altering the patient's native DNA;
- AAV vectors have a demonstrated safety profile across multiple human clinical trials in several indications; and
- AAV vectors are versatile, having the ability to carry therapeutic gene sequences of up to 4,000 base pairs in length into a patient's cell. As more than 90% of human genes have coding sequences less than 3,000 base pairs in length, this allows AAV vectors to be used in a wide variety of indications.

Vector Design

After selection of the vector type, there are other critical factors to be considered to maximize the safety and efficacy of the final gene therapy product:

- **Gene of Interest:** The first step in vector design is to identify either the therapeutic protein that we want the patient's own cells to produce (which is expressed from a DNA sequence that defines the gene of interest), or other cargo content, such as gene editing components or an RNA targeting sequence. In many cases the DNA sequence must be engineered to be stable during manufacturing and delivery.
- **Promoter:** Production of the protein in the cell requires a promoter, which is a genetic element that drives expression. Certain promoters function well only in certain cell types, whereas other promoters function well in almost any cell type. We make our selection by comparing different promoters in the specific type of cells that are affected in each disease target, ideally in an animal whose physiology is close to that of humans, to find the promoter that best enables production of therapeutic levels of protein in that cell type. We have on-going internal and external research efforts to design promoters that optimize therapeutic constructs for maximum expression with a smaller size, better expression and increased cell specificity.
- **Capsid:** after the promoter and gene of interest are selected, these elements must be packaged into an AAV capsid. There are 10⁶ to 10⁹ variations of AAV capsids with different abilities to bind to and enter varying cell types. Not only do we engineer these capsids in-house, we also collaborate with commercial and academic researchers to develop novel capsids that efficiently enter the type of cells that are affected by each of our targeted diseases.

Vector Manufacturing

We have developed a proprietary, high-yield vector manufacturing process using scalable technologies. While our manufacturing method uses the herpes virus as a helper in the first step of a four-step AAV vector manufacturing process, there is no herpes virus in the final product. Our proprietary process for AAV manufacturing uses robust cell lines that are well characterized and have been included in multiple regulatory submissions in the United States, Canada and Europe. This process is highly efficient and selective, generating more packaged vector with higher fidelity of target sequences than other production systems. We have developed and transferred over 30 robust and quantitative product-specific assays consistent with expected requirements for clinical development and are currently validating the assays as required for regulatory approval. We supplement our deep manufacturing experience with characterization of the resulting candidate technology. We have successfully completed technology transfer for vector manufacturing to multiple Contract Manufacturing Organizations (CMOs) and multiple partners. Additionally, we have made several process improvements leading to a ten-fold increase in productivity and conversion to a fully scalable suspension process.

Our manufacturing process has been reviewed by the FDA, Health Canada, the Irish Medicines Board, and the Israeli Ministry of Health and has been authorized for production of product candidates for use in clinical trials in the United States, Canada, Europe and Israel. To date we have successfully manufactured clinical trial material for seven different indications using three different manufacturing vendors, to ensure sufficient capacity, and

[Table of Contents](#)

believe we are the only AAV gene therapy company with this level of experience. Our manufacturing process is reproducible and scalable. Our process development facility is operational and we are conducting equipment evaluation runs with multiple vendors to support development of commercial processes for our product candidates.

We own or have licensed 67 issued patents, nine pending patent applications and three allowed patent applications covering our manufacturing technology. We believe that our core competency and intellectual property estate in vector manufacturing differentiate us competitively and provide a key differentiating element of our gene therapy platform.

The complexity of gene therapy manufacturing and lack of dedicated infrastructure to support it have historically resulted in poor reproducibility and lack of reliability in meeting material needs beyond the early human clinical setting. rAAV vector manufacturing has been limited by inefficient constructs, poor scalability, inadequate yields and insufficient purity. We have committed substantial resources to developing an integrated production and testing platform capable of meeting both clinical and commercial needs, including:

- Our propriety platform for AAV production generates high quality rAAV vectors with high packaging fidelity, high infectivity and low empty particles across multiple serotypes.
- Our AAV production system generates high volumetric productivities and has been demonstrated to work in multiple vendors' single-use bioreactor (SUB) systems and has achieved more than 10-fold improvement in productivity compared to other manufacturing formats.
- We have adapted our HSV helper manufacturing system to SUBs, removing scale and format limitations attendant with adherent cell culture.
- We have optimized purification and formulation activities to yield multiple rAAV serotypes in a dose-ready form with exceptional purity at previously unattainable genomic concentrations.
- Our integrated testing platform has generated over 30 product-specific characterization assays that have been successfully transferred for the evaluation of HSV helpers and AAV vectors at contract testing organizations.
- The robust cell substrates we employ are well characterized and have been reviewed in several regulatory submissions in the US, Canada, Israel and Europe.
- Our ability to successfully transfer the technology to multiple contract manufacturing organizations as well as collaboration partners demonstrates the robustness of our manufacturing process.

Taken together, we believe the efficiency, productivity, scalability, characterization and regulatory definition of our proprietary rAAV manufacturing platform uniquely position us to accelerate from early phase human clinical trials to late phase, BLA-enabling data in all our clinical programs. We are currently at commercial scale for our orphan ophthalmology programs given the relatively small volume per doses required per treatment and the ability to achieve thousands of doses from a small bioreactor. As such, in the near term, it is more efficient for us to pursue a hybrid strategy where we have developed and optimized the manufacturing process and leverage a CDMO's investment in capital equipment when needed

Vector Delivery

Our gene therapy platform allows for vector delivery by a variety of methods, and we select the method that is best suited for the disease and cell type that we are targeting.

In ophthalmology, the product candidate can best be delivered to cells in the eye by either injecting the product candidate under the retina, sub-retinal injection or by injecting the product candidate into the vitreous of the eye, an intravitreal injection. We are using sub-retinal injection as the method of delivery for our XLRP and

[Table of Contents](#)

ACHM product candidates in our ongoing clinical trials and have developed an extensive training program for surgeons in order to assure consistent delivery across patients. We expect to use intravitreal injection as the method of delivery for Bionic Sights' optogenetic product candidate.

Established surgical techniques used to introduce AAV in otology indications include microinjection into the cochlea via an apical cochleostomy or through the round window membrane. Like the eye, the inner ear sensory organ – the organ of Corti – is bathed by fluid-filled spaces, enabling accessible vector administration.

Once a product candidate is identified in our ALD discovery program, we expect it will be administered by intrathecal delivery, which is an injection into the cerebrospinal fluid.

Our Product Candidate Pipeline

Our most advanced product candidates address ophthalmology indications XLRP, ACHM B3, and ACHM A3, which are orphan diseases of the eye that are caused by mutations in single genes, significantly affect visual function starting at birth and currently lack effective medical treatments. Ophthalmology is attractive to us as a clinical stage company because treatments for diseases affecting vision have clearly defined, objective clinical endpoints with validated measurement tools that are accepted by regulatory authorities. Other orphan drug companies have spent considerable time and resources working with regulatory authorities to identify acceptable clinical endpoints and develop measurement tools in rare diseases with limited epidemiology data available. In ophthalmology there are four accepted endpoints—visual acuity, visual fields, contrast sensitivity and color vision—that are well understood by clinicians. In addition, the FDA consistently applies these endpoints and works with industry to provide guidance on how much improvement is required for clinical relevancy. We believe that these endpoints could help accelerate the process of clinical study and regulatory approval for our ophthalmic product candidates. We have also been encouraged by guidance from FDA for rare and inherited retinal disease that we believe signals the agency's willingness to work collaboratively on novel clinical design and novel endpoints that could help advance products to patients more efficiently.

Our lead programs

X-linked Retinitis Pigmentosa (XLRP)

Retinitis pigmentosa is an inherited retinal disease with progressive loss of vision, meaning children are born with defective genes that cause poor visual function that significantly affects daily activities and worsens over time. XLRP is commonly first observed in boys and young men who notice problems with vision under low light conditions, or night blindness, followed by a restriction of peripheral visual fields, or tunnel vision, leading to poor central vision and eventually to total blindness.

The incidence rate for retinitis pigmentosa is about one in 4,000 people, according to a published study, and we estimate that there are about 75,000 people in the United States and 125,000 people in Europe with retinitis pigmentosa, or 200,000 people in the United States and Europe. According to a published study, about 10% of cases of retinitis pigmentosa are XLRP, from which we therefore estimate that there are about 20,000 persons with XLRP in the United States and Europe combined.

Our XLRP product candidate

Our gene therapy approach to the treatment of XLRP involves using an AAV vector to insert a functional copy of the RPGR gene into the patient's photoreceptor cells. Our XLRP product candidate contains an optimized and stabilized RPGR gene and a promoter that have been shown in preclinical studies to drive efficient gene expression in primate rods and cones as well as restore photoreceptor function in dog and mouse models of XLRP

[Table of Contents](#)

Clinical development

We are currently enrolling patients in a Phase 1/2 clinical trial at multiple clinical sites that specialize in inherited retinal diseases. The primary endpoint of this clinical trial is safety, and available data thus far have shown that the XLRP product candidate is generally safe and well tolerated. In addition to safety, this trial will measure biologic activity by assessing changes in several measures of visual function and quality of life.

The clinical protocol is designed as a dose escalating trial to evaluate our product candidate in XLRP patients at multiple dose levels. As of September 26, 2019, we have completed enrollment of 22 patients in the dose escalation and expansion portions of the XLRP trial. We will continue additional dosing under the Phase 1/2 protocol to further enrich our analysis and build a robust set of safety and efficacy data to support our BLA filing, maximize the benefit to the greatest range of patients, and create the strongest data package for approval and commercialization.

On September 26th 2019 we provided the planned XLRP topline six-month data from the dose escalation groups as well as a preliminary look at three-month data from the XLRP dose expansion group showing a favorable safety profile with stability of visual function in peripherally dosed patients and improvement of visual function in 50% of centrally dosed patients.

We are also conducting a natural history study in patients with XLRP caused by RPGR mutations. This study documents the progression of the disease in the absence of treatment and is providing important information about the best methods for measuring visual function and other parameters in these patients, which will guide us in the design and evaluation of subsequent clinical trials in which our product candidate will be tested for safety and efficacy.

Successful completion of the Phase 1/2 clinical study and the natural history study will guide us in finalizing the design of the pivotal clinical trial. If successful, we believe the results of this pivotal trial could support our submission of a BLA to the FDA and of an MAA to the EMA for our XLRP product candidate. We expect the trial to include approximately 46 patients randomized into two dose groups with an active phase of 12 months. We currently expect that the most likely endpoint will be microperimetry supported by continued safety as well as stable OCT and stable or improving visual acuity.

Achromatopsia (ACHM)

ACHM is an inherited retinal disease, meaning that children are born with the defective gene that causes poor visual function, which significantly affects daily activities. ACHM is present from birth and throughout life and is characterized by a lack of cone photoreceptor function. Cone photoreceptors which are concentrated in the macula and the fovea, respond to moderate or bright intensity light and mediate fine visual acuity. Individuals with ACHM have markedly reduced visual acuity, photophobia or light sensitivity, and complete loss of color discrimination. Their only functioning photoreceptors are rod photoreceptors, which respond to low intensity light conditions and mediate night vision but cannot achieve fine visual acuity. Best-corrected visual acuity in persons affected by ACHM, even under subdued light conditions, is usually about 20/200, a level at which people are considered legally blind. They also experience extreme light sensitivity resulting in even worse visual acuity under normal daylight conditions, or day blindness.

ACHM can be caused by mutations in any of at least five genes that are required for normal cone photoreceptor function. The most common causes are mutations in the CNGB3 gene (about half of all cases) or CNGA3 gene (about one-fourth of all cases). These genes encode the CNGB3 and CNGA3 proteins, which combine to form a channel in the photoreceptor membrane that is required for photo-transduction, the process of converting light into electrical signals that the brain can understand. According to published reports, the incidence rate for ACHM is approximately one in 30,000 people, and we therefore estimate that there are about 10,000 people in the United States and about 17,000 people in Europe with ACHM. Of these, more than 75% have disease caused by mutations in the CNGA3 or CNGB3 gene.

[Table of Contents](#)

Our ACHM product candidates

Our gene therapy approach to treatment of ACHM involves using an AAV vector to insert a functional copy of the CNGB3 or CNGA3 gene into the patient's photoreceptor cells. Our ACHM product candidates contain either the CNGB3 or the CNGA3 gene and a proprietary cone specific promoter that has been shown in preclinical studies to drive efficient gene expression in all three types of primate cone photoreceptors and restores cone photoreceptor function in dog, mouse and sheep models of ACHM.

Clinical development of our CNGB3 and CNGA3 related ACHM product candidate

We are currently enrolling patients in two Phase 1/2 clinical trials at multiple clinical sites that specialize in inherited retinal diseases. The primary endpoint of these clinical trials is safety, and while available data thus far have shown that the ACHM CNGB3 and CNGA3 product candidates are generally safe and well tolerated, we did experience initial variability in surgical procedures, which we have now resolved through our extensive surgical training procedures. In addition to safety, these trials will measure biologic activity by assessing changes in visual function and quality of life. The clinical protocols are designed as dose escalating trials to evaluate our product candidates in ACHMA3 and ACHMB3 patients at multiple dose levels.

As of September 26, 2019, we completed enrollment of 15 and 12 patients in the dose escalation portions of the CNGB3 and CNGA3 trials, respectively. The safety profile in both trials remains favorable; the Data Safety Monitoring Committee (DSMC) has allowed dose escalation and dosing of pediatric patients. We will continue additional dosing under our Phase 1/2 clinical protocol to enrich and build a robust set of safety and efficacy data to support our BLA filing, maximize the benefit to the greatest range of patients and create the strongest data package for approval and commercialization.

On September 26, 2019, we provided early achromatopsia (ACHM) data indicating biologic activity in the dose escalation portions in both the B3 and the A3 trials. At the middle dose level one of three patients in each trial and at the high dose level 2 of 3 patients in the B3 trial have shown clinically meaningful improvements, defined as greater than one log change from baseline, in light discomfort at three months. Anecdotal statements from the patients support these improvements as being meaningful to their daily lives.

We have also completed enrollment in a natural history study in persons affected by ACHM caused by CNGB3 mutations and CNGA3 mutations and results from the studies will be presented in appropriate scientific meetings and publications.

Successful completion of the Phase 1/2 clinical studies and the natural history studies will guide us in finalizing the design of the pivotal clinical trial. If successful, we believe the results of this pivotal trial could support our submission of a BLA to the FDA and of an MAA to the EMA for our ACHM product candidates.

Ongoing Research in Support for our Current and Future Clinical Programs

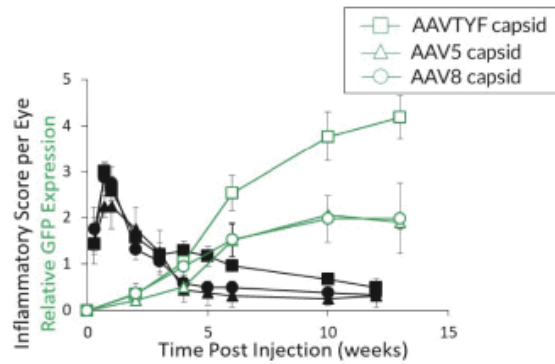
In support of our clinical programs described above, we continue to conduct research to fully understand the underlying technology. Additionally, we have initiated or continued several programs that are in early safety and preclinical proof of concept stages that are described below.

XLRP product candidate differentiation

Three AAV gene therapy vectors are currently in Phase 1/2 clinical development for treatment of patients with XLRP. To compare the relative attributes of these vectors, a study was conducted which compared the photoreceptor transduction efficiency of subretinally delivered AAVTYF, the AAV capsid used in AGTC product candidates, AAV5 and AAV8 capsids in a head-to-head non-human primate (NHP) experiment. Non-human primates were injected with each of the vectors and were followed for 13 weeks. Safety parameters

Table of Contents

included ocular exams, clinical observations, clinical pathology, and anatomic histopathology. A direct comparison between AAVTYF (n=12), AAV5 (n=4) and AAV8 (n=8) revealed that AAVTYF was comparable to or superior to both AAV5 or AAV8 in transduction of photoreceptors in NHPs when delivered subretinally, while demonstrating a similar, moderate inflammatory response. Therefore, AAVTYF represents, an attractive therapeutic choice for human XLRP gene therapy.

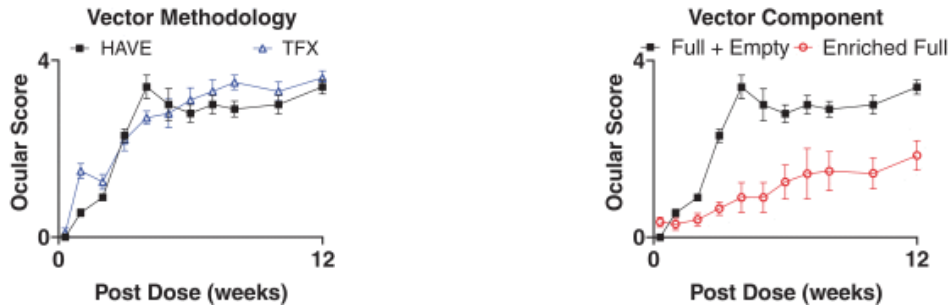


Understanding the ocular inflammatory response to AAV administration

Both intravitreal, and to a lesser extent, subretinal administration elicits an inflammatory response to AAV. In the eye, it remains unclear what specific property of the vector preparation drives inflammation. To this end, through a series of detailed, well-controlled studies in non-human primates, we performed a systematic evaluation of the potential contributory factors involved. A brief summary of the studies conducted is shown in the table below, and the accompanying illustrative figures.

<u>Purpose</u>	<u>Parameters</u>	<u>Observations</u>
Vector Methodology (Transfection (TFX) versus HAVE (Herpes simplex virus system))	Ocular inflammation following intravitreal administration	No difference in ocular inflammatory response between manufacturing methodologies
Vector Components (Full capsids, empty capsids, process residuals)	In-life ocular inflammation, transduction efficiency, and cytokine/cellular immune responses following intravitreal administration	Reduction of empty capsids lowers inflammation and enhances transduction Transient minimal response in cytokines or immune cells (local and systemic), with no clear distinction across treatment groups
Capsid serotype (AAVTYF, AAV5, AAV8)	In-life ocular inflammation, transduction efficiency following sub-retinal administration	No difference in ocular inflammatory response between capsid serotypes, two-fold improvement of transduction efficiency with AAVTYF relative to AAV5 & AAV8
Pre-existing Immunity (Low, Medium & High)	In-life ocular inflammation, prevention of vector transduction, and neutralizing antibody correlation between eyes following intravitreal administration	Pre-existing immunity has no impact on ocular inflammation, and is not sufficient in itself to block vector transduction Neutralizing antibody in one eye does not impact neutralizing antibody levels in the contralateral eye

[Table of Contents](#)



The ocular inflammation is most strongly correlated to total vector dose, and appears to occur in two phases: immediate, surgery/injection related (more explicit with sub-retinal injections) and delayed, in response to vector (processing of capsid and/or transgene expression). The studies outlined above have allowed us to eliminate the following as key drivers of inflammation: production methodology (transfection versus HSV), characteristics of the AAV product (transgene and process residuals) and capsid serotype (AAV2 versus AAV8) or novel engineered variant (AAVTYF). To date, none of the studies indicate that we should make changes in our product candidates, but we continue to work in non-human primates to understand ocular inflammation. The first publication of this work has recently been accepted by Human Gene Therapy (Timmers et al., 2019; see <https://agtc.com/science/>).

Advanced Retinal Disease

As part of our collaboration with Bionic Sight we are developing an optogenetic candidate treatment for individuals having retinitis pigmentosa (RP) who have lost light sensitivity. RP is a large group of inherited retinal disorders in which progressive degeneration of photoreceptors or retinal pigment epithelium (RPE) leads to vision loss which is independent of a patients' genetic mutation. In Europe and the United States, about 200,000 patients suffer from RP and every year between 15,000 and 20,000 patients with RP suffer vision loss. The clinical manifestations of affected individuals present first as defective dark adaptation or "night blindness," followed by reduction of peripheral visual fields and, eventually, loss of central vision. While the photoreceptor cell layers of these patients degenerate, the ganglion cell layer remains intact.

Optogenetics is a biological technique by which cells are modified by AAV vectors to express light-sensitive proteins. These light sensitive proteins open or close in response to light and allow millisecond-scale temporal manipulation of electrical events. Therefore, optogenetics provides a way to manipulate the activity of cells by controlling these proteins with light.

The candidate treatment being developed by AGTC and Bionic Sight is a recombinant AAV that expresses an optogenetic protein, ChronosFP, in the retinal ganglion cells. Light then activates the ChronosFP to send electrical signals from the retinal ganglion cells to the brain. Bionic Sight is developing a device with that uses an algorithm to provide light signals to the retinal ganglion cells that will result in an image the brain can recognize and may significantly enhance vision in patients who have received the optogenetic treatment. Bionic Sight filed an IND for the program in advance of completing the final formulation and testing of clinical trial material produced by their contract manufacturing organization. The FDA has put the trial on hold pending full review of the final testing to assure comparability to the material in the toxicology study. Bionic Sight has reported that it expects clearance of the IND and initiation of the Phase 1/2 clinical trial in the second half of calendar 2019.

X-linked Retinoschisis (XLRS)

XLRS is an inherited retinal disease, meaning that children are born with the defective gene that causes poor visual function that significantly affects daily living activities. XLRS is specifically caused by mutations in the

[Table of Contents](#)

RS1 gene, which is located on the X chromosome and encodes the retinoschisin, or RS1, protein which provides structural integrity in the retina.

We previously conducted a phase 1/2 clinical trial for our XLRS gene therapy product candidate. In December 2018, we announced the topline interim six-month data from the phase 1/2 clinical trial of our XLRS product candidate that showed it is generally safe and well-tolerated but demonstrated no signs of clinical activity at six months. Per the study protocol, we will continue to monitor enrolled patients at scheduled visits through the end of the study, but we do not plan to continue clinical development of our XLRS product candidate. On September 14, 2019 Dr. Mark Pennesi presented 12-month data that was consistent with the 6-month data.

Other opportunities in ophthalmology

We believe our advanced gene therapy platform will enable us to develop and test new AAV vectors that carry gene sequences for other inherited diseases in ophthalmology (it is estimated that approximately 290 genes causing inherited retinal disease have been identified), and that by leveraging our work on our lead programs we can reduce the need for early research work. In this way, we anticipate being able to move products efficiently through preclinical studies and into clinical development. We have recently added two additional ophthalmology programs to our preclinical pipeline:

- **New Orphan Ophthalmology Indication:** We have selected a new orphan ophthalmology indication with a substantial patient population, defined clinical phenotype and available animal models to move forward towards the clinic. We are currently conducting a final non-human primate, or NHP, targeting study of the product candidate that we will need to complete before moving into IND-enabling safety studies
- **Dry AMD:** An estimated 15 million people in North America have age-related macular degeneration (AMD), of which 85-90 percent are diagnosed with the non-exudative dry form (www.aao.org). This medical condition may result in blurred or no vision in the center of the visual field. Loss of central vision can make it hard to recognize faces, read, drive and perform daily activities. This program leverages our deep expertise in ophthalmic gene delivery and large-scale manufacturing while providing another opportunity to expand our pipeline beyond diseases that result solely from mutations in single genes. We are currently analyzing data from proof of concept animal studies that we will need to complete prior to initiating IND-enabling safety studies.

Central Nervous System

A new strategic area of focus for AGTC is in the central nervous system, or CNS, where we see unique opportunities to leverage our comprehensive capabilities in vector design, delivery and manufacturing to address severe unmet medical needs in several diseases. We are actively developing three opportunities and have established a world-class scientific advisory board to assist and guide our efforts as we advance these programs through preclinical development:

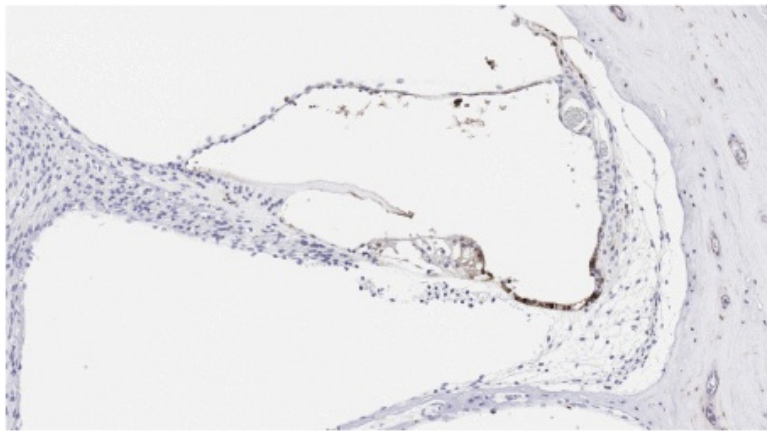
Adrenoleukodystrophy (ALD): This disease is an X-linked disorder of fatty acid metabolism that leads to accumulation of very long chain fatty acids in tissues throughout the body, mainly in the central nervous system and the adrenal gland. Patients with ALD cannot break down long-chain fatty acids, leading to their accumulation in cells of the nervous system, brain and adrenal gland. This leads to progressive loss of the membrane that insulates nerves in the brain and spinal cord and may cause damage to the outer layer of the adrenal gland. Clinically, ALD is a heterogeneous disorder with several distinct phenotypes, including rapidly declining neurological function and early death in young boys or progressive muscular weakness leading to lower limb paralysis in adults. There are approximately 14,000 patients with ALD in the United States. Early data from our preclinical studies support a gene therapy-based approach to treating the disease and warrant advancing it to our preclinical pipeline. We have made significant progress on vector design, animal model proof of concept and targeting studies in non-human primates [NHP] in order to obtain data to support moving a potential product candidate to IND enabling studies.

[Table of Contents](#)

Two Additional CNS indications: We are working on two additional rare genetic CNS indications that have substantial patient populations and well-defined clinical phenotypes. We have access to robust animal models and are using novel vector transgene engineering technologies to design the gene cassette and exploring the optimum approach to administering the AAV to the brain and spinal cord.

Otology

Hearing loss is one of the most common human sensory deficits and it is estimated that nearly half of the cases have a genetic origin. Of the inherited forms of hearing loss, more than 300 genetic causes have been defined with the specific gene identified for more than 70. Despite the impairment that can be caused by deafness, very little progress has been made in developing therapies that go beyond the temporary and partial solutions provided by hearing aids and cochlear implants. In multiple academic research studies, replacement of defective genes in animal models with normal copies has been shown to improve sound propagation in the auditory hair cells, making this a potentially promising application of AAV gene therapy. Additionally, the inner ear shares many of the characteristics that make ophthalmology attractive: it is anatomically well defined and is a small, well contained space where the target cells to be treated are easily identified. Also, the clinical outcome measures for treatments for hearing loss are well defined. Developing product candidates for conditions having these characteristics is a natural complement to our ophthalmology portfolio strategy as we apply our core capabilities and expertise to a new disease field. As part of our efforts in otology, we formed a scientific advisory board and have conducted a detailed evaluation of the development and commercial landscape. From these efforts, we have selected targets which we believe are technically feasible and commercially viable. To augment this exercise, we have been actively screening novel capsid variants in mouse and guinea-pig for their ability to transduce the key cell types of the cochlear – inner and outer hair cells, and support cells. We are advancing the most promising candidates into non-human primate studies to demonstrate the feasibility of safely administering AAV into the ear, both unilaterally and bilaterally, without adversely affecting auditory brainstem responses. Below is a representative example from one of the studies demonstrating GFP reporter transgene expression by immunohistochemistry (shown as brown staining in the figure) in the cell types of interest.



In addition to the capsid identification studies, we intend to control the specificity of transgene expression by designing and testing novel synthetic promoters for the cochlear cell types of interest highlighted above. Such promoters, when placed upstream of the transgene of interest, will ensure that the gene replacement occurs in the correct cell, and limit the likelihood of inappropriate gene expression leading to adverse consequences from a safety perspective.

[Table of Contents](#)

Strategic collaborations

We have formed strategic alliances in which both parties contribute expertise to enable the discovery and development of potential gene therapy product candidates. To access the substantial funding and other resources required to develop and commercialize gene therapy products, we intend to seek additional opportunities to form strategic alliances with collaborators who can augment our industry-leading gene therapy expertise.

On February 2, 2017, we entered into a strategic research and development collaboration agreement with Bionic Sight to develop therapies for patients with visual deficits and blindness due to retinal disease. Through the AGTC-Bionic Sight collaboration, the companies seek to develop a new optogenetic therapy that leverages AGTC's deep experience in gene therapy and ophthalmology and Bionic Sight's innovative neuro-prosthetic device and algorithm for retinal coding.

Under the agreement, AGTC made an initial \$2.0 million payment to Bionic Sight for an equity interest, of approximately 5 percent, in that company. In addition to the initial investment, AGTC will contribute to ongoing research and development costs through additional payments or other in-kind contributions. These payments and contributions will be made over time, up to the date that Bionic Sight has received both investigational new drug clearance from the FDA and receipt of written approval from an institutional review board to conduct clinical trials from at least one clinical site for that product candidate.

AGTC will receive additional equity, based on the valuation in place at the beginning of the agreement, for these cash and in-kind research and development contributions and will be obligated to purchase additional equity in Bionic Sight for \$4.0 million, at a pre-determined valuation, upon the filing of an IND for the product candidate and successful clearance by a relevant Institutional Review Board (IRB), both of which are required before a clinical trial can proceed. Bionic Sight filed an IND for the program in March 2019 in advance of completing the final formulation and testing of clinical trial material produced by their contract manufacturing organization. The FDA has put the Bionic Sight trial on hold pending full review of the final testing to assure comparability to the material in the toxicology study. Bionic Sight expects clearance of the IND and the IRB in the second half of calendar year 2019, at which time we will be required to make the additional \$4.0 million equity investment.

We previously entered into a Collaboration and License Agreement (the "Collaboration Agreement") with Biogen MA Inc. ("Biogen") on July 1, 2015. Effective March 8, 2019, Biogen terminated the Collaboration Agreement.

Under the terms of the Collaboration Agreement, we agreed to collaborate with Biogen to develop, seek regulatory approval for and commercialize gene therapy products to treat XLRS and XLRP based on our AAV vector technologies. The Collaboration Agreement also provided for discovery programs targeting three indications using our AAV technology whereby we would conduct discovery, research and development activities for those additional drug candidates through the stage of clinical candidate designation, after which, Biogen would have been eligible to exercise an option to continue to develop, seek regulatory approval for and commercialize the designated clinical candidate. Upon termination of the Collaboration Agreement, we received back the exclusive license rights to develop, manufacture or commercialize XLRP, XLRS and the three discovery programs.

We will continue to seek to partner with other gene therapy companies and academic institutions to leverage our expertise in vector design, research, manufacturing and the regulatory process. The goal of these collaborations would be to forge strategic partnerships around technologies and programs that would fit with our current and future development pipeline. In general, we would seek new intellectual property, development programs in rare diseases, pipeline products where the regulatory pathway is understood, partners with strong scientific, clinical, commercialization and management expertise, and programs that have synergy with our current knowledge base and product pipeline that would add to our industry leadership. We would also be looking at programs where the disease being treated has a large enough patient population that there would be adequate financial returns for the investment of resources.

[Table of Contents](#)

Our relationship with the University of Florida

All of our scientific founders spent part of their careers at the University of Florida, or UF, and two are still UF faculty members. Since our inception we have licensed significant technology from and funded research at multiple labs at UF. Pursuant to four agreements, we have licensed three U.S. patents and multiple pending applications covering inventions made at UF. UF has multiple capabilities in genetic cloning, gene therapy manufacturing, novel capsid identification, animal model development and facilities for both small and large animal testing, and in certain instances we have benefited from the ability to conduct important research at UF without having to expand in-house facilities and personnel.

In May 2013, we and UF were jointly awarded an \$8.3 million grant from the National Eye Institute to support development of our ACHM CNGB3 product candidate, with Dr. William Hauswirth, one of our scientific founders a Professor and holder of the Rybaczki-Bullard Chair in the Department of Ophthalmology at UF, as principal investigator. As of June 30, 2019, we have received payments in the aggregate amount of \$3.2 million under this grant.

Our relationships with patient advocacy groups and academic centers

We have long believed that when developing product candidates to treat orphan indications it is important to form strong relationships with patient advocacy groups, and we have done this successfully with both the Foundation Fighting Blindness, or FFB (U.S.), and the Alpha-1 Foundation. Both organizations are well known for their advocacy of patients' interests in obtaining diagnosis, developing treatments and providing for reimbursement. Both actively support research into treatment, and we have been awarded three research grants totaling \$1.6 million from the FFB and one grant of \$0.3 million from the Alpha-1 Foundation. More importantly, both organizations have been instrumental in assisting us in forming ties with disease experts, recruiting patients into clinical trials and helping us to understand the needs, wants and concerns of patients. We also have relationships with other advocacy organizations such as Achroma Corp, the BCM Family Foundation, MOMS For Sight, Curing Retinal Blindness Foundation, Sofia Sees Hope, National Organization for Rare Disorders, ALD Connect, FFB (Canada), Italian Achromatopsia Association (IAA), and Alliance for Regenerative Medicine Global Genes.

In addition, we have formed strong relationships with key academic centers across the United States that have core competencies in gene therapy, orphan ophthalmology and AAT deficiency. These centers conduct sponsored research, act as advisors and collaborate with us on grant proposals. Since our inception, we have been awarded a variety of grant funding, either independently or with our collaborators. This funding has provided peer-reviewed scientific validation of our programs and has facilitated critical early stage research for our lead product candidates.

Intellectual property

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to the development of our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties and seeking patent term extensions where available. We also rely on trade secrets relating to our proprietary technology platform and on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of gene therapy that may be important for the development of our business. In addition to IP and trade secrets, we also will rely on regulatory protection afforded through orphan drug designations, data exclusivity and market exclusivity for our product candidates, when possible.

Our commercial success may depend 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

[Table of Contents](#)

enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial product candidates and methods of manufacturing the same.

We have developed or in-licensed numerous patents and patent applications and possess substantial know-how and trade secrets relating to the development, commercialization and manufacture of gene therapy product candidates. Our proprietary intellectual property, including patent and non-patent intellectual property, is generally directed to, for example, certain genes and promoters, methods of transferring genetic material into cells, processes to manufacture our AAV-based product candidates and other proprietary technologies and processes related to our lead product candidates.

As of September 1, 2019, our patent portfolio included approximately 71 patents and patent applications that we own and approximately 56 patents and patent applications that we have licensed. More specifically, we own nine U.S. patents, eight pending U.S. applications, 32 foreign patents and 22 foreign patent applications. We have licensed six U.S. patents, four pending U.S. applications, 41 foreign patents and two pending foreign patent applications. Of the patents and patent applications that we own or license, 79 cover methods to manufacture AAV vectors, the longest lived and most significant of which is expected to expire in 2029. In October 2017, we were awarded US Patent Number 9,783,826 directed to methods of producing recombinant AAV viral particles using suspension BHK cells. This patent extends the protection on our AAV manufacturing platform from 2025 to 2029. Two of the patents and 18 of the patent applications that we own are directed to small cone promoters and uses thereof. A patent issuing from this group could have an expiration date in 2034.

Our objective is to continue to expand our portfolio of patents and patent applications in order to protect our gene therapy product candidates and AAV manufacturing process. Our owned and licensed patent portfolio includes patents and patent applications directed to our XLR5, ACHM, and XLRP programs, as well as our foundational AAV production platform. See also “License agreements”.

In addition to the above, we have established expertise and development capabilities focused in the areas of preclinical research and development, manufacturing and manufacturing process scale-up, quality control, quality assurance, regulatory affairs and clinical trial design and implementation. We believe that our focus and expertise will help us develop product candidates based on our proprietary intellectual property and to expand our intellectual property portfolio.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. The issued patents that are material to our business are expected to expire on various dates from 2019 to 2029.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration of a U.S. patent as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent per approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple product candidates, it can

[Table of Contents](#)

only be extended based on one product candidate. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a BLA, we expect to apply for patent term extensions for patents covering our product candidates and their methods of use.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

License agreements

We have rights to use and exploit multiple technologies disclosed in issued and pending patents under licenses from other entities. We consider the commercial terms of these licenses, which provide for modest milestone and royalty payments, and their provisions regarding diligence, insurance, indemnification and other similar matters, to be reasonable and customary for our industry.

Information about our principal licenses is set forth below.

The University of Florida

We currently have four agreements with the University of Florida Research Foundation, or UFRF, an affiliate of UF, of which the principal licenses are as follows:

- A joint license from UFRF and Johns Hopkins University, or JHU, signed in October 2003 relates to a particular HSV construct and various compositions thereof. We have an exclusive license in all fields of use.

Under the terms of this license, we made cash and stock-based up-front payments to UFRF and JHU and are required to make payments ranging from the mid-five figures to the low-six figures based upon development, regulatory and commercial milestones for any product candidates covered by the in-licensed intellectual property. Assuming that we meet each of the specified development, regulatory and commercial milestones not more than once for each product candidate, which we expect will be the case, the maximum aggregate milestone payments payable under this license with respect to any individual product candidate that we commercialize will be \$0.5 million. We will also be required to pay a royalty on net sales of product candidates covered by the in-licensed intellectual property in the low-single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of such license income in the low-double digits. We are required to make annual maintenance payments in the low four figures under this license, which payments are creditable against royalty payments on a year-by-year basis.

This license will terminate upon the earlier to occur of the expiration of all of the patents subject to the license and the date on which royalty payments, once commenced, cease for more than three calendar quarters. Additionally, UFRF and JHU may terminate this license upon certain breaches by us of the terms of the license and we may terminate the license at any time by submitting written notice to UFRF.

[Table of Contents](#)

The longest-lived patent covered by this license is expected to expire in 2022.

- Two licenses from UFRF, signed in September and November 2012, respectively, relate to the use of engineered AAV capsids. We have an exclusive license to the patents covered by the November 2012 license in the fields of ACHM, XLR5 and XLRP and a semi-exclusive license in all other fields of orphan ophthalmology. We have a non-exclusive license in all fields of use with respect to the patents covered by the September 2012 license. Currently these patents are most useful for ACHM, XLR5 and XLRP but could be important for treating a wide variety of diseases as the mutant capsids have been shown to be able to enter cells more effectively than standard AAV capsids.

Under the terms of these licenses, we made cash-up-front payments to UFRF and are required to make payments ranging from the mid-five figures to the low-six figures based upon development, regulatory and commercial milestones for any product candidates covered by the in-licensed intellectual property. Assuming that we meet each of the specified development, regulatory and commercial milestones not more than once for each product candidate, which we expect will be the case, the maximum aggregate milestone payments payable under these licenses with respect to any individual product that we commercialize will be \$0.6 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low-single digits. We have the right to sublicense our rights under these agreements, and we will be required to pay a percentage of such license income in the mid-single digits. We are required to make annual maintenance payments in the mid four figures under these licenses, which payments are creditable against royalty payments on a year-by-year basis.

These licenses will continue until the expiration of all of the patents subject to the licenses, provided or, if later, a date specified in the license. Additionally, UFRF may terminate this license upon certain breaches by us of the terms of the licenses and we may terminate the licenses at any time by submitting written notice to UFRF.

The longest-lived patent covered by these licenses is expected to expire in 2029. There are also patent applications pending under these licenses.

- An Evaluation and License Agreement from UFRF, signed in May 2019, relate to the use of engineered AAV capsids in the field of otology. Under the terms of the agreement, we are evaluating promising capsid candidates for potential application in otology.

The University of Alabama at Birmingham

A license agreement from the UAB Research Foundation affiliated with The University of Alabama at Birmingham signed in 2006, relates to one U.S. patent with claims covering the use of HSV helpers to produce AAV vectors. The patent is expected to expire in 2025. Effective in July 2015, we modified the license from co-exclusive to exclusive.

Under the terms of this license, we made a cash-up-front payment to the UAB Research Foundation, and we will be required to make payments ranging from the mid-five figures to the low-six figures based upon development and regulatory milestones for any products covered by the in-licensed intellectual property. Assuming that we meet each of these development and regulatory milestones not more than once for each product, which we expect will be the case, the maximum aggregate milestone payments payable under this license with respect to any individual product that we commercialize will be \$0.5 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low-single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of such license income in the mid-single digits. We are required to make annual maintenance payments in the mid-four figures under this license, which payments are creditable against royalty payments on a year-by-year basis.

This license will terminate upon the expiration of all of the patents subject to the license. Additionally, the UAB Research Foundation may terminate this license upon certain breaches by us of the terms of the license and we may terminate the license at any time by submitting written notice to the UAB Research Foundation.

[Table of Contents](#)

Collaborations with 4DMT and Synpromics

In April 2015, the Company entered into a collaboration and option agreement with 4D to discover and develop optimized AAV vectors to treat specific ophthalmic disease indications. The AGTC Agreement expired in October 2018 when AGTC chose to not exercise its option to license during the option period. We continue to collaborate with Synpromics in order to develop novel synthetic promoters.

Competition

The biotechnology and pharmaceutical industries, including the gene therapy field, are characterized by intense and rapidly changing competition to develop new technologies and proprietary products, and any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. While we believe that our proprietary technology estate and scientific expertise in the gene therapy field provide us with competitive advantages, we face potential competition from many different sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions and governmental agencies and public and private research institutions that may develop potentially competitive products or technologies.

Currently there are no approved products for any of our lead orphan ophthalmology indications of ACHM and XLRP. We are aware of a number of companies focused on developing gene therapies in various indications, including Adverum Biotechnologies Inc., Allergan plc, Biogen Inc., bluebird bio, Inc., Editas Medicine, Inc., 4D Molecular Therapeutics, GenSight Biologics S.A., Horama, S.A., Limelight Bio, Inc., MeiraGTx Limited (partnered with Janssen Pharmaceuticals), IVERIC bio, Oxford Biomedica plc, ProQR Therapeutics N.V., REGENXBIO Inc., the Roche Group (acquiring Spark Therapeutics), Ultragenyx Pharmaceuticals, Inc. and uniQure N.V., as well as several companies addressing other methods for modifying genes and regulating gene expression. Any advances in gene therapy technology made by a competitor may be used to develop therapies that could compete against any of our product candidates. For XLRP, MeiraGTx and Biogen are developing AAV-based gene therapies and MeiraGTx also has competing programs in ACHM-B3 and ACHM-A3. We believe companies such as REGENXBIO and others could be planning to initiate clinical trials in the future that have the potential to be competitive with AGTC's programs. We believe the key competitive factors that will affect the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience of administration and delivery, price, the level of generic competition, market exclusivity and the availability of reimbursement from government and other third-party payors.

Government Regulation

Biological products, including gene therapy products, are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products. Before clinical testing of biological products may begin, we must submit an IND which must go into effect, and each clinical trial protocol for a gene therapy product candidate is reviewed by the FDA and, in some instances, potentially the NIH, through its Novel and Exceptional Technology and Research Advisory Committee, or NExTRAC, formerly the Recombinant DNA Advisory Committee, or RAC, which now focuses on emerging areas of research including, but not restricted to, technologies surrounding advances in recombinant or synthetic nucleic acid research. FDA approval of a BLA also must be obtained before marketing of biological products in the United States. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals.

Within the FDA, the Center for Biologics Evaluation and Research, or CBER, regulates gene therapy products. CBER works closely with the NIH, both of which may engage in a public discussion of scientific, safety, ethical

[Table of Contents](#)

and societal issues related to proposed and ongoing gene therapy protocols. The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols. The FDA also has published guidance documents related to, among other things, gene therapy products in general, their preclinical assessment, observing subjects involved in gene therapy studies for delayed adverse events, potency testing, and chemistry, manufacturing and control information in gene therapy INDs, and gene therapy products for rare diseases and retinal disorders.

Ethical, social and legal concerns about gene therapy, genetic testing and genetic research have led to the enactment of legislation such as the Genetic Information Nondiscrimination Act of 2008 and 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 product candidates are unsafe or pose a hazard could prevent us from commercializing any product candidates. 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.

Recent developments in regulation of gene therapy

In August 2017, Kymriah (tisagenlecleucel) became the first gene therapy product approved by the FDA. It was followed by three additional gene therapy approvals, including Luxturna (voretigene neparvovec-rzyl) in December 2017. The Luxturna approval is of relevance to AGTC because it is a subretinally administered AAV vector that treats patients with a rare form of inherited vision loss. It is also the first FDA approved gene therapy that targets a disease caused by mutations in a specific gene.

FDA's acknowledged recognition of the promise of gene therapy and their expectation that the field will continue to expand has led them to take additional steps this past year to support the advancement of gene therapy products. In July 2018 they issued a suite of draft guidance documents that provide insight into their expectations for product development including manufacturing, clinical trial design and development in rare diseases. AGTC's review of the draft guidelines found we are aligned with the Agency's approach to product development and we see opportunities to advance our programs as anticipated following the collection of appropriate safety and efficacy data.

In Europe, six gene therapy products have been approved. In 2012, the EMA approved a gene therapy product called Glybera, which is the first gene therapy product approved by regulatory authorities anywhere in the Western world. Most recently, Zynteglo became the sixth gene therapy product approved by the EMA.

United States biological products development process

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

- completion of nonclinical laboratory tests and animal studies according to applicable good laboratory practices, or GLP, requirements 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;
- performance of adequate and well-controlled human clinical trials according to good clinical practice, or GCP, standards and IND and human subject protection regulations, and requirements to ensure the privacy and confidentiality of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product candidate for its intended use;

[Table of Contents](#)

- validation of the biological product candidate manufacturing and control processes;
- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product candidate is produced to assess compliance with GMP requirements, to assure that the facilities, methods and controls are adequate to preserve the biological product candidate's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA prior to any commercial marketing or sale of the product candidate in the United States.

Before testing any biological product candidate, including a gene therapy product candidate, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including applicable GLP requirements.

Sponsors or institutions receiving NIH funding are responsible for compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or the NIH Guidelines. However, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. The oversight bodies at the clinical site(s) (Institutional Review Board (IRB) and Institutional Biosafety Committee (IBC)) are responsible for determining whether or not the clinical study may be conducted there. The IBC may determine that the protocol raises novel or particularly important scientific, safety or ethical considerations, and may refer it to the OSP. Should the OSP determine that public review is required, the protocol could be reviewed by the new NExTRAC, which is expected to hold its first meeting in late 2019.

The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, although IND sponsors generally wait until the FDA affirmatively provides notice that the agency has no issues with the IND. If the FDA places the clinical trial on a clinical hold within that 30-day time period, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. With gene therapy protocols, if the FDA allows the IND to proceed, and the trial oversight bodies and the OSP decide that full public review of the protocol is warranted, initiation of the protocol could be delayed if the new NExTRAC implements a review process similar to the RAC. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to, for example, safety concerns, deficiencies in the study design, or non-compliance with IND regulations. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the

[Table of Contents](#)

IND. Clinical trials must be conducted and monitored in accordance with the GCP standards, human subject protection requirements, and FDA's investigational new drug requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Clinical trials also must be reviewed by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Human clinical trials are typically conducted in three sequential phases that may overlap, be combined, or be bifurcated into two parts:

- *Phase 1.* The biological product candidate is initially introduced into healthy human subjects and tested for safety. In the case of some product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2.* The biological product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for product approval and labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be required as a condition of approval or may be recommended after initial marketing approval if required. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. Depending on the type of product and mechanism of action, the FDA may recommend that sponsors observe subjects for potential gene therapy-related delayed adverse events as part of a long-term follow up that includes annual examinations and/or annual queries, either in person or by questionnaire, of trial subjects.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected suspected adverse reactions, any findings from other trials, 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 trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor, or its data safety monitoring board may suspend a clinical trial 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 trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients.

[Table of Contents](#)

Human gene therapy products are a new category of therapeutics. Although the FDA recently approved four gene therapy products in the United States, gene therapy remains a relatively new and expanding area of novel therapeutic interventions. Consequently, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of human gene therapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval. Over the last several years the FDA has issued helpful guidance on development of gene therapy products and has recently shown an increased willingness to work closely with developers, especially with those working in orphan disease areas.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product candidate as well as finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with the use of biological products, the PHS Act 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. 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.

United States review and approval processes

After the completion of clinical trials of a biological product candidate, FDA approval of a BLA must be obtained before commercial marketing of the biological product candidate. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product candidate, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological 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 candidate is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product candidate for an indication for which orphan designation has been granted. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule for fiscal year 2020, which becomes effective October 1, 2019, the user fee for an application requiring clinical data, such as a BLA, is \$2,942,965. PDUFA also imposes an annual prescription drug program fee (\$325,424) for certain approved products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for product candidates designated as orphan drugs, unless the product candidate also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product candidate is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product candidate is being manufactured in accordance with cGMP regulations to ensure

[Table of Contents](#)

and preserve the product candidate'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 candidate. A REMS may be imposed to ensure safe use of the drug, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. 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 will inspect the facilities at which the product candidate is manufactured. The FDA will not approve the product candidate unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to ensure consistent production of the product candidate within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to ensure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

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

If a product candidate 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 candidate. 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 trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

One of the performance goals agreed to by the FDA under the PDUFA is to review 90% of standard BLAs in 10 months and 90% of priority BLAs in six months, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if 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.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product candidate intended to treat a rare disease or condition, which is defined as 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 if there is no

[Table of Contents](#)

reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product candidate. Orphan product designation must be requested before submitting an NDA or BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. Orphan designation may also be rescinded if the product candidate no longer meets the criteria for designation.

If a product candidate 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 product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years; however, the FDA has not yet established what characteristics of a gene therapy product are relevant to determining whether two gene therapy products would be considered the same for purposes of orphan drug market exclusivity. The FDA may approve a second drug or biological product during an exclusivity period in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product does not have exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar, but not identical, benefits.

Expedited development and review programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product candidate at any time during the clinical development of the product candidate. Unique to a Fast Track product candidate, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product candidate submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product candidate is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product candidate designated for priority review in an effort to facilitate the review, and aims to review such applications within six months as opposed to ten months for standard review. Additionally, a product candidate 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 trials establishing that the product candidate 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 other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence

[Table of Contents](#)

of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product candidate receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires, as a condition for accelerated approval, the pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a “breakthrough therapy.” A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug 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 designated as breakthrough therapies are also eligible for accelerated approval and receive the same benefits as drugs with Fast Track designation. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Following the establishment of the breakthrough therapy designation, FDA established the regenerative medicine advanced therapy (RMAT) designation in conjunction with the 2016 21st Century Cures Act. Like the breakthrough designation, the RMAT designation requires preliminary clinical evidence indicating that the therapy has the potential to address unmet medical needs. However, the RMAT designation does not require evidence to indicate that the drug may offer a substantial improvement over the available therapies, which the breakthrough therapy designation does. Fast Track, breakthrough therapy, and RMAT designations may also be rescinded if the product candidate does not continue to meet the designation criteria.

Fast Track designation, priority review, accelerated approval, breakthrough therapy designation and RMAT designation do not change the standards for approval but may expedite the development or approval process.

Post-approval requirements

Maintaining compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product may also be subject to official lot release. In this case, as part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer’s tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

We also must comply with the FDA’s advertising and promotion requirements, such as the prohibition of preapproval promotion, requirements related to direct-to-consumer advertising, the prohibition on promoting products for uses or in-patient populations that are not described in the product’s approved labeling (known as “off-label use”), limitations on industry-sponsored scientific and educational activities, and promotional activities

[Table of Contents](#)

involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

United States patent term restoration and marketing exclusivity

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

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be

[Table of Contents](#)

expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. On June 23, 2016 the Price Relief, Innovation, and Competition for Essential Drugs (PRICED) Act was introduced, which would reduce exclusivity for biological drugs from twelve to seven years. The first biologic product submitted under the biosimilar abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

Pharmaceutical coverage, pricing and reimbursement

Sales of our products, when and if approved for marketing, will depend, in part, on the extent to which our products will be covered by third-party payors, such as federal, state, and foreign government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor not to cover our product candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Given the potential for long term durable therapeutic benefit from the single administration of a gene therapy product, the question of appropriate pricing and method of payment, including annuity payments and "pay for performance" schemes, is currently an active discussion and, depending on outcome, could affect the use of our products and our financial performance.

Other healthcare laws

Although we currently do not have any products on the market, we may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations, many of which may become more applicable to us if our product candidates are approved and we begin commercialization. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Research and Development

Our research and development expenses were \$33.2 million for the year ended June 30, 2019 and \$32.2 million for the year ended June 30, 2018.

[Table of Contents](#)

Employees

As of June 30, 2019, we had 85 full-time employees, 51 of whom have Ph.D., M.D. or other post-graduate degrees. Of these full-time employees, 61 are engaged in research and development activities and 24 are engaged in finance, human resources, facilities and general management.

As of June 30, 2019, all of our personnel were co-employees of AGTC and a professional human resource service organization, TriNet HR Corporation, or TriNet. Under our agreement with TriNet, TriNet was a co-employer of our personnel, and was responsible for administering all payroll functions, including tax withholding, and providing health insurance and other benefits for these individuals. We reimbursed TriNet for these costs and paid TriNet an administrative fee for its services. We were responsible for, and controlled, all aspects of the hiring, retention, compensation, management and supervision of our personnel. We consider the terms of our contract with TriNet to be reasonable and customary and believe this arrangement provided substantial benefit to us, in the form of lower costs for employee benefits and a reduced administrative burden on us. Effective as of July 1, 2019, we engaged Insperty PEO Services, L.P. to replace TriNet as our professional human resource service organization.

We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages. We consider our relations with our employees to be good.

Corporate information

We were incorporated in Florida in January 1999 and reincorporated in Delaware in October 2003. On April 1, 2014, we completed our initial public offering of our common stock, which is traded on the Nasdaq Global Market under the symbol "AGTC." Our principal executive offices are located at 14193 NW 119th Terrace, Suite 10, Alachua, Florida 32615, and our telephone number is (386) 462-2204. Our corporate website address is www.agtc.com. Through our website, we make available, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as well as proxy statements, and, from time to time, other documents as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information contained on or accessible through our website is not a part of this annual report.

We use "AGTC" and the double helix logo as trademarks in the United States and other countries. As of June 30, 2019, these trademarks have been registered in the United States, European Union and Japan.

This annual report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this annual report, including logos, artwork, and other visual displays, may appear without the or TM symbols, but such references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. 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 such companies.

Item 1A. Risk factors

You should carefully consider the risks and uncertainties described below, together with the information included elsewhere in this Annual Report on Form 10-K and other documents we file with the SEC. The risks and uncertainties described below are those that we have identified as material, but are not the only risks and uncertainties facing us. Our business is also subject to general risks and uncertainties that affect many other companies, such as overall U.S. and non-U.S. economic and industry conditions including a global economic slowdown, geopolitical events, changes in laws or accounting rules, fluctuations in interest and exchange rates, terrorism, international conflicts, major health concerns, natural disasters or other disruptions of expected economic and business conditions. Additional risks and uncertainties not currently known to us or that we currently believe are immaterial also may impair our business operations and liquidity.

Risks related to our financial condition and capital requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage biotechnology company, and we have not yet generated revenues from product sales. With the exception of the fiscal year ended June 30, 2017, in which we reported net income of \$0.4 million due in part to the amortization associated with our collaboration agreement with Biogen, we have incurred losses from operations in each year since our inception in 1999. For the fiscal years ended June 30, 2019 and 2018, we reported net losses of \$2.0 million and \$21.3 million, respectively. As of our most recent fiscal year ended June 30, 2019, we had an accumulated deficit of \$135.5 million. Our prior losses, combined with expected future losses, have had and may continue to have an adverse effect on our stockholders' equity and working capital.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. To date, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, through research grants from third parties or milestone payments from a collaborator. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or additional grants. We anticipate that it will be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our product candidates in those markets.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our research and preclinical and clinical development of our product candidates;
- expand the scope of our current clinical trials for our product candidates;
- initiate additional preclinical studies, clinical trials or other studies for our product candidates;
- further develop our gene therapy platform, including the process for design, delivery and manufacturing of our vectors for our product candidates;
- change or add additional manufacturers or suppliers;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above.

[Table of Contents](#)

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

Our ability to generate revenue from product sales is highly uncertain and we may never achieve or sustain profitability, which could depress the market price of our common stock, and could cause you to lose part or all of your investment.

All of our revenue generated to date has come from research grants from third parties or license fees or milestone payments from collaborations. Our ability to generate substantial revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners such as Bionic Sight, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We do not anticipate generating revenues from product sales for at least the next several years, if ever. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products and services to support clinical development and the market demand for our product candidates, if approved;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining and maintaining adequate coverage and reimbursement from third-party payors for our product candidates;
- obtaining market acceptance of our product candidates and gene therapy as a viable treatment option;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- identifying and validating new gene therapy product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate, particularly to the extent that we seek to commercialize any product for an indication, such as wet AMD, that has a patient population significantly larger than those addressed by our current lead product candidates. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other regulatory agencies, domestic or foreign, to perform clinical trials and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may

[Table of Contents](#)

need to obtain additional funding to continue operations. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

As a result of the termination of the Biogen Collaboration Agreement, we will not receive any future milestone-based or royalty payments under the agreement after March 8, 2019.

Effective March 8, 2019, Biogen terminated the Biogen Collaboration Agreement. Under the terms of the Collaboration Agreement, we agreed to collaborate with Biogen to develop, seek regulatory approval for and commercialize gene therapy products to treat XLRS and XLRP based on our AAV vector technologies. The Collaboration Agreement also provided for discovery programs targeting three indications using our AAV technology whereby we would conduct discovery, research and development activities for those additional drug candidates through the stage of clinical candidate designation, after which, Biogen would have been eligible to exercise an option to continue to develop, seek regulatory approval for and commercialize the designated clinical candidate. We also granted Biogen: (i) an exclusive, royalty-bearing license, with the right to grant sublicenses, to use adeno-associated virus vector technology and other technology controlled by us for the purpose of researching, developing, manufacturing and commercializing licensed products developed under the agreement and (ii) a non-exclusive, worldwide, royalty-free, fully paid license, with the right to grant sublicenses, of our interest in other intellectual property developed pursuant to the agreement. Upon the termination of the Collaboration Agreement, we received back the exclusive license rights to develop, manufacture or commercialize XLRP, XLRS and the three discovery programs. However, as a result of the termination of the Collaboration Agreement, we will not receive any future milestone-based or royalty payments.

In order to obtain regulatory approval for and commercialize our product candidates, we will need to raise additional funding in the future, which may not be available on acceptable terms, or at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Other than our product candidates for the treatment of XLRS, XLRP, ACHM CNGB3 and ACHM CNGA3, all of our lead programs in orphan ophthalmology and otology are currently in preclinical development. Developing gene therapy products is expensive, and we expect our research and development expenses to increase substantially as we advance our current product candidates in clinical trials and as we undertake preclinical studies of new product candidates.

Our operations have consumed substantial amounts of cash since inception. As of June 30, 2019, and 2018, our cash and cash equivalents and investments amounted to \$82.0 million and \$104.9 million, respectively. Our research and development expenses were \$33.2 million and \$32.2 million for the fiscal years ended June 30, 2019 and 2018, respectively. We believe that our existing cash and cash equivalents at June 30, 2019 will be sufficient to enable us to advance planned preclinical studies and clinical trials for our lead product candidates into the first half of 2021. In order to complete the process of obtaining regulatory approval for our lead product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidates, if approved, we will require substantial additional funding. Also, our current operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches.

Any such fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, financing may not be available to us in the future in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our

[Table of Contents](#)

shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and a portion of our operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and we may be required to relinquish or license on unfavorable terms rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, financial condition, results of operations and prospects and cause the price of our common stock to decline.

As a result of the termination of the Biogen Collaboration Agreement, we will not receive any future milestone-based or royalty payments under that agreement which will make it more likely that we will need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. If we are unable to obtain needed funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition, results of operations and prospects and cause the price of our common stock to decline.

Risks related to the discovery and development of our product candidates

All of our product candidates are in preclinical or clinical development. Clinical drug development is expensive, time consuming and uncertain, and we may ultimately not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities, which regulations differ from country to country. Our product candidates are in various stages of development and are subject to the risks of failure typical of drug development. The development and approval process is expensive and can take many years to complete, and its outcome is inherently uncertain. We have not submitted an application for or received marketing approval for any of our product candidates. We have limited experience in conducting and managing the later-stage clinical trials necessary to obtain regulatory approvals, including approval by the FDA. To receive regulatory approval, we must, among other things, demonstrate with substantial evidence from clinical trials that the product candidate is safe, pure and effective for each indication for which approval is sought, and failure can occur in any stage of development. Satisfaction of the approval requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might receive regulatory approvals for any of our product candidates currently under development.

The FDA and foreign regulatory authorities also have substantial discretion in the drug approval process. The number and types of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. 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, and there may be varying interpretations of data obtained from preclinical studies or clinical trials, either of which may cause delays or limitations in the approval or the decision not to approve an application. Regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

[Table of Contents](#)

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the patients recruited for a particular clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the results may not confirm the positive results from earlier preclinical studies or clinical trials;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of FDA or comparable foreign regulatory authorities to support the submission of a biologics license application, or BLA, or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- regulatory agencies might not approve or might require changes to our manufacturing processes or facilities; or
- regulatory agencies may change their approval policies or adopt new regulations in a manner rendering our clinical data insufficient for approval.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price. Furthermore, any regulatory approval to market a product candidate may be subject to limitations on the indicated uses for which we may market the product candidate. These limitations may limit the size of the market for the product candidate.

We are not permitted to market our product candidates in the United States or in other countries until we receive approval of a BLA from the FDA or marketing authorization from applicable regulatory authorities outside the United States. We are also not permitted to promote our product candidates as safe and effective therapies until after receiving approval. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States, which will significantly impair our ability to generate any revenues. In addition, failure to comply with FDA and non-U.S. regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning letters or untitled letters alleging violations;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;

[Table of Contents](#)

- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending BLAs or supplements to approved BLAs.

Even if we do receive regulatory approval to market a product candidate, any such approval may be subject to limitations on the indicated uses for which we may market the product. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us or our collaborators to commence product sales. Any delay in obtaining, or an inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability.

Our gene therapy product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval. To date, four gene therapy products have been approved in the United States and five such products have been approved in Europe.

We have concentrated our product research and development efforts on our gene therapy platform, and our future success depends on the successful development of this approach. There can be no assurance that any development problems we experience in the future related to our gene therapy platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience unanticipated problems or delays in expanding our manufacturing capacity or transferring our manufacturing process to commercial partners, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA, the EMA and other regulatory agencies 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 such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. For example, the FDA 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 conducted at institutions that receive funding for recombinant DNA research from the United States National Institutes of Health, or the NIH, are also subject to review by the NIH Novel and Exceptional Technology and Research Advisory Committee, or NExTRAC, formerly the Recombinant DNA Advisory Committee, or RAC, which now focuses on emerging areas of research including, but not restricted to, technologies surrounding advances in recombinant or synthetic nucleic acid research. Although the FDA decides whether individual gene therapy protocols may proceed, it is possible the NExTRAC review process, which is still being implemented, could delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and approved its initiation. Before a clinical trial can begin at a study site, that institution's Institutional Review Board, or IRB, and its Institutional Biosafety Committee, or IBC, have to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups, and comply with applicable

[Table of Contents](#)

guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected for orphan ophthalmology product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

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

Trial designs and results from animal studies or previous clinical trials are not necessarily predictive of our future clinical trial designs or results, and interim results of a clinical trial are not necessarily indicative of final results. Our product candidates may also fail to show the desired safety and efficacy in clinical development despite demonstrating positive results in animal studies or having successfully advanced through initial clinical trials. There can be no assurance that the success we achieved in the animal studies for our lead product candidates will result in success in our clinical trials of those product candidates.

There is a high failure rate for drugs and biological products proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of our product candidate development.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. If patients are unwilling to participate in our gene therapy studies because of negative publicity from adverse events in the biotechnology or gene therapy industries or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our product candidates may be delayed. For example, trials using early versions of lentiviral vectors, which integrate with, and thereby alter, the host cell's DNA, have led to several well-publicized adverse events, including reported cases of leukemia. If there are delays in accumulating the required number of clinical events in trials for our product candidates where clinical events are a primary endpoint, there may be delays in completing the trial. These delays could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with the required or desired characteristics to achieve diversity in a trial, to complete our clinical trials in a timely manner. For example, enrolling eligible patients in novel orphan drug trials can be challenging and we previously encountered slower-than-expected enrollment in our phase 1/2 clinical trial for our XLRS product candidate as a result of patients not meeting one or more study eligibility criteria. Challenges such as these in enrolling a sufficient number of patients to conduct our clinical trials as planned, may cause us to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business. We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates.

In particular, most of the conditions for which we plan to evaluate our product candidates are rare genetic disorders with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials will further limit the pool of available trial participants.

[Table of Contents](#)

Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the clinical trial protocol;
- size and nature of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- our ability to monitor patients adequately during and after treatment.

We plan to seek initial marketing approval for our product candidates in the United States and the European Economic Area, or EEA. We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA, the EMA or other foreign regulatory authorities. 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 contract research organizations, or CROs, and physicians;
- different standards for conducting clinical trials;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments.

We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidates in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Our clinical trials have and may continue to be delayed by the necessity to re-test study agent, the decision to use a single surgeon to treat patients and protocol amendments that require approval by institutional review boards at the clinical sites. A failure of one or more clinical trials can occur at any stage of testing.

Events that may prevent successful or timely completion of clinical development include:

- delays in raising, or inability to raise, sufficient capital to fund the planned clinical trials;
- inability to generate sufficient preclinical, toxicology, or other data to support the initiation of human clinical trials;
- delays in reaching a consensus with regulatory agencies on trial design;

Table of Contents

- identifying, recruiting and training suitable clinical investigators;
- delays in reaching agreement on acceptable terms with prospective 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;
- delays in obtaining required IRB and IBC approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- delays due to changing standard of care for the diseases we are targeting;
- adding new clinical trial sites;
- imposition of a clinical hold by regulatory agencies, after review of an IND application or equivalent application or an inspection of our clinical trial operations or trial sites;
- failure by our CROs, other third parties or us to adhere to clinical trial requirements;
- loss of product due to shipping delays or delays in customs in connection with delivery to foreign countries for use in clinical trials;
- failure to perform in accordance with the FDA's good clinical practices, or GCP requirements or applicable regulatory guidelines in other countries;
- delays in the manufacture, testing, release, import or export for the use of sufficient quantities of our product candidates for the use in clinical trials by our vendors, such as the vendor testing errors previously experienced in our ongoing clinical trials; failure by us or our vendors to manufacture our product candidate in accordance with FDA's good manufacturing practice, or GMP, requirements or applicable regulatory guidelines in other countries;
- delays by us or our contract vendors in the testing, validation and delivery of our product candidates to the clinical trial sites;
- delays in having patients' complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or clinical trial sites or patients dropping out of a trial;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements, FDA policy, and guidance that require amending or submitting new clinical protocols;
- the costs of clinical trials of our product candidates may be greater than we anticipate; or
- 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 drug development programs.

Further, a clinical trial may be suspended or terminated by us, our collaborators, the IRBs, in the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In appropriate circumstances, we may also elect to temporarily suspend an ongoing clinical trial to further study unexpected results, even if those results would not require us to formally suspend the trial under the applicable regulatory requirements or clinical protocols. Such temporary suspension could include further testing of trial

[Table of Contents](#)

materials and the need to review subject responses to ensure safety. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we or our third-party collaborators make manufacturing or formulation changes to product candidates, we or they may need to conduct additional trial to bridge the modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

If the results of our clinical trials are inconclusive or if there are safety concerns or adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes with 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 regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our product candidates.

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

As with many pharmaceutical and biological products, treatment with our product candidates may produce undesirable side effects or adverse reactions. These adverse reactions may occur despite our belief that our AAV vectors have a generally acceptable safety profile.

Known adverse reactions that could occur with treatment with AAV vectors include an immunologic reaction to the capsid protein or gene at early time points after administration. In previous clinical trials involving AAV viral vectors for gene therapy, some subjects experienced serious adverse events, including the development of T-cell response due to immune response against the vector capsid proteins. If our vectors demonstrate a similar effect, or other adverse events, we may be required to halt or delay further clinical development of our product candidates. In addition, theoretical adverse reactions of AAV vectors include replication and spread of the virus

[Table of Contents](#)

to other parts of the body and insertional oncogenesis, which is the process whereby the insertion of a functional gene near a gene that is important in cell growth or division results in uncontrolled cell division, also known as cancer, which could potentially enhance the risk of malignant transformation. Potential procedure-related adverse reactions, including inflammation, can also occur and have, in fact, been observed in our XLR5, XLRP and ACHM CNGB3 trials. There is also the potential risk of delayed adverse reactions following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. If any such adverse reactions occur, our clinical trials could be suspended or terminated and the FDA, the EMA or other foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial. If we elect or are required to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if any of our product candidates receive marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of gene therapies for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by our product candidate, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent or delay us from achieving or maintaining market acceptance of our product candidates and could significantly harm our business, prospects, financial condition and results of operations.

We may be unable to obtain orphan product designation or exclusivity for some of our product candidates. If our competitors are able to obtain orphan product exclusivity for their products that are considered to be the same as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals diagnosed annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union Community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when,

[Table of Contents](#)

without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product. Our product candidates for the treatment of XLRS, ACHM (in the form caused by mutations in the CNGB3 and CNGB3 genes) and XLRP (in the form caused by mutations in the RPGR gene) have been granted orphan medicinal product designation by the FDA and the European Commission. We may request orphan drug designation for our other product candidates in the future but there can be no assurances that the FDA will grant any of our product candidates such designation. Additionally, the designation by the FDA of any of our product candidates as an orphan drug does not guarantee that the FDA will accelerate regulatory review of or ultimately approve that product candidate. Orphan drug designation may also be rescinded if FDA concludes that the product candidate no longer meets the criteria for designation.

Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The FDA has not defined the meaning of “same drug” specifically for gene therapy products and it is possible that the FDA could conclude that no two gene therapy products could be considered the same. The applicable period is seven years in the United States and 10 years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition, or if a gene product considered to be the same as our product candidate is superior in certain respects.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate or the approval may be for a narrower indication than we expect.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies 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 agency policy during the period of product development, clinical trials and the review process. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested, may not approve the price we intend to charge for our product candidate, may impose significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use or may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

[Table of Contents](#)

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

Even if we obtain regulatory approval in a jurisdiction for our product candidates, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. FDA guidance advises that patients treated with some types of gene therapy undergo follow-up observations for potential adverse events and this follow-up may extend for many years. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers are subject to payment of program fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or with the integrity or sufficiency of data, records, or documentation, or disagrees with the promotion, marketing or labeling of that product, a regulatory agency may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain product or otherwise require the withdrawal of product from the market;
- refuse to permit the import or export of products; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenues.

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

[Table of Contents](#)

Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval for our product candidates outside of the United States, which would limit our market opportunities and adversely affect our business.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries must also approve the manufacturing and marketing of the product candidates in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. We intend to submit a marketing authorization application to the EMA for approval in the EEA, but obtaining such approval is a lengthy and expensive process and the EMA has its own procedures for approval of product candidates. Even if a product candidate is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the EEA also have requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval of a product candidate in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected.

Risks related to our reliance on third parties

We expect to rely on third parties to conduct aspects of our product manufacturing and protocol development, and these third parties may not perform satisfactorily.

We do not expect to independently conduct all aspects of our vector production, product manufacturing, protocol development, and monitoring and management of our ongoing and planned preclinical and clinical programs. We have expanded our internal capabilities to include a full-scale pilot facility to facilitate continued improvement in our manufacturing process. We have completed the design phase for a cGMP facility at our Florida headquarters to support later stage clinical development. We currently rely, and expect to continue to rely, to a significant degree, on third parties for the production of our clinical trial materials. In such cases, we expect to control only certain aspects of their activities.

Under certain circumstances, these third parties may be entitled to terminate their engagements with us or we may seek to terminate our engagement with them. Because of the complexities inherent in gene therapy manufacturing, we expect that any engagement by us of a new third-party manufacturer for our product candidates would take a substantial amount of time to establish. Accordingly, if we need to enter into alternative arrangements, it could delay our product development activities. We are currently negotiating with and conducting pilot work at three alternative third-party manufacturers to expand our capacity and mitigate risk. Our

[Table of Contents](#)

reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study and trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study and trial plans and protocols, or if there are disagreements between us and these third parties, we will not be able to complete, or may be delayed in completing, the preclinical studies and clinical trials required to support future IND submissions and approval of our product candidates. In some such cases, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay with respect to the approval of our product candidates and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- delays in the production of our product candidates associated with transitioning to a new third-party manufacturer;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future product candidates. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of product manufacture.

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

All parties involved in the preparation of therapeutics for clinical trial or commercial sale are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with GMP requirements. These regulations govern manufacturing processes and procedures (including record keeping) 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 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 GMP requirements enforced by the FDA through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates 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 manufacturers. If any such inspection or audit identifies a

[Table of Contents](#)

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 our third-party manufacturers 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 manufacturing facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

As described above in “Business,” we have encountered delays in clinical trial material availability as a result of difficulties in proper testing. If we or any of our third-party manufacturers or testing contractors fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate, or revocation of a pre-existing approval. Such an occurrence may cause our business, financial condition and results of operations to be materially harmed.

Additionally, if supply from an approved manufacturer is interrupted, there could be a significant disruption in commercial supply of our products. Because of the complexities inherent in our gene therapy manufacturing, we expect that there will be a significant period of time following our engagement of an alternative third-party manufacturer before that manufacturer will be in a position to provide an adequate supply of our product candidates for our clinical trials. In addition, any alternative manufacturer will also need to be qualified through a BLA supplement which could result in further delay. The regulatory agencies may also require additional trials 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.

We expect to rely on third parties to conduct and supervise our clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We expect to continue to rely on academic research institutions and CROs along with clinical trial sites to ensure our clinical trials are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance and will control only certain aspects of our CROs’ activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA’s and other regulatory authorities’ GCP, GMP and good laboratory practice, or GLP, requirements for conducting, recording and reporting the results of our preclinical studies and clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these requirements through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCP requirements, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCP requirements, which may render the data generated in those trials unreliable. In addition, our future clinical trials will require a sufficient number of test subjects to evaluate the safety and effectiveness of our product candidates. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and, except for remedies available to us under our agreements with such CROs, we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our

[Table of Contents](#)

clinical and nonclinical programs. Our CROs also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. 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 our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

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

We also expect to rely on other third parties to store and distribute our vectors and products for any clinical trials that we may conduct. Any performance failure on the part of our distributors could delay clinical development, regulatory review or marketing approval of our product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

Collaborations with third parties may be important to our business. If these collaborations are not successful, our business could be adversely affected.

In addition to our current collaborations, we may in the future seek third-party collaborators for the development and commercialization of product candidates based on our gene therapy platform. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from any future collaboration or license agreement will depend on the collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any collaborators may have the right to abandon research or development projects and terminate applicable agreements, including any funding obligations, prior to or upon the expiration of the agreed upon terms. For example, on December 7, 2018, we received notice from Biogen that the Biogen Collaboration Agreement would be terminated effective March 8, 2019. As a result of the termination, we will not receive any future milestone-based or royalty payments under the Collaboration Agreement after March 8, 2019.

Our current collaborations or any collaboration that we enter into in the future, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- exclusivity rights we negotiate with our collaborators may be unenforceable in certain jurisdictions;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

[Table of Contents](#)

- collaborators may decide not to continue the development of collaboration products and could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- take-over or step-in rights granted to a collaborator with respect to one or more of our product candidates, may cause us to have limited control over future development activities and/or realize diminished economic or other benefits upon the ultimate commercialization of that product candidate;
- a collaborator with marketing, distribution and commercialization rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- if we fail to obtain orphan product designation for a partnered product, we may realize diminished economic benefit upon the ultimate commercialization of that product candidate;
- restrictions and commitments contained in collaborations may have the effect of preventing us from independently undertaking development and other efforts that may appear to be attractive to us;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, might cause delays or termination of the research, development or commercialization of such product candidates, might lead to additional responsibilities for us with respect to such product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated at the convenience of the collaborator or for a material breach by either party, and, if a collaboration is terminated, we could be required to make payments to the collaborator or have our potential payments under the collaboration reduced; and
- in the event of the termination of a collaboration, like the termination of the Biogen Collaboration Agreement effective as of March 8, 2019, we could be required to raise additional capital to pursue further development or commercialization of the product candidates returned to us by our former collaborator.

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 our gene therapy platform and product candidates could be delayed and we may need additional resources to develop product candidates and gene therapy platform. As a result of these or other factors, we may not receive the benefits that we expect from our collaborations.

Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

[Table of Contents](#)

We may in the future determine to collaborate with other pharmaceutical and biotechnology companies for development and potential commercialization of product candidates other than those covered by our collaboration with Biogen. 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 with any such new party 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 a number of factors. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license product candidates, 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. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our gene therapy platform and our business may be materially and adversely affected.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our viral vectors and our product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our gene therapy platform, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets.

Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint research and development programs that may require us to share trade secrets under the terms of

[Table of Contents](#)

our research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks related to commercialization of our product candidates

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues.

We currently have no sales and marketing organization and have no experience selling and marketing our product candidates. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. The establishment and development of our own sales force or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming, particularly to the extent that we seek to commercialize any product for an indication, such as wet AMD, that has a patient population significantly larger than those addressed by our current lead product candidates, and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may enter into collaborations with other entities to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If our future collaborators do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

The biotechnology and pharmaceutical industries are characterized by intense and rapidly changing competition to develop new technologies and proprietary products, and any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. While we believe that our proprietary technology estate and scientific expertise in the gene therapy field provide us with competitive advantages, we face potential competition from many different sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions and governmental agencies and public and private research institutions that may develop potentially competitive products or technologies.

Currently there are no approved products for any of our lead orphan ophthalmology indications of XLRS, ACHM and XLRP. We believe the key competitive factors that will affect the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

A number of companies have announced that they are working on AAV-based gene therapy technology and there are companies developing gene therapies in the field of orphan ophthalmology, on which we are currently focused, which have programs that are at the clinical and pre-clinical stages. Other companies could also potentially seek to enter this field.

[Table of Contents](#)

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and the commercialization of those treatments. To the extent that we develop product candidates for indications with larger patient populations, such as wet AMD, we expect to experience particularly intense competition from larger and better funded pharmaceutical companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. 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. 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, market exclusivity provisions for products with orphan designation could severely limit the sales potential for any of our product candidates that do not gain first-to-market approval.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our products, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

We expect the cost of a single administration of gene therapy products such as those we are developing to be substantial, when and if they achieve regulatory approval. We expect that coverage and reimbursement by governmental and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government authorities, private health coverage insurers and other third-party payors. Coverage and reimbursement by a third-party payor may depend upon a number of 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 governmental and private payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to receive a positive coverage determination. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Currently, no gene therapy products have been approved for coverage under the Medicare program. The Centers for Medicare & Medicaid Services, or CMS, the agency responsible for administering the Medicare program, covers some items and services nationally through National Coverage Determinations. More

[Table of Contents](#)

frequently, coverage determinations for new products are made by the individual Medicare Administrative Contractors (MACs) that operate the program on a day-to-day basis in their awarded geographic jurisdictions. It is difficult to predict what CMS or the local MACs will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Moreover, Medicare reimbursement is determined in part based on where the drug or biologic is administered. Drugs or biologics administered in the inpatient setting are bundled along with other services into Diagnosis Related Groups for payment purposes. In the outpatient setting drugs and biologics such as our product candidates are generally reimbursed at Average Sales Price (ASP) + 6 %. Outside of the United States, agencies in Europe may be more conservative than CMS with respect to reimbursement. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

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, Canada, and other countries has 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. In general, the prices of medicines under such systems are substantially lower than in the United States. 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 and delay their commercial launch. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced or delayed compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and potential legislative changes on both the federal and state levels. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Gene therapy remains a novel technology, with only four gene therapy products approved to date in the United States and only five gene therapy products approved to date in Europe. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. For example, trials using early versions of lentiviral vectors, which integrate with, and thereby alter, the host cell's DNA, have led to several well-publicized adverse events, including reported cases of leukemia. Although none of our current product candidates utilize lentiviral vectors, our product candidates use a viral delivery system. Adverse events in our clinical trials or the clinical trials of other gene therapy companies, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable

[Table of Contents](#)

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.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, or the ACA, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biologic products to potential competition by lower-cost biosimilars, addresses 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, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and subjects additional drugs to lower pricing under the 340B drug pricing program by adding new entities to the program.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013. We expect that additional state and federal 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 reduced demand for our product candidates or additional pricing pressures.

Some of the provisions of the ACA have been subject to judicial and Congressional challenges, and we expect there to be further challenges in the future. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. More recently, President Trump has been seeking to repeal or replace all or portions of the ACA but to date they have been unable to agree on any such legislation. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact our business. We cannot predict what legislation, if any, to repeal or replace the ACA will become law, or what impact any such legislation may have on us or our partners' business and financial condition, if any.

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Ethical, social and legal concerns about gene therapy and genetic research could result in additional regulations restricting or prohibiting the products and processes we may use. Even with the requisite approvals from the FDA in the United States and other government bodies internationally, the commercial success of our product candidates will depend in part on the medical community's, patients', and third-party payors' acceptance of gene therapy products in general, and our product candidates in particular, as medically necessary, cost-effective, and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market

[Table of Contents](#)

acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of product candidates over alternative treatments;
- the clinical indications for which the product candidate is approved;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the cost of treatment relative to alternative treatments;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- label limitations required by regulatory authorities, which could limit size of market;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage and reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors. If any of our product candidates is approved but fails to achieve market acceptance among physicians, patients, or health care payors, we will not be able to generate significant revenues from such product, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for approval of drugs and biologics in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- unexpected changes in tariffs, trade barriers and regulatory requirements;

[Table of Contents](#)

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

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

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates based on our gene therapy platform. Although certain of our product candidates are currently in clinical or preclinical development, we may fail to identify other potential product candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

If any of these events occur, we may be forced to abandon our development efforts with respect to a particular product candidate, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

Risks related to our business operations

We previously identified a material weakness in our internal control over financial reporting, which has now been remediated. If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to report our financial results timely and accurately, which could adversely affect investor confidence in the Company, and in turn, our results of operations and our stock price.

Effective internal controls are necessary for us to provide reliable financial reports and operate successfully as a public company. Section 404 of the Sarbanes-Oxley Act of 2002 requires that companies evaluate and report on their systems of internal control over financial reporting.

As disclosed in our Form 10-K for the fiscal year ended June 30, 2017, we previously identified a material weakness in our internal controls over financial reporting relating to the design and operation of our closing and financial reporting processes. We completed our remediation efforts related to the material weakness by, among other things, hiring additional employees to provide further support to our finance and accounting team;

[Table of Contents](#)

restructuring our finance team to better align the functional areas to the overall strategy of the company, while at the same time providing more focus for the accounting team in maintaining proper control over the financial reporting process commensurate to support standalone external financial reporting under public company or SEC requirements; providing functional and system training to employees and preparing detailed documentation to clearly define key tasks and actions, as well as the positions responsible for those tasks and actions; engaging a consulting firm to assist in documenting and formalizing our accounting policies and internal control processes and to help strengthen supervisory reviews by our management; designing and implementing monthly manual controls to manage our financial reporting close processes and to help ensure an adequate level of segregation of duties within our finance and accounting function; developing and implementing policies and procedures related to security access, including security access reviews of our key financial systems' users to ensure the appropriateness of their roles and security access levels; and performing testing related to the functioning of these controls, and continuing to monitor these controls and make enhancements as needed.

Although we have remediated this material weakness in our internal controls over financial reporting, any failure to maintain effective internal controls could cause a delay in compliance with our reporting obligations, SEC rules and regulations or Section 404 of the Sarbanes-Oxley Act of 2002, which could subject us to a variety of administrative sanctions, including, but not limited to, SEC enforcement action, ineligibility for short form registration, the suspension or delisting of our common stock from the stock exchange on which it is listed and the inability of registered broker-dealers to make a market in our common stock, which could adversely affect our business and the trading price of our common stock

If we are unable to manage expected growth in the scale and complexity of our operations, our performance may suffer.

If we are successful in executing our business strategy, we will need to continue to expand our managerial, operational, financial and other systems and resources to manage our operations, continue our research and development activities, and, in the longer term, build a sales force and commercial infrastructure to support commercialization of any of our product candidates that are approved for sale. Future growth would impose significant added responsibilities on members of management. It is possible that our management, finance, development personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and products requires that we continue to develop more robust business processes and improve our systems and procedures in each of these areas and to attract and retain sufficient numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and growth goals.

We may enter into or seek to enter into business partnerships, combinations and/or acquisitions which may be difficult to integrate, disrupt our business, divert management attention or dilute stockholder value.

A key element of our strategy is to enter into business partnerships, combinations and/or acquisitions. We have limited experience in making acquisitions, which are typically accompanied by a number of risks, including:

- the difficulty of integrating the operations and personnel of the acquired companies;
- the potential disruption of our ongoing business and distraction of management;
- potential unknown liabilities and expenses;
- the failure to achieve the expected benefits of the combination or acquisition;
- the maintenance of acceptable standards, controls, procedures and policies; and
- the impairment of relationships with employees as a result of any integration of new management and other personnel.

If we are not successful in completing acquisitions that we may pursue in the future, we would be required to reevaluate our business strategy and we may have incurred substantial expenses and devoted significant

[Table of Contents](#)

management time and resources in seeking to complete the acquisitions. In addition, we could use substantial portions of our available cash as all or a portion of the purchase price, or we could issue additional securities as consideration for these acquisitions, which could cause our stockholders to suffer significant dilution.

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

We are highly dependent on our executive officers, the loss of whose services may adversely impact the achievement of our objectives. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives and scientific personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in preclinical studies or clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development and commercialization objectives.

In order to induce valuable employees to remain at AGTC, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams have in the past and may in the future terminate their employment with us. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, prospects, financial condition or results of operations. We do not maintain “key man” insurance policies on the lives of these individuals or any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Many of the other biotechnology and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we can offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can discover, develop and commercialize product candidates will be limited.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities.

We are exposed to the risk that our employees, CROs, principal investigators, consultants and commercial partners may engage in fraudulent conduct or other illegal activity or may fail to disclose unauthorized activities to us. Misconduct by these parties could include intentional, reckless and/or negligent failures to comply with:

- the laws and regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulatory bodies;
- manufacturing standards we have established;
- healthcare fraud and abuse laws and regulations in the United States and similar foreign laws; or
- laws requiring the accurate reporting of financial information or data or the disclosure of unauthorized activities to us.

[Table of Contents](#)

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, 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 these laws or regulations. 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, including the imposition of significant fines or other sanctions.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our operations may be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, many of these laws will become more directly applicable to our operations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal False Claims Acts and Physician Payments Sunshine Act and regulations. These laws may impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Health Care Program Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other government payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers;
- federal transparency laws, including the federal Physician Payment Sunshine Act that requires disclosure of payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- the ACA and its implementing regulations, which may impact, among other things, reimbursement rates by federal health care programs and commercial insurers;

[Table of Contents](#)

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs, when and if approved; participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, when and if approved, increased infrastructure costs and potentially limit our ability to offer certain marketplace discounts; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict certain payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states.

In addition, any sale of our products or product candidates, if commercialized outside of the United States, may also subject us to foreign laws governing prescription drug marketing and fraud and abuse, including laws similar to the U.S. healthcare laws mentioned above. Because of the breadth of these laws 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, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirements of the federal Anti-Kickback Statute and the criminal statute governing healthcare fraud. A person or entity can now be found guilty of violating the Anti-Kickback Statute and the federal criminal healthcare fraud statute without actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If the use of our product candidates harms patients, we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. For example, we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend against product liability claims,

[Table of Contents](#)

we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to trial participants, patients or other claimants;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. While we believe our product liability insurance coverage is sufficient in light of our current clinical programs. The amount of the product liability coverage that we carry varies from time to time, depending on a number of factors, the most significant of which are the nature and scope of the clinical trials in which we are engaged and the number of patients being treated with our product candidates in these trials. This amount may increase or decrease in the future. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability and any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the commercial sale of our products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, manufacture and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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 or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

[Table of Contents](#)

We rely on our relationship with a professional employer organization for our human relations function and as aco-employer of our personnel, and if that party failed to perform its responsibilities under that relationship, our relations with our employees could be damaged and we could incur liabilities that could have a material adverse effect on our business.

All of our personnel, including our executive officers, are co-employees of AGTC and a professional employer organization, Insuperity. Under the terms of our arrangement, Insuperity is the formal employer of all of our personnel, and is responsible for administering all payroll, including tax withholding, and providing health insurance and other benefits for these individuals. We reimburse Insuperity for these costs, and pay Insuperity an administrative fee for its services. If Insuperity fails to comply with applicable laws, or its obligations under this arrangement, our relationship with our employees could be damaged. We could, under certain circumstances, be held liable for a failure by Insuperity to appropriately pay, or withhold and remit required taxes from payments to, our employees. In such a case, our potential liability could be significant and could have a material adverse effect on our business.

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.

Substantially all of our manufacturing operations and a majority of our research and development operations are conducted from our headquarters located near Gainesville, Florida. Hurricanes or other natural disasters could severely disrupt our operations, damage our research facilities or destroy stored research materials that could be difficult to replace, and otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. In addition, despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors and consultants and collaborators 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 development programs and our business 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 or that otherwise disrupted our operations or the operations of our third-party contract manufacturer, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. For example, the loss of clinical trial data from our clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If our security measures, disaster recovery and business continuity plans are not adequate in the event of such a breach, serious disaster or similar event, we could incur substantial expenses and the further development and commercialization of our product candidates could be delayed, which could have a material adverse effect on our business.

Interruptions in the supply of product or inventory loss may adversely affect our operating results and financial condition.

Our product candidates are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture and storage of our products, subjects us to production risks. While product batches released for use in clinical trials or for commercialization undergo sample testing, such testing is subject to human error and some defects may only be identified following product release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. Most of our product candidates must be stored and transported at temperatures within a certain range. If these environmental conditions deviate, our product candidates' remaining shelf lives could be impaired or their efficacy and safety could become adversely affected, making them no longer suitable for use. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and

[Table of Contents](#)

remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches. Any interruption in the supply of finished products or the loss thereof could hinder our ability to timely distribute our products and satisfy customer demand. Any unforeseen failure in the storage of the product or loss in supply could delay our clinical trials and, if our product candidates are approved, result in a loss of our market share and negatively affect our revenues and operations.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates 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 strategic 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, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

The U.S. Tax Cuts and Jobs Act enacted in December 2017 includes significant changes from prior tax law which could result in significant changes to our future tax positions.

The U.S. Tax Cuts and Jobs Act (the “Tax Act”) enacted in December 2017 contains many provisions which differ from prior tax law. These changes include, but are not limited to, the reduction in the federal corporate income tax rate from 35% to 21% and the elimination of a corporation’s ability to carryback net operating losses to prior taxable income periods. We accounted for the Tax Act during the year ended June 30, 2018, which resulted in a decrease to the deferred tax asset and a decrease to the valuation allowance due to the reduction of the federal corporate income tax rate from 35% to 21%. Given the complexity of the Tax Act, anticipated guidance from the U.S. Treasury regarding implementation of the Tax Act, and potential for guidance from the Securities and Exchange Commission or the Financial Accounting Standards Board related to the Tax Act, adjustments may be required in future periods to reflect any such guidance provided.

Our ability to use our net operating loss carryforwards may be subject to limitation.

Under Section 382 of the Internal Revenue Code of 1986, as amended, substantial changes in our ownership may limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset our taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such annual limitation may significantly reduce the utilization of our net operating loss carryforwards before they expire. We believe it is likely that transactions that have occurred in the past and other transactions that may occur in the future, could trigger an ownership change pursuant to Section 382, which could limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset our taxable income, if any.

Further, the Tax Act changed the federal rules governing net operating loss carryforwards. For net operating loss carryforwards arising in tax years beginning after December 31, 2017, the Tax Act limits a taxpayer’s ability to utilize such carryforwards to 80% of taxable income. In addition, net operating loss carryforwards arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. Net operating loss carryforwards generated before January 1, 2018 will not be subject to the Tax Act’s taxable income limitation and will continue to have a twenty-year carryforward period. Nevertheless, our net operating loss carryforwards and other tax assets could expire before utilization and could be subject to limitations, which could harm our business, revenue, and financial results.

[Table of Contents](#)

Cyber-attacks or other breaches of network or other information technology security could have an adverse effect on our business.

Cyber-attacks or other breaches of network or information technology security may cause equipment failures or disruptions to our operations. While, to date, we have not been subject to cyber-attacks or other cyber incidents which, individually or in the aggregate, have been material to our operations or financial condition, the preventative actions we take to prevent or detect the risk of cyber incidents and protect our information technology and networks may be insufficient to prevent or detect a major cyber-attack in the future. If we fail to prevent the theft of valuable information such as financial data, sensitive information about the us, our patients or our intellectual property, or if we fail to protect the privacy of patient and employee confidential data against breaches of network or information technology security, it would result in damage to our reputation, which could adversely impact the confidence of our partners, investors and employees. Any of these occurrences could result in a material adverse effect on our results of operations and financial condition.

Risks related to our intellectual property

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

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 proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. 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 know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. 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 issued patents that protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our

[Table of Contents](#)

patent rights, 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, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, 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 products. 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 owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Third parties may initiate legal proceedings alleging claims of intellectual property infringement, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* reexamination proceedings before the United States Patent and Trademark Office and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, methods for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available 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 access to the same technologies licensed to us.

[Table of Contents](#)

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. 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. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to gene therapy product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have rights to the intellectual property to develop our gene therapy product candidates. Because a key element of our business strategy is to pursue in-licensing and intellectual property acquisitions for additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify on terms that we find acceptable, or at all. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with United States and foreign 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 right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

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. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

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.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. We are a party to intellectual property license agreements with the University of Florida Research Foundation, an affiliate of the University of Florida, Johns Hopkins University and the UAB Research Foundation, an affiliate of The University of Alabama at Birmingham, each of which is important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. It is possible that we may fail to obtain any of these

[Table of Contents](#)

licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

In many cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. 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 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.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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

Competitors may infringe our patents or other intellectual property or the patents or other intellectual property of our licensors. In response, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us, alleging that we infringe their patents. Additionally, if the party against whom we bring a claim of infringement has a relationship with one or more of our collaborators, licensors or other strategic counterparties, our relationship with that counterparty may be harmed. Similarly, because our intellectual property is potentially useful for the treatment of serious diseases, any third-party infringers may be viewed sympathetically by the public and our assertion of an infringement claim against them may hurt our reputation. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensors is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome

[Table of Contents](#)

could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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 material adverse effect on the price of our common stock.

Issued patents covering our product candidates or methods of manufacturing could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, or methods of manufacturing our product candidates, the defendant could counterclaim that the patent covering our product candidate or method 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 United States Patent and Trademark Office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions. Such proceedings could result in the revocation of or amendment to our patents in such a way that they no longer cover our product candidates or manufacturing methods. 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 and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our product candidates or methods of manufacturing our products. Such a loss of patent protection could have a material adverse impact on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have enacted policies and procedures designed to ensure that our employees, consultants and independent contractors 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 our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. 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.

[Table of Contents](#)

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

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. While it is our policy to require our employees and contractors who may be involved in the 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 develops intellectual property that we regard as our own. We could be subject to ownership disputes arising, for example, from conflicting obligations of 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 ownership. If we 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, valuable intellectual property. Such an outcome could have a material adverse effect on our business. 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.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

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 technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative it could have a substantial adverse effect on the price 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. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining our 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 governmental fees on patents and/or applications will be due to be paid to the United States Patent and Trademark Office and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The United States Patent and Trademark Office and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our business.

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

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological

[Table of Contents](#)

and legal complexity, and therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith 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 have a material adverse effect on our business and financial condition.

Moreover, recent United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the federal courts, and the United States Patent and Trademark Office, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We have not yet sought FDA approval of names for any of our product candidates and failure to secure such approvals could adversely affect our business.

Any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. 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 their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. 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 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 or

[Table of Contents](#)

marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, 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. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks related to ownership of our common stock

The market price for our common stock has been, and is likely to continue to be volatile, which could contribute to the loss of your investment.

Fluctuations in the price of our common stock could contribute to the loss of all or part of your investment. Our stock price has been volatile and could be subject to wide fluctuations in response to various factors, many of which are beyond our control. Since our initial public offering in March 2014 and through August 31, 2019, the price of our common stock on the Nasdaq Global Market has ranged from \$2.26 to \$34.37. Any of the factors listed below could have a material adverse effect on your investment in our common stock. In such circumstances, the trading price of our common stock may not recover and may experience a further decline.

Factors affecting the trading price of our common stock may include:

- our failure to develop and commercialize our product candidates;
- actual or anticipated fluctuations in our quarterly financial results or the quarterly financial results of companies perceived to be similar to us;
- changes in the market's expectations about our operating results;
- adverse results or delays in our preclinical studies or clinical trials;
- reports of adverse events in other gene therapy products or clinical studies of such products;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- any delay in filing an IND or BLA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND or BLA;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our product candidates;
- success of competitive products;
- adverse developments concerning our collaborations and our manufacturers;
- inability to obtain adequate product supply for any product candidate for clinical trials or commercial sale or inability to do so at acceptable prices;
- the termination of a collaboration or the inability to establish additional collaborations;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- our ability to effectively manage our growth;
- the size and growth, if any, of the orphan ophthalmology and other targeted markets;
- our operating results failing to meet the expectation of securities analysts or investors in a particular period or failure of securities analysts to publish reports about us or our business;

Table of Contents

- changes in financial estimates and recommendations by securities analysts concerning our company, the gene therapy market, or the biotechnology and pharmaceutical industries in general;
- operating and stock price performance of other companies that investors deem comparable to us;
- overall performance of the equity markets;
- announcements by us or our competitors of acquisitions, new product candidates or programs, significant contracts, commercial relationships or capital commitments;
- our ability to successfully market our product candidates;
- changes in laws and regulations affecting our business, including but not limited to clinical trial requirements for approvals;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates and gene therapy platform;
- commencement of, or involvement in, litigation involving our company, our general industry, or both;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our common stock available for public sale;
- additions or departures of key scientific or management personnel;
- any major change in our board or management;
- changes in accounting practices;
- ineffectiveness of our internal control over financial reporting;
- sales of substantial amounts of common stock by our directors, executive officers or significant stockholders or the perception that such sales could occur; and
- general economic and political conditions such as recessions, interest rates, fuel prices, international currency fluctuations and acts of war or terrorism.

Broad market and industry factors may materially harm the market price of our common stock irrespective of our operating performance. The stock market in general, and The Nasdaq Global Market and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the particular companies affected. The trading prices and valuations of these stocks, and of ours, may not be predictable. A loss of investor confidence in the market for technology or software stocks or the stocks of other companies which investors perceive to be similar to us, the opportunities in the digital simulation market or the stock market in general, could depress our stock price regardless of our business, prospects, financial conditions or results of operations.

If securities analysts do not publish research or reports about our business or if they downgrade our stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. As a newly public company, we have only limited coverage by securities analysts. If securities analysts do not continue to cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

[Table of Contents](#)

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities, potential acquisitions, in-licenses, or collaborations and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on the appreciation in the price of our common stock.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to fund our future growth and do not expect to declare or pay any dividend on shares of our common stock in the foreseeable future. As a result, you may only receive a return on your investment in our common stock if the market price of our common stock appreciates and you sell your shares at a price above your cost.

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 biotechnology 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.

Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions in Delaware law, might discourage, delay or prevent a change of control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Our certificate of incorporation, bylaws and Delaware law contain provisions that could have the effect of rendering more difficult or discouraging an acquisition deemed undesirable by our board of directors, even if doing so would benefit our stockholders or remove our current management. Our corporate governance documents include provisions:

- providing for three classes of directors with the term of office of one class expiring each year, commonly referred to as a staggered board;
- authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock;
- limiting the liability of, and providing indemnification to, our directors and officers;
- eliminating the ability of our stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors;
- controlling the procedures for the conduct and scheduling of board and stockholder meetings;
- limiting the determination of the number of directors on our board and the filling of vacancies or newly created seats on the board to our board of directors then in office; and
- providing that directors may be removed by stockholders only for cause.

[Table of Contents](#)

These provisions, alone or together, could delay hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business 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 you could receive a premium for your common stock in an acquisition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 2. PROPERTIES

Alachua, Florida

Our corporate headquarters are located in Alachua, Florida. In January 2016, we moved into a new combined-use facility consisting of approximately 21,500 square feet of laboratory and office space. The initial lease term for this facility is 12 years and we have options to extend the term of the lease for three additional five-year periods.

Cambridge, Massachusetts

In August 2015, we entered into a two-year lease to occupy approximately 3,000 square feet of office and laboratory space in Cambridge, Massachusetts. On July 31, 2017, we entered into a new lease to increase our office and laboratory space in Cambridge by approximately 5,000 square feet to a total of approximately 8,000 square feet and extend the term of the lease for an additional seven years, with an option to further extend the lease for one additional three-year term. The Cambridge facility primarily focuses on business development, pharmacology, and basic research and development.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any pending 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****Market Information**

Our common stock has been listed on The NASDAQ Global Market under the symbol “AGTC” since March 27, 2014. Prior to that date, there was no public market for our common stock.

As of September 24, 2019, a total of 18,218,402 shares of our common stock were outstanding and we had 27 holders of record of our common stock.

Dividend policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to finance the growth and development of our business. We do not expect to pay any cash dividends on our common stock in the foreseeable future.

Securities authorized for issuance under equity compensation plans

For information regarding securities authorized for issuance under our equity compensation plans, see Part III, Item 12, “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.”

Issuer Purchases of Equity Securities

The following table provides certain information with respect to our purchases of shares of the Company’s common stock during the fourth quarter of fiscal 2019.

Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased^(a)	Average Price Paid per Share^(a)	Total Number of Shares Purchased as Part of Publicly Announced Plan	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plan
April 1, 2019 through April 30, 2019	606	\$ 4.61	—	\$ —
May 1, 2019 through May 31, 2019	685	\$ 4.06	—	\$ —
June 1, 2019 through June 30, 2019	685	\$ 3.70	—	\$ —
Total	<u>1,976</u>	<u>\$ 4.12</u>	<u>—</u>	<u>—</u>

(a) These columns reflect the surrender to the Company of an aggregate of 1,976 shares of common stock to satisfy tax withholding obligations in the connection with the vesting of restricted stock issued to an employee during the fourth quarter of fiscal 2019.

ITEM 6: SELECTED FINANCIAL DATA

Not applicable.

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 the financial statements and notes included in Part IV, Item 15 of this Annual Report on Form 10-K. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, including but not limited to those set forth in "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors."

Overview

We are a clinical-stage biotechnology company that uses a proprietary gene therapy platform to develop transformational genetic therapies for patients suffering from rare and debilitating diseases. Our initial focus is in the field of ophthalmology, where we have active clinical programs in X-linked retinoschisis (XLRS), X-linked retinitis pigmentosa (XLRP), and achromatopsia (ACHM) and a preclinical program in optogenetics. In addition to ophthalmology, we have initiated preclinical programs in adrenoleukodystrophy (ALD) and otology. With a number of important clinical milestones on the horizon, we believe we are well positioned to advance multiple programs towards pivotal studies. In addition to our product pipeline, we have also developed broad technological capabilities through our collaborations with Synpromics Limited (Synpromics) and the University of Florida, which provide us with expertise in vector design and manufacturing as well as synthetic promoter development and optimization.

Since our inception in 1999, we have devoted substantially all of our resources to development efforts relating to our proof-of-concept programs in ophthalmology and alpha-1 antitrypsin deficiency, or AAT deficiency, an inherited orphan lung disease, including activities to manufacture product in compliance with good manufacturing practices, preparing to conduct and conducting clinical trials of our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily through public offering of our common stock, private placement of preferred stock, and collaborations. We have also been the recipient, either independently or with our collaborators, of grant funding administered through federal, state, and local governments and agencies, including the United States Food and Drug Administration, or FDA, and by patient advocacy groups such as The Foundation Fighting Blindness, or FFB, and the Alpha-1 Foundation.

We have incurred losses from operations in each year since inception, except for fiscal 2017, in which we reported net income of \$0.4 million due in part to the amortization associated with our collaboration agreement with Biogen. For the fiscal years ended June 30, 2019 and 2018, we reported net losses of \$2.0 million and \$21.3 million, respectively. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant operating expenses for at least the next several years and anticipate that such expenses will increase substantially in connection with our ongoing activities, as we:

- conduct preclinical studies and clinical trials for our XLRS, ACHM and XLRP product candidates;
- continue our research and development efforts, including exploration through early preclinical studies of potential applications of our gene therapy platform in:
 - orphan ophthalmology indications;
 - non-orphan ophthalmology indications including wet AMD and other inherited retinal diseases; and
 - other inherited diseases, such as otology and CNS indications.
- manufacture clinical trial materials and develop larger-scale manufacturing capabilities;

[Table of Contents](#)

- seek regulatory approval for our product candidates;
- further develop our gene therapy platform;
- add personnel to support our collaboration, product development and commercialization efforts; and
- continue to operate as a public company.

As of June 30, 2019, we had cash and cash equivalents and investments totaling \$82.0 million.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and which we believe is subject to significant uncertainty. We believe that our existing cash and cash equivalents and investments at June 30, 2019, will be sufficient to allow us to generate data from our ongoing clinical programs, to move our pre-clinical optogenetic program in collaboration with Bionic Sight into the clinic and to fund our currently planned research and discovery programs into the first half of 2021. In order to complete the process of obtaining regulatory approval for our lead product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidates, if approved, we will require substantial additional funding. Also, our current operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

Strategic Collaborations

Biogen

In July 2015, we entered into a Collaboration Agreement (the “Collaboration Agreement”) with Biogen, pursuant to which we and Biogen collaborated to develop, seek regulatory approval for and commercialize gene therapy products to treat XLRs, XLRP, and discovery programs targeting three indications based on the Company’s adeno-associated virus vector technologies. Effective March 8, 2019, Biogen terminated the Collaboration Agreement. Upon termination, we received back the exclusive license rights to develop, manufacture and commercialize the product candidates for all of our partnered programs including our XLRP program, XLRs program and our three discovery programs. As we reported on December 12, 2018, based on topline interim six-month data from our Phase 1/2 clinical trial of our XLRs product candidate that showed no clinical activity at six-months, we will complete patient monitoring activities on the XLRs program according to the clinical protocol, but we will not further develop our XLRs product candidate. We plan to continue to advance our XLRP and ACHM product candidates, as we believe the general safety and tolerability of our gene delivery platform is supported by our XLRs clinical data.

During the term of the Collaboration Agreement, we received an aggregate of \$111.5 million in upfront payments and milestone payments. For the fiscal years ended June 30, 2019 and 2018, we recognized revenue of approximately \$41.1 million and \$24.1 million, respectively, under the Collaboration Agreement, including \$20.4 million recognized in fiscal 2019, which was the remaining deferred revenue balance as of the termination date.

Bionic Sight, LLC

In February 2017, we entered into a collaboration agreement with Bionic Sight to develop a gene therapy treatment to be used with Bionic Sight’s innovative neuroprosthetic device and algorithm for retinal coding.

[Table of Contents](#)

Under the agreement, AGTC made an initial \$2.0 million payment to Bionic Sight for an equity interest in that company. This initial investment represents an approximate 5 percent equity interest in Bionic Sight. In addition to the initial investment, we are contributing to ongoing research and development support costs through additional payments or other in-kind contributions. These payments and contributions will be made over time, up to the date that Bionic Sight has received both investigational new drug clearance from the FDA and receipt of written approval from an internal review board to conduct clinical trials from at least one clinical site for that product candidate (the “IND Trigger”). As of June 30, 2019, we had incurred approximately \$2.0 million in research and development support cost related to in-kind contributions. If and when, the IND Trigger is attained, we will receive additional equity, based on the valuation in place at the beginning of the agreement, for its cash and research and development contributions and will be obligated to purchase additional equity in Bionic Sight for \$4.0 million. Bionic Sight filed an IND for the program on March 1, 2019 in advance of completing the final formulation and testing of clinical trial material produced by their contract manufacturing organization. The FDA has put the trial on hold pending full review of the final testing to assure comparability to the material in the toxicology study. Bionic Sight expects the FDA to lift the hold on the IND and the Phase 1/2 clinical trial to be initiated in the first half of fiscal year 2020.

Financial operations overview

Revenue

We primarily generate revenue through collaboration agreements, sponsored research arrangements with nonprofit organizations for the development and commercialization of product candidates and from federal research and development grant programs. In the future, we may generate revenue from a combination of: product sales, license fees, milestone payments, development services, research and development grants, and from collaboration and royalty payments for the sales of products developed under licenses of our intellectual property.

We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development programs, manufacturing efforts and reimbursements, collaboration milestone payments, and the sale of our products, to the extent any are successfully commercialized. We do not expect to generate revenue from product sales for the foreseeable future, if at all. If we or our collaborators fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, our results of operations and financial position would be materially adversely affected. Following the termination of the Collaboration Agreement, we do not expect to receive any material collaboration related payments in the near term.

On July 1, 2018, we adopted Accounting Standard Codification (ASC) 606, *Revenue from Contracts with Customers* (“Topic 606”) using the modified retrospective method. For further information, refer to Note 2: Revenue Recognition, to the financial statements set forth in this Annual Report on Form 10-K.

Bionic Sight, LLC, In-Kind Contributions

We assessed the nature of in-kind contributions under the scope of ASC 606, *Revenue from Contracts with Customers*, following the five-step approach, as the services rendered represent a distinct service delivered to a counterparty that meets the definition of a customer. The Company considered these services to represent one combined performance obligation. Given that the consideration that the Company is entitled to is contingent upon achievement of the IND Trigger, the consideration is determined to be variable. The Company believes that the amount of variable consideration related to the achievement of the IND Trigger should be fully constrained as the achievement of this event is highly susceptible to factors outside of the Company’s control. The Company evaluates the amount of potential receipt of the variable consideration and the likelihood that the consideration will be received. Utilizing the most likely amount method, and if it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price. The variable consideration related

[Table of Contents](#)

to Bionic Sight agreement has been fully constrained since the inception of the agreement and no amounts have been recognized as revenue to date. If IND Trigger is achieved, we expect to receive equity interest in Bionic Sight based on the valuation in place at the beginning of the agreement and recognize revenue equal to the amount of in-kind contributions.

Research and development expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and share-based compensation expense;
- expenses incurred under agreements with academic research centers, contract research organizations, or CROs, and investigative sites that conduct our clinical trials;
- license and sublicense fees and collaboration expenses;
- the cost of acquiring, developing, and manufacturing clinical trial materials; and
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing as well as any additional clinical trials and other research and development activities;
- the timing and level of activity as determined by us or jointly with our partners;
- the level of funding received from our partners;
- whether or not we elect to cost share with our collaborators;
- the countries in which trials are conducted;
- future clinical trial results;
- uncertainties in clinical trial enrollment rates or drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies or elected as best practice by us;
- increased cost and delay associated with manufacturing or testing issues, including ongoing quality assurance, qualifying new vendors and developing in-house capabilities;
- significant and changing government regulation; and
- the timing and receipt of any regulatory approvals.

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 development of that product candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those

[Table of Contents](#)

that we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in or execution of any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

From inception through June 30, 2019, we have incurred approximately \$202.4 million in research and development expenses. We expect our research and development expenses to increase for the foreseeable future as we continue the development of our product candidates and explore potential applications of our gene therapy platform in other indications.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including share-based compensation and travel expenses for our employees in executive, operational, legal, business development, finance and human resource functions. Other general and administrative expenses include costs to support employee training and development, board of directors' costs, depreciation, insurance expenses, facility-related costs not otherwise included in research and development expense, professional fees for legal services, including patent-related expenses, and accounting, investor relations, corporate communications and information technology services. We anticipate that our general and administrative expenses will continue to increase in the future as we hire additional employees to support our continued research and development efforts, collaboration arrangements, and the potential commercialization of our product candidates. Additionally, if and when we believe a regulatory approval of the first product candidate appears likely, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Other income/(expense), net

Other income/(expense), net consists primarily of investment income on cash and cash equivalents and our held-to-maturity investments.

Critical accounting policies and estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in conformity with U.S. generally accepted accounting principles (U.S. GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and equity at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. On an ongoing basis, we evaluate our estimates, judgments and methodologies. Estimates are based on historical experience, current conditions and on various other assumptions that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amounts of revenues and expenses. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in Note 2 to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies are most critical to the preparation of our financial statements.

Revenue recognition

We have generated revenue primarily through collaboration agreements, sponsored research arrangements with nonprofit organizations for the development and commercialization of product candidates and revenues from federal research and development grant programs. Under Topic 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of Topic 606, we perform the following five

[Table of Contents](#)

steps: (i) identification of the contract; (ii) determination of whether the promised goods or services are performance obligations; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect consideration we are entitled to in exchange for the goods or services we transfer to the customer.

Performance obligations are promises to transfer distinct goods or services to the customer. Promised goods or services are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own or whether the required expertise is readily available.

We estimate the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include both fixed consideration or variable consideration. At the inception of an arrangement that includes variable consideration and at each reporting period, we evaluate the amount of potential payment and the likelihood that the payments will be received. We utilize either the most likely amount method or expected amount method to estimate the amount to be received based on which method better predicts the amount expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price. We will assess our revenue generating arrangements in order to determine whether a significant financing component exists and conclude that a significant financing component does not exist in any of our arrangements if: (a) the promised consideration approximates the cash selling price of the promised goods and services or any significant difference is due to factors other than financing; and (b) timing of payment approximates the transfer of goods and services and performance is over a relatively short period of time within the context of the entire term of the contract.

Our contracts will often include development and regulatory milestone payments. At contract inception and at each reporting period, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the customer's control, such as regulatory approvals, are not included in the transaction price. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment.

For arrangements that may include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our collaboration arrangements.

We allocate the transaction price based on the estimated standalone selling price of the underlying performance obligations or in the case of certain variable consideration to one or more performance obligations. We must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

[Table of Contents](#)

For performance obligations consisting of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress at each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. If the license is determined to be distinct from the other performance obligations identified in the arrangement, then we will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

We receive payments from its customers based on billing terms established in each contract. Such billings generally have 30-day payment terms. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the right to consideration is unconditional.

Research and development expenses

Research and development costs include costs incurred in identifying, developing and testing product candidates and generally comprise compensation and related benefits and non-cash share-based compensation to research related employees; laboratory costs; animal and laboratory maintenance and supplies; rent; utilities; clinical and pre-clinical expenses; and payments for sponsored research, scientific and regulatory consulting fees and testing.

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. The significant estimates in our accrued research and development expenses are related to expenses incurred with respect to academic research centers, CROs, and other vendors in connection with research and development activities for which we have not yet been invoiced.

There may be instances in which our service providers require advance payments at the inception of a contract or in which payments made to these vendors will exceed the level of services provided, resulting in a prepayment of the research and development expense. Such prepayments are charged to research and development expense as and when the service is provided or when a specific milestone outlined in the contract is reached.

Share-based compensation

We account for share-based awards issued to employees in accordance with Accounting Standard Codification (ASC) Topic 718, *Compensation—Stock Compensation* (ASC 718) generally recognize share-based compensation expense on a straight-line basis over the periods during which the employees and non-employee directors are required to provide service in exchange for the award. In addition, we issue stock options and restricted shares of common stock to non-employees in exchange for consulting services and account for these in accordance with the provisions of ASC Subtopic 505-50, *Equity-Based Payments to Non-employees* (ASC 505-50). Under ASC 505-50, share-based awards to non-employees are subject to periodic fair value re-measurement over their vesting terms.

For purposes of calculating stock-based compensation, we estimate the fair value of stock options using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected volatility is primarily based on the historical volatility of peer company data while the expected life of the stock options is based on historical and

[Table of Contents](#)

other economic data trended into the future. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of our stock options. The dividend yield assumption is based on our history and expectation of no dividend payouts. If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining stock-based compensation expense and the actual factors which become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining stock-based compensation costs for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made.

Income taxes

We use the asset and liability method for accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

As required by U.S. GAAP, we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense. The Company is subject to examination of its income tax returns in the federal and state income tax jurisdictions in which it operates. On December 28, 2015, the United States Internal Revenue Service, or IRS, notified the Company of an income tax audit for the tax period ending June 30, 2014. As of June 30, 2017, the IRS audit was closed, and the Company incurred no penalties or payment liabilities for its income tax positions. For fiscal years ended June 30, 2019 and 2018, we recorded income tax expense as a result of uncertainties related to state income taxes.

The Tax Cut and Jobs Act (the “Tax Act”) was enacted on December 22, 2017. The Tax Act contains several key provisions including, among other things, reducing the U.S. federal corporate tax rate from 35% to 21%. We have enacted this reduction in tax rate effective January 1, 2018, and as such is using a blended rate for the fiscal year ended June 30, 2018. In addition, federal net operating losses (NOLs) generated during future periods will be carried forward indefinitely but will be subject to an 80% utilization against taxable income. The Company has completed its evaluation of the Tax Act with no material adjustments to its initial analysis.

For the fiscal year ended June 30, 2019, the Company recorded an income tax provision as a result of uncertainties related to state income taxes.

Recent Accounting Pronouncements

Refer to Note 2 to our financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data,” of this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our business.

[Table of Contents](#)

Results of operations

Comparison of the fiscal years ended June 30, 2019 and 2018

Revenue

In thousands	Year ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
Collaboration revenue				
License and related services	\$27,000	\$18,529	\$ 8,471	46%
Development services	2,736	3,028	(292)	(10)%
Milestone revenue	11,392	\$ 2,500	8,892	356%
Total Collaboration revenue	\$41,128	\$24,057	\$ 17,071	71%
Grant revenue	564	129	435	337%
Total revenue	<u>\$41,692</u>	<u>\$24,186</u>	<u>\$ 17,506</u>	<u>72%</u>

Total revenue for fiscal year 2019 increased by \$17.5 million to \$41.7 million compared to fiscal year 2018 primarily due to increased milestone revenue of \$8.9 million, increased license and related services revenue of \$8.5 million, and increased grant revenue of \$0.4 million, which was partially offset by decreased development services revenue of \$0.3 million. The increase in license and related services revenue was primarily due to recognizing revenue of \$18.0 million as result of the termination of the Collaboration Agreement with Biogen effective March 8, 2019, partially offset by the Company's revised pattern of revenue recognition under ASC 606. The increase in grant revenue was attributable to higher research and development activities on grant-funded projects. The increase in milestone revenue was primarily due to recognizing revenue of \$8.3 million associated with the receipt of a \$10.0 million milestone payment from Biogen under the Collaboration Agreement during the first quarter of fiscal year 2019, recognizing revenue of \$0.6 million under ASC Topic 606 and recognizing revenue of \$2.4 million as a result of the termination of the Collaboration Agreement with Biogen, partially offset by recognizing revenue of \$2.5 million in fiscal year 2018 associated with receiving a milestone payment from Biogen. The decrease in development services revenue was primarily due to timing of Phase 1/2 study activities related to the Company's XLRP program and due to the termination of the Collaboration Agreement with Biogen.

Research and development expenses

The following table summarizes our research and development expenses by product candidate or program for the fiscal year ended June 30, 2019 and 2018:

In thousands	Year Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
External research and development expenses				
ACHM	\$ 4,729	\$ 4,202	\$ 527	13%
XLRS	1,197	2,399	(1,202)	(50)%
XLRP	4,539	2,688	1,851	69%
Research and discovery programs	3,363	6,077	(2,714)	(45)%
Total external research and development expenses	<u>13,828</u>	<u>15,366</u>	<u>(1,538)</u>	<u>(10)%</u>
Internal research and development expenses				
Employee-related costs	10,908	8,897	2,011	23%
Share-based compensation	1,895	2,443	(548)	(22)%
Other	6,552	5,475	1,077	20%
Total internal research and development expenses	<u>19,355</u>	<u>16,815</u>	<u>2,540</u>	<u>15%</u>
Total research and development expense	<u>\$33,183</u>	<u>\$ 32,181</u>	<u>\$ 1,002</u>	<u>3%</u>

Table of Contents

External research and development costs consist of clinical trial, collaboration, licensing, manufacturing, testing, and other miscellaneous expenses that are directly attributable to our most advanced product candidates and discovery programs. We do not allocate personnel-related costs, including stock-based compensation, costs associated with broad technology platform improvements or other indirect costs, to specific programs, as they are deployed across multiple projects under development and, as such, are separately classified as internal research and development expenses in the table above.

Research and development expenses for fiscal 2019 were \$33.2 million, compared to \$32.2 million for fiscal 2018, an increase of \$1.0 million, or 3%. This increase was primarily attributable to:

- \$2.0 million of increased employee-related expenses associated with the hiring of additional employees to support clinical trial execution and research and development activities;
- \$1.9 million of increased external spending related to XLRP primarily due to incurring sublicense expenses associated with receiving a \$10.0 million XLRP milestone payment from Biogen under the Collaboration Agreement;
- \$1.1 million of increased general research and development expenses associated with consulting, depreciation and rent expense; and
- \$0.5 million of increased external spending related to ACHM primarily due to increased patient enrollment.

These increases were partially offset by:

- \$2.7 million of decreased research and discovery spending primarily due to decreased pre-clinical ophthalmology activities;
- \$1.2 million of decreased external XLRP expenses primarily due to reaching full enrollment on the Phase 1/2 clinical trial; and
- \$0.5 million of decreased share-based compensation expenses primarily due to timing of grants.

General and administrative expenses

In thousands	Year Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
Employee-related costs	\$ 4,773	\$ 5,557	\$ (784)	(14)%
Share-based compensation	2,134	2,751	(617)	(22)%
Legal and professional fees	774	437	337	77%
Other general and administrative expenses	5,178	5,644	(466)	(8)%
Total general and administrative expenses	<u>\$12,859</u>	<u>\$ 14,389</u>	<u>\$ (1,530)</u>	<u>(11)%</u>

General and administrative expenses for the fiscal 2019 were \$12.9 million, compared to \$14.4 million for fiscal 2018, a decrease of \$1.5 million, or 11%. The decrease was primarily driven by a decrease in employee-related costs of \$1.4 million and a decrease in other general and administrative expenses of \$0.5 million attributable to decrease in bad debt expense and other administrative expenses incurred during normal course of business operations for the year ended June 30, 2019.

Other income/(expense), net

Other income/(expense), net, which consists primarily of investment income, increased to \$2.5 million for the year ended June 30, 2019, compared to \$1.2 million for the year ended June 30, 2018. The increase in other income/(expense), net of \$1.3 million was primarily due to better investment performance and settlement of recovery cost as result of the termination of the Collaboration Agreement with Biogen.

[Table of Contents](#)**Liquidity and capital resources**

We have incurred cumulative losses and negative cash flows from operations since our inception in 1999, and as of June 30, 2019, we had an accumulated deficit of \$135.5 million. It will be several years, if ever, before we have a product candidate ready for commercialization. We expect that our research and development and general and administrative expenses will continue to increase and as a result, we anticipate that we will require additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

As of June 30, 2019, our cash and cash equivalents were held in bank accounts and money market funds, while our investments consisted of U.S. Treasury Securities, none of which mature more than 12 months after the balance sheet date, consistent with our investment policy that seeks to maintain adequate liquidity and preserve capital.

Cash flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

In thousand	June 30, 2019	June 30, 2018
Net cash and cash equivalents provided by (used in):		
Operating activities	\$ (23,457)	\$ (32,520)
Investing activities	19,027	33,015
Financing activities	68	(136)
Net (decrease)/increase in cash and cash equivalents	<u>\$ (4,362)</u>	<u>\$ 359</u>

Operating activities. Cash used in operating activities of \$23.5 million for the fiscal year ended June 30, 2019 was primarily due to changes in operating assets and liabilities of \$25.6 million, partially offset by non-cash items of \$4.2 million, including \$4.0 million in stock-based compensation expense, and a net loss of \$2.0 million. For the fiscal year ended June 30, 2019, the change in operating assets and liabilities was primarily due to recognizing the entire deferred revenue balance as a result of the termination of the Collaboration Agreement. Cash used in operating activities of \$32.5 million during the fiscal year ended June 30, 2018 was primarily due to changes in operating assets and liabilities of \$18.2 million, partially offset by non-cash items of \$7.0 million, including \$5.2 million of stock-based compensation expense, and a net loss of \$21.3 million.

Investing activities. Cash provided by investing activities of \$19.0 million for the fiscal year ended June 30, 2019 was primarily due to maturity of investments of \$94.1 million, partially offset by purchases of investments of \$74.8 million and the purchase of property and equipment of \$0.2 million and intellectual property of \$0.1 million. Cash provided by investing activities of \$33.0 million for the fiscal year ended June 30, 2018 was primarily due to maturity of investments of \$100.9 million, partially offset by purchases of investments of \$67.1 million and the purchase of property and equipment and intellectual property of \$0.8 million.

Financing activities. Net cash (used in)/provided by financing activities for fiscal year 2019 and 2018 was \$68,000 and (\$136,000), respectively. Net cash provided in financing for year ended June 30, 2019 consisted primarily of proceeds from the exercise of common stock options. Net cash used in financing activities for the year ended June 30, 2018 was associated with deferred offering costs.

Operating capital requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We

[Table of Contents](#)

anticipate that we will continue to generate losses for the foreseeable future as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all of the risks incident in the development of new gene therapy products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We believe that our existing cash and cash equivalents and investments at June 30, 2019, will be sufficient to allow us to generate data from our ongoing clinical programs, to move our pre-clinical optogenetic program in collaboration with Bionic Sight into the clinic and to fund our currently planned research and discovery programs into the first half of 2021. In order to complete the process of obtaining regulatory approval for our lead product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidates, if approved, we will require substantial additional funding.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and costs our clinical trials for our XLRP and ACHM product candidates;
- the timing and costs of our preclinical studies of our discovery program product candidates;
- the timing and level of activity as determined by us or jointly with our partners;
- the level of funding received from our partners;
- whether or not we elect to cost share with our partners;
- the initiation, progress, timing, costs and results of preclinical studies relating to potential applications of our gene therapy platform in other indications;
- our success in scaling our manufacturing method and expanding our manufacturing capabilities;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- subject to receipt of marketing approval, revenue received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the extent to which we in-license or acquire other products and technologies; and
- the timing of payments for our additional equity purchase obligations under the Bionic Sight collaboration agreement.

Contractual obligations and commitments

Our current leased facilities encompass approximately 21,500 square feet of laboratory and office space in Alachua, Florida under a lease arrangement that will expire in December 31, 2027. In addition, we occupy

[Table of Contents](#)

approximately 8,000 square feet of office and laboratory space in Cambridge, Massachusetts. On July 31, 2017, we entered into a new lease to increase our office and laboratory space in Cambridge by approximately 5,000 square feet to a total of approximately 8,000 square feet and extend the term of the lease for an additional seven years, with an option to further extend the lease for one additional three-year term.

Contingent contractual obligations

We also have obligations arising under our license agreements to make future payments to third parties that become due and payable on the achievement of certain development, regulatory and commercial milestones (such as the start of a clinical trial, filing of a Biologics License Application, or BLA, approval by the FDA or product launch). We have not included these obligations on our balance sheet or in the table above because the achievement and timing of these milestones is not fixed nor determinable. These obligations include:

- Under each of our various licenses with the University of Florida Research Foundation, or UFRF, covering the AAV construct containing the AAT gene and the method to treat AAT deficiency using this construct, a small cone cell specific promoter, and the use of engineered capsids and under our joint license with UFRF and Johns Hopkins University covering a particular HSV construct and various compositions thereof, we will be required to make payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of such license income. We are required to make annual maintenance payments under these licenses, which payments are creditable against royalty payments on a year-by-year basis.
- Under our license agreement with the UAB Research Foundation pursuant to which we license a patent covering the use of HSV helpers to produce AAV vectors, we will be required to make payments based upon development and regulatory milestones for any products covered by the in-licensed intellectual property. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of such license income. We are required to make annual maintenance payments under this license, which payments are creditable against royalty payments on a year-by-year basis.

If any of our product candidates that utilize technology licensed under these agreements reached commercialization, we will be obligated to make royalty payments ranging from 0.5% to 4.0% of our net sales of the applicable product. We are responsible for a portion of the costs related to the preparation, filing, issuance, prosecution and maintenance of the patents covered by the license agreements.

We enter into contracts in the normal course of business with contract research organizations for preclinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

[Table of Contents](#)

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

APPLIED GENETIC TECHNOLOGIES CORPORATION
INDEX TO FINANCIAL STATEMENTS

	<u>Page(s)</u>
Report of Independent Registered Public Accounting Firm	88
Financial Statements	
Balance Sheets at June 30, 2019 and 2018	89
Statements of Operations for the years ended June 30, 2019 and 2018	90
Statements of Stockholders' Equity for the years ended June 30, 2019 and 2018	91
Statements of Cash Flows for the years ended June 30, 2019 and 2018	92
Notes to Financial Statements	93-116
Schedule II—Valuation and Qualifying Accounts	124

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Applied Genetic Technologies Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Applied Genetic Technologies Corporation (the Company) as of June 30, 2019 and 2018, the related statements of operations, stockholders' equity and cash flows for each of the two years in the period ended June 30, 2019, and the related notes and financial statement schedule listed in the Index at Item 15(a) (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 at June 30, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended June 30, 2019, in conformity with U.S. generally accepted accounting principles.

Adoption of New Accounting Standard

As discussed in Note 2 to the financial statements, the Company changed its method for accounting for revenue recognition in 2019.

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/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Tampa, Florida
September 26, 2019

APPLIED GENETIC TECHNOLOGIES CORPORATION
BALANCE SHEETS

In thousands, except per share data	As of June 30,	
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 26,703	\$ 31,065
Investments	55,292	73,840
Grants receivable	13	210
Prepaid and other current assets	2,276	4,009
Total current assets	<u>84,284</u>	<u>109,124</u>
Property and equipment, net	4,430	5,254
Intangible assets, net	1,013	968
Investment in Bionic Sight	1,945	1,980
Other assets	544	1,206
Total assets	<u>\$ 92,216</u>	<u>\$ 118,532</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,331	\$ 945
Accrued and other liabilities	8,024	7,155
Deferred revenue	—	6,295
Total current liabilities	<u>9,355</u>	<u>14,395</u>
Deferred revenue, net of current portion	—	610
Other long-term liabilities	4,152	4,345
Total liabilities	<u>13,507</u>	<u>19,350</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value \$.001 per share, 150,000 shares authorized; 18,226 and 18,137 shares issued; 18,207 and 18,126 shares outstanding as of June 30, 2019, and 2018, respectively	18	18
Additional paid-in capital	214,324	210,139
Shares held in treasury of: 19 and 11 as of June 30, 2019 and 2018 respectively	(85)	(49)
Accumulated deficit	<u>(135,548)</u>	<u>(110,926)</u>
Total stockholders' equity	<u>78,709</u>	<u>99,182</u>
Total liabilities and stockholders' equity	<u>\$ 92,216</u>	<u>\$ 118,532</u>

The accompanying notes are an integral part of these financial statements.

APPLIED GENETIC TECHNOLOGIES CORPORATION
STATEMENTS OF OPERATIONS

In thousands, except per share data	<u>Year Ended June 30,</u>	
	<u>2019</u>	<u>2018</u>
Revenue:		
Collaboration revenue	\$41,128	\$ 24,057
Grant revenue	564	129
Total revenue	<u>41,692</u>	<u>24,186</u>
Operating expenses:		
Research and development	33,183	32,181
General and administrative	12,859	14,389
Total operating expenses	<u>46,042</u>	<u>46,570</u>
Loss from operations	(4,350)	(22,384)
Other income/(expense):		
Investment income, net	2,009	1,301
Other income/(expense)	446	(125)
Total other income, net	<u>2,455</u>	<u>1,176</u>
Loss before provision for income taxes	(1,895)	(21,208)
Provision for income taxes	76	72
Loss before equity in net losses of affiliate	(1,971)	(21,280)
Equity in net losses of affiliate	(35)	(20)
Net Loss	<u>\$ (2,006)</u>	<u>\$ (21,300)</u>
Loss per share:		
Basic	\$ (0.11)	\$ (1.18)
Diluted	\$ (0.11)	\$ (1.18)
Weighted average shares outstanding:		
Basic	18,157	18,105
Diluted	18,157	18,105

The accompanying notes are an integral part of these financial statements.

APPLIED GENETIC TECHNOLOGIES CORPORATION
STATEMENTS OF STOCKHOLDERS' EQUITY

In thousands	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Outstanding Shares	Amount	Outstanding Shares	Amount			
Balance, June 30, 2017	18,088	\$ 18	—	\$ —	\$ 204,937	\$ (89,626)	\$ 115,329
Share-based compensation expense	—	—	—	—	5,193	—	5,193
Shares (purchased)/issued under employee plans	38	—	11	(49)	9	—	(40)
Net loss	—	—	—	—	—	(21,300)	(21,300)
Balance, June 30, 2018	<u>18,126</u>	<u>18</u>	<u>11</u>	<u>\$ (49)</u>	<u>\$ 210,139</u>	<u>\$ (110,926)</u>	<u>\$ 99,182</u>
Cumulative impact of adoption of ASC 606	—	—	—	—	—	(22,616)	(22,616)
Share-based compensation expense	—	—	—	—	4,029	—	4,029
Shares (purchased)/issued under employee plans	81	—	8	(36)	156	—	120
Net loss	—	—	—	—	—	(2,006)	(2,006)
Balance, June 30, 2019	<u>18,207</u>	<u>\$ 18</u>	<u>19</u>	<u>\$ (85)</u>	<u>\$ 214,324</u>	<u>\$ (135,548)</u>	<u>\$ 78,709</u>

The accompanying notes are an integral part of these financial statements.

APPLIED GENETIC TECHNOLOGIES CORPORATION
STATEMENTS OF CASH FLOWS

In thousands	Year Ended June 30	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (2,006)	\$ (21,300)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	4,029	5,193
Depreciation and amortization	1,273	1,175
Investment premium amortization/(discount accretion)	(790)	85
(Recovery)/provision for uncollectible accounts, net	(358)	375
Equity in net losses of affiliate	35	20
Loss on disposal of property, plant and equipment	—	1
Loss on disposal of intangible assets	—	126
Changes in operating assets and liabilities:		
Grants receivable	186	(36)
Prepaid and other assets	1,635	(1,903)
Accounts payable	327	(53)
Deferred revenues	(28,392)	(18,529)
Accrued and other liabilities	604	2,326
Net cash used in operating activities	(23,457)	(32,520)
Cash flows from investing activities:		
Purchase of property and equipment	(163)	(662)
Purchase of and capitalized costs related to intangible assets	(148)	(141)
Investment in Bionic Sight	—	—
Maturity of investments	94,119	100,900
Purchase of investments	(74,781)	(67,082)
Net cash provided by investing activities	19,027	33,015
Cash flows from financing activities:		
Proceeds from exercise of common stock options	156	9
Taxes paid related to equity awards	(36)	—
Payments made toward capital lease obligations	(52)	(43)
Deferred offering costs	—	(102)
Net cash provided by/(used in) financing activities	68	(136)
Net (decrease)/increase in cash and cash equivalents	(4,362)	359
Cash and cash equivalents, beginning of year	31,065	30,706
Cash and cash equivalents, end of year	\$ 26,703	\$ 31,065
Supplemental information:		
Cash paid during the year for income taxes	\$ —	\$ 617
Capital lease obligation related to the purchase of equipment	\$ —	\$ 240
Lease incentive obligation related to the purchase of leasehold improvements	\$ —	\$ 2,588
Costs related to future offering costs included in accounts payable and accrued liabilities	\$ —	\$ 163
Cost related to purchase of property and equipment included in accounts payable and accrued liabilities	\$ 124	\$ —
Cost related to purchase of intellectual property included in accounts payable	\$ 59	\$ —
Issuance of restricted stock for no consideration	\$ 36	\$ 49

The accompanying notes are an integral part of these financial statements.

APPLIED GENETIC TECHNOLOGIES CORPORATION
NOTES TO FINANCIAL STATEMENTS

1. Organization and Operations

Applied Genetic Technologies Corporation (the “Company” or “AGTC”) was incorporated as a Florida corporation on January 19, 1999 and reincorporated as a Delaware corporation on October 24, 2003. The Company is a clinical-stage biotechnology company that uses a proprietary gene therapy platform to develop transformational genetic therapies for patients suffering from rare and debilitating diseases.

In July 2015, the Company entered into a collaboration agreement (the “Collaboration Agreement”) with Biogen MA, Inc., a wholly owned subsidiary of Biogen Inc. (“Biogen”), pursuant to which the Company and Biogen collaborated to develop, seek regulatory approval for and commercialize gene therapy products to treat X-linked retinoschisis (“XLRs”), X-linked retinitis pigmentosa (“XLRP”), and discovery programs targeting three indications based on the Company’s adeno-associated virus vector technologies. The Collaboration Agreement became effective in August 2015. On December 7, 2018, the Company received notice from Biogen that it had elected to terminate the Collaboration Agreement, which became effective on March 8, 2019. The Collaboration Agreement and other transactions with Biogen are discussed further in Note 7 to these financial statements.

The Company has devoted substantially all of its efforts to research and development, including clinical trials. The Company has not completed the development of any products. The Company has generated revenue from collaboration agreements, sponsored research payments and grants, but has not generated product revenue to date and is subject to a number of risks similar to those of other early stage companies in the biotechnology industry, including dependence on key individuals, the difficulties inherent in the development of commercially viable products, the need to obtain additional capital necessary to fund the development of its products, development by the Company or its competitors of technological innovations, risks of failure of clinical studies, protection of proprietary technology, compliance with government regulations and ability to transition to large-scale production of products. As of June 30, 2019, the Company had an accumulated deficit of \$135.5 million. While the Company expects to continue to generate some revenue from partnering, the Company expects to incur losses for the foreseeable future. The Company has funded its operations to date primarily through public offerings of its common stock, private placements of its preferred stock, and collaborations. As of June 30, 2019, the Company had cash and cash equivalents and liquid investments of \$82.0 million.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and, in the opinion of management, include all adjustments necessary for a fair presentation of the Company’s financial position, results of operations, and cash flows for each period presented.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, we have viewed our operations and managed our business as one segment.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP and U.S. Securities and Exchange Commission (“SEC”), requires management to make estimates and assumptions that affect the reported amounts

[Table of Contents](#)

of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

Cash and cash equivalents

Cash consists of funds held in bank accounts. Cash equivalents consist of short-term, highly liquid investments with original maturities of 90 days or less at the time of purchase and generally include money market accounts.

Investments

The Company's investments consist of certificates of deposit and debt securities classified as held-to-maturity. Management determines the appropriate classification of debt securities at the time of purchase and reevaluates such designation as of each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity securities are stated at amortized cost, adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in investment income. Interest on securities classified as held-to-maturity is included in investment income.

The Company uses the specific identification method to determine the cost basis of securities sold.

Investments are considered to be impaired when a decline in fair value is judged to be other-than-temporary. The Company evaluates an investment for impairment by considering the length of time and extent to which market value has been less than cost or amortized cost, the financial condition and near-term prospects of the issuer as well as specific events or circumstances that may influence the operations of the issuer and the Company's intent to sell the security or the likelihood that it will be required to sell the security before recovery of the entire amortized cost. Once a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded to other income/(expense) and a new cost basis in the investment is established.

Concentrations of Credit Risk

The Company maintains its cash and cash equivalents and certificates of deposit with two financial institutions that are federally insured. Some of these financial instruments are in excess of federally insured limits and as a result, could potentially expose the Company to significant concentrations of credit risk. To date, the Company has not experienced any losses associated with this credit risk and continues to believe that this exposure is not significant. The Company invests its excess cash primarily in money market funds, certificates of deposit, and debt instruments of corporations and U.S. government agencies. These investments generally mature within a two-year period from their purchase date, in line with the Company's investment policy that seeks to maintain adequate liquidity and preserve capital.

Inventory

Purchases of clinical materials stored for master and working viral banks that remain at the sites in anticipation of their future use at that site are charged to expense when they are incurred. Since the Company can use each of the raw materials in only a single product, each raw material is deemed to have no future economic value independent of the development status of that single drug.

Fair value of financial instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 820, Fair Value Measurements and Disclosures

[Table of Contents](#)

(“ASC 820”), establishes a hierarchy of inputs used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are those that reflect the Company’s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of financial instruments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company’s own assumptions that are both significant to the fair value measurement and are unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Property and equipment

Property and equipment, consisting of laboratory equipment, furniture and fixtures, computer equipment and leasehold improvements, are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which are generally three to ten years. The weighted average useful life is 6.8 years. Leasehold improvements are stated at cost and are amortized over the shorter of the estimated useful lives of the assets or the lease term, including any renewal periods that are deemed to be reasonably assured. Repair and maintenance costs that do not improve service potential or extend an asset’s economic life are recorded as an expense when incurred.

Intangible assets

Intangible assets primarily include licenses and patents. The Company obtains licenses from third parties and capitalizes the costs related to exclusive licenses that have alternative future use in multiple potential programs. The Company also capitalizes costs related to filing, issuance, and prosecution of patents. The Company reviews its capitalized costs periodically to determine that such costs relate to patent applications that have future value and an alternative future use and writes off any costs associated with patents that are no longer being actively pursued or that have no future benefit.

Amortization expense is computed using the straight-line method over the estimated useful lives of the assets, which are generally eight to twenty years. The weighted average amortization period is 8.6 years. The Company amortizes in-licensed patents and patent applications from the date of the applicable license and internally developed patents and patent applications from the date of the initial application. Licenses and patents converted to research use only are immediately written off to expense.

Impairment of long-lived assets

The Company reviews its long-lived assets for impairment when impairment indicators are present. If impairment indicators exist, management determines whether impairment in value has occurred by comparing the estimated undiscounted cash flows from future operations with the carrying values of the assets. Management

[Table of Contents](#)

considers several indicators in assessing impairment, including trends and prospects, as well as the effects of obsolescence, demand, competition and other economic factors. No impairment charges were recorded for each of the fiscal years ended June 30, 2019 and 2018.

Revenue recognition

Effective July 1, 2018, the Company adopted the provisions of ASC 606, *Revenue from Contracts with Customers*, (“Topic 606”), using the modified retrospective transition method. Under this method, the Company recorded the cumulative effect of initially applying the new standard to all contracts in process as of the date of adoption. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards.

The adoption of the new revenue recognition guidance resulted in an increase of \$22.6 million in deferred revenue and accumulated deficit as of July 1, 2018. For the year ended June 30, 2019, revenue increased by \$25.4 million, net income increased by \$25.4 million and basic and diluted earnings per share increased by \$1.40 per share, respectively, based on revenue recognition under Topic 606 as compared to the Company’s prior revenue recognition methodology under ASC 605, *Revenue Recognition*. These changes were primarily caused by the differences in determining and allocating transaction price and recognizing revenue on a proportional performance basis under Topic 606.

Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of Topic 606, the Company performs the following five steps: (i) identification of the contract; (ii) determination of whether the promised goods or services are performance obligations; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

Performance obligations are promises to transfer distinct goods or services to the customer. Promised goods or services are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own or whether the required expertise is readily available.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include both fixed consideration or variable consideration. At the inception of an arrangement that includes variable consideration and at each reporting period, the Company evaluates the amount of potential payment and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected amount method to estimate the amount to be received based on which method better predicts the amount expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price. The Company will assess its revenue generating arrangements in order to determine whether a significant financing component exists and conclude that a significant financing component does not exist in any of its arrangements if: (a) the promised consideration approximates the cash selling price of the promised goods and services or any significant difference is due to factors other than financing; and (b) timing of payment approximates the transfer of goods and services and performance is over a relatively short period of time within the context of the entire term of the contract.

The Company’s contracts will often include development and regulatory milestone payments. At contract inception and at each reporting period, the Company evaluates whether the milestones are considered probable of

[Table of Contents](#)

being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the customer's control, such as regulatory approvals, are not included in the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment.

For arrangements that may include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of the Company's collaboration arrangements.

The Company allocates the transaction price based on the estimated standalone selling price of the underlying performance obligations or in the case of certain variable consideration to one or more performance obligations. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

For performance obligations consisting of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress at each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

The Company receives payments from its customers based on billing terms established in each contract. Such billings generally have 30-day payment terms. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the right to consideration is unconditional.

Collaboration revenue

To date, the Company's collaboration revenue has been generated from its collaboration arrangement with Biogen as further described in Note 7, "*Collaboration Agreements*".

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first

[Table of Contents](#)

determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606.

Income taxes

The Company uses the asset and liability method for accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

The Tax Cut and Jobs Act (the “Tax Act”) was enacted on December 22, 2017. The Tax Act contains several key provisions including, among other things, reducing the U.S. federal corporate tax rate from 35% to 21%. In addition, federal net operating losses (“NOLs”) will be carried forward indefinitely but will be subject to an 80% utilization against taxable income. For the year ended June 30, 2018, the Company followed the guidance in SEC Staff Accounting Bulletin 118 (SAB 118) which provides additional clarification regarding the application of ASC Topic 740 in situations where the Company does not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Act for the reporting period in which the Act was enacted. SAB 118 provides for a measurement period beginning in the reporting period that includes the Act’s enactment date and ending when the Company has obtained, prepared, and analyzed the information needed in order to complete the accounting requirements but in no circumstances should the measurement period extend beyond one year from the enactment date. The Company has enacted the reduction in tax rate effective January 1, 2018, which resulted in a decrease to the deferred tax asset and a decrease to the valuation allowance. For the year ended June 30, 2019, the Company has completed the analysis of the Tax Act with no material adjustments to its initial analysis.

For the fiscal year ended June 30, 2019, the Company recorded an income tax provision, as a result of uncertainties related to state income tax. For the fiscal year ended June 30, 2018, the Company recorded an income tax provision, related to the Company’s Federal alternative minimum tax credit and uncertainties related to state income taxes.

As required by U.S. GAAP, the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense. The Company is subject to examination of its income tax returns in the federal and state income tax jurisdictions in which it operates for the tax years ended June 30, 2015 through 2019.

The uncertain tax position liability for years ended June 30, 2019 and 2018, was \$2,035,000 and \$1,959,000, respectively.

Research and development expenses

Research and development costs include costs incurred in identifying, developing and testing product candidates and generally comprise compensation and related benefits and non-cash share-based compensation to research related employees; laboratory costs; animal and laboratory maintenance and supplies; rent; utilities; clinical and pre-clinical expenses; and payments for sponsored research, scientific and regulatory consulting fees and testing.

As part of the process of preparing financial statements, the Company is required to estimate its accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been

[Table of Contents](#)

performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice the Company monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known to it at that time. The significant estimates in the Company's accrued research and development expenses are related to expenses incurred with respect to academic research centers, contract research organizations ("CROs"), and other vendors in connection with research and development activities for which it has not yet been invoiced.

There may be instances in which the Company's service providers require advance payments at the inception of a contract or in which payments made to these vendors will exceed the level of services provided, resulting in a prepayment of the research and development expense. Such prepayments are charged to research and development expense as and when the service is provided or when a specific milestone outlined in the contract is reached.

Prepayments related to research and development activities were approximately \$0.7 million and \$1.0 million at June 30, 2019 and 2018, respectively, and are included within the prepaid and other current assets line item on the balance sheets.

Share-based compensation

The Company accounts for share-based awards issued to employees in accordance with ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718") and generally recognizes share-based compensation expense on a straight-line basis over the periods during which the employees are required to provide service in exchange for the award. In addition, the Company issues stock options and restricted shares of common stock to non-employees in exchange for consulting services and accounts for these in accordance with the provisions of ASC Subtopic 505-50, *Equity-Based Payments to Non-employees* ("ASC 505-50"). Under ASC 505-50, share-based awards to non-employees are subject to periodic fair value re-measurement over their vesting terms.

For purposes of calculating stock-based compensation, the Company estimates the fair value of stock options using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the Company's stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected volatility is primarily based on the historical volatility of peer company data while the expected life of the stock options is based on historical and other economic data trended into the future. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of the Company's stock options. The dividend yield assumption is based on the Company's history and expectation of no dividend payouts. If factors change and the Company employs different assumptions, stock-based compensation expense may differ significantly from what has been recorded in the past. If there is a difference between the assumptions used in determining stock-based compensation expense and the actual factors which become known over time, specifically with respect to anticipated forfeitures, the Company may change the input factors used in determining stock-based compensation costs for future grants. These changes, if any, may materially impact the Company's results of operations in the period such changes are made.

Net loss per share

Basic net loss per share is calculated by dividing net loss by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculations, stock options are considered to be common stock equivalents if they are dilutive. The dilutive impact of stock options for the years ended June 30, 2019 and 2018 was 0.2 million.

[Table of Contents](#)

The dilutive impact of stock options has been excluded from the calculation of diluted net loss per share for the year ended June 30, 2019 and 2018 as their effect would be anti-dilutive. Therefore, for the years ended June 30, 2019 and 2018 basic and diluted net loss per share were the same.

Comprehensive loss

Comprehensive loss consists of net loss and changes in equity during a period from transactions and other equity and circumstances generated from non-owner sources. The Company's net loss equals comprehensive loss for all periods presented.

New Accounting Pronouncements

Adopted in the current period

Revenue recognition

In May 2014, Topic 606, replaced the existing accounting standards for revenue recognition with a single comprehensive five-step model. The core principle is to recognize revenue upon the transfer of goods or services to customers at an amount that reflects the consideration expected to be received. It also requires enhanced disclosures about revenue, provides guidance for transactions that were not previously addressed comprehensively, and improves guidance for multiple-element arrangements. The guidance was effective for public companies for annual periods beginning after December 15, 2017 as well as interim periods within those annual periods using either the full retrospective approach or modified retrospective approach. The Company adopted the new standard effective July 1, 2018 using the modified retrospective approach. Refer to Note 7 for the impact of adoption.

Share-Based Compensation

In May 2017, the FASB issued Accounting Standards Update ("ASU") No. 2017-09, Scope of Modification Accounting, which amends ASC Topic 718, Compensation—Stock Compensation. The standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The amendment is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years and early adoption is permitted. The Company has adopted this standard in the first quarter of fiscal 2019 and it did not have a material effect on its financial statements.

Financial Instrument Accounting

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The new standard amends certain aspects of accounting and disclosure requirements of financial instruments, including the requirement that equity investments with readily determinable fair values be measured at fair value with changes in fair value recognized in the results of operations. The new standard was effective July 1, 2018. The Company adopted ASU No. 2016-01 in the first quarter of 2019. The adoption of the new standard did not have a material impact on the Company's financial position and results of operations.

To be adopted in future periods

Leases

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which supersedes FASB ASC Topic 840, Leases (Topic 840) and provides principles for the recognition, measurement, presentation and disclosure of

Table of Contents

leases for both lessees and lessors. The new accounting guidance will require the recognition of all long-term lease assets and lease liabilities by lessees and sets forth new disclosure requirements for those lease assets and liabilities. The standard requires lessees to recognize right-of-use assets and lease liabilities on the balance sheet using a modified retrospective approach at the beginning of the earliest comparative period in the financial statements. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. The FASB subsequently issued several ASUs amending the new standard. This standard will be effective for the Company on July 1, 2019. Early adoption is permitted. The Company is currently evaluating the potential impact on its financial position and results of operations of adopting this guidance. The Company is in the process of finalizing the impact of adoption of the ASU on its financial statements, and it has determined that the most significant change will be related to the recognition of right-of-use assets and lease liabilities on the Company's balance sheet.

Financial Instruments—Credit Losses

In June 2016, the FASB issued ASUNo. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The new standard requires financial assets measured at amortized cost basis to be presented at the net amount expected to be collected and separately measure an allowance for credit losses that is deducted from the amortized cost basis of the financial assets. This standard will be effective for the Company on July 1, 2020. Early adoption is permitted. The adoption of this guidance is not expected to have a significant impact on the Company's financial statements.

Share-Based Compensation

In June 2018, the FASB issued ASUNo. 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The new standard aligns the measurement and classification guidance for share-based payments to nonemployees with the guidance for share-based payments to employees, with certain exceptions. Under the guidance, the measurement of equity-classified nonemployee awards will be fixed at the grant date, which may lower their cost and reduce volatility in the income statement. The standard will be effective for the Company on July 1, 2020. Early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of this standard on its financial statements.

Fair Value Measurement

In August 2018, the FASB issued ASUNo. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement. The new standard eliminates, adds and modifies certain disclosure requirements for fair value measurement as part of its disclosure framework project. The amount and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy will no longer be required to be disclosed, but public companies will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. This standard will be effective for the Company on July 1, 2020. Early adoption is permitted. The adoption of this guidance is not expected to have a significant impact on the Company's financial statements.

Collaborative Arrangements

In November 2018, the FASB issued ASUNo. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. The new standard clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. It precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The guidance amends ASC 808 to refer to the unit-of-account guidance in ASC 606 and requires it to be used only when

Table of Contents

assessing whether a transaction is in the scope of ASC 606. This standard will be effective for the Company on July 1, 2021. Early adoption is permitted. The adoption of this guidance is not expected to have a significant impact on the Company's financial statements.

3. Investments

Cash in excess of our immediate requirements is invested in accordance with the Company's investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

The net carrying amounts of the Company's investments by category are as follows:

In thousands	As of June 30, 2019	As of June 30, 2018
Certificates of deposit	\$ —	\$ 2,106
Debt securities—held-to-maturity (due in one year or less)	55,292	71,734
Total investments	<u>\$ 55,292</u>	<u>\$ 73,840</u>

A summary of the Company's debt investment securities classified asheld-to-maturity is as follows:

In thousands	June 30, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury Securities	<u>\$ 55,292</u>	<u>\$ 78</u>	<u>\$ —</u>	<u>\$ 55,370</u>
Total investments	<u>\$ 55,292</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 55,370</u>

In thousands	June 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury Securities	<u>\$ 69,731</u>	<u>\$ —</u>	<u>\$ (60)</u>	<u>\$ 69,671</u>
Corporate obligations	<u>2,003</u>	<u>—</u>	<u>(1)</u>	<u>2,002</u>
Total investments	<u>\$ 71,734</u>	<u>\$ —</u>	<u>\$ (61)</u>	<u>\$ 71,673</u>

The Company believes that the unrealized losses disclosed above were primarily driven by interest rate changes rather than by unfavorable changes in the credit ratings associated with these securities and as a result, the Company continues to expect to collect the principal and interest due on its debt securities that have an amortized cost in excess of fair value. At each reporting period, the Company evaluates securities for impairment when the fair value of the investment is less than its amortized cost. The Company evaluated the underlying credit quality and credit ratings of the issuers, noting neither a significant deterioration since purchase nor other factors leading to other-than-temporary impairment.

4. Fair Value Measurements

Certain assets and liabilities are measured at fair value in the Company's financial statements or have fair values disclosed in the notes to the financial statements. These assets and liabilities are classified into one of three levels of a hierarchy defined by U.S. GAAP. The Company's assessment of the significance of a particular item to the fair value measurement in its entirety requires judgment, including the consideration of inputs specific to the asset or liability.

Table of Contents

The following methods and assumptions were used to estimate the fair value and determine the fair value hierarchy classification of each class of financial instrument included in the table below:

Cash and Cash Equivalents. The carrying value of cash and cash equivalents approximates fair value as maturities are less than three months.

Certificates of Deposit. The Company's certificates of deposit are placed through an account registry service. The fair value measurement of the Company's certificates of deposit is considered Level 2 of the fair value hierarchy as the inputs are based on quoted prices for identical assets in markets that are not active. The carrying amounts of the Company's certificates of deposit reported in the balance sheets approximate fair value.

Debt securities—held-to-maturity. The Company's investments in debt securities classified as held-to-maturity generally include U.S. Treasury Securities, government agency obligations and corporate obligations. U.S. Treasury Securities are valued using quoted market prices. Valuation adjustments are not applied. Accordingly, U.S. Treasury Securities are considered Level 1 of the fair value hierarchy. The fair values of U.S. government agency obligations and corporate obligations are generally determined using recently executed transactions, broker quotes, market price quotations where these are available or other observable market inputs for the same or similar securities. As such, the Company classifies its investments in U.S. government agency obligations and corporate obligations within Level 2 of the hierarchy. The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis.

In thousands	(Level 1)	(Level 2)	(Level 3)	Total Fair Value
June 30, 2019				
Cash and cash equivalents	\$ 26,703	\$ —	\$ —	\$ 26,703
Held-to-maturity investments:				
U.S. Treasury Securities	55,370	—	—	55,370
Total assets	<u>\$ 82,073</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 82,073</u>
June 30, 2018				
Cash and cash equivalents	\$ 31,065	\$ —	\$ —	\$ 31,065
Certificates of deposit	—	2,100	—	2,100
Held-to-maturity investments:				
Corporate obligations	—	2,002	—	2,002
U.S. Treasury Securities	69,671	—	—	69,671
Total assets	<u>\$100,736</u>	<u>\$ 4,102</u>	<u>\$ —</u>	<u>\$104,838</u>

5. Property and Equipment, Net

Property and equipment consist of the following:

In thousands	June 30,	
	2019	2018
Laboratory equipment	\$ 2,938	\$ 2,929
Equipment construction in progress	206	—
Leasehold improvements	3,851	3,835
Office equipment	1,074	1,077
Property and equipment, gross	8,069	7,841
Less: Accumulated depreciation	(3,639)	(2,587)
Property and equipment, net	<u>\$ 4,430</u>	<u>\$ 5,254</u>

[Table of Contents](#)

Depreciation expense of \$1.1 million and \$0.9 million was recorded for fiscal years ended June 30, 2019 and 2018, respectively.

6. Intangible Assets, Net

Intangible assets subject to amortization consist of the following:

In thousands	June 30, 2019		
	Cost	Accumulated Amortization	Net of Accumulated Amortization
Patents	\$2,392	\$ (1,499)	\$ 893
Licenses	289	(199)	90
Other	49	(19)	30
Intangible assets, net	<u>\$2,730</u>	<u>\$ (1,717)</u>	<u>\$ 1,013</u>

In thousands	June 30, 2018		
	Cost	Accumulated Amortization	Net of Accumulated Amortization
Patents	\$2,193	\$ (1,357)	\$ 836
Licenses	289	(182)	107
Other	54	(29)	25
Intangible assets, net	<u>\$2,536</u>	<u>\$ (1,568)</u>	<u>\$ 968</u>

Amortization expense related to intangible assets for the years ended June 30, 2019 and 2018 was \$163,000 and \$266,000, respectively.

Estimated amortization expense (in thousands) for the next five years and thereafter is as follows:

<u>Year Ending June 30,</u>	<u>Amount</u>
2020	\$ 160
2021	160
2022	143
2023	60
2024	27
Thereafter	440
	<u>\$ 990</u>

7. Collaboration Agreements

Biogen

On July 1, 2015, the Company entered into a Collaboration Agreement with Biogen, pursuant to which the Company and Biogen collaborated to develop, seek regulatory approval for and commercialize gene therapy products to treat XLRS, XLRP, and discovery programs targeting three indications based on the Company's adeno-associated virus vector technologies. Effective March 8, 2019, Biogen terminated the Collaboration Agreement.

Under the Collaboration Agreement, the Company granted to Biogen with respect to the XLRS and XLRP programs, and upon exercise of the option for the applicable discovery program, an exclusive, royalty-bearing

[Table of Contents](#)

license, with the right to grant sublicenses, to use adeno-associated virus vector technology and other technology controlled by the Company for the licensed products or discovery programs developed under the Collaboration Agreement. Biogen and the Company also granted each other worldwide licenses, with the right to grant sublicenses, of their respective interests in other intellectual property developed under the collaboration outside the licensed products or discovery programs. Biogen pre-funded the Company to conduct all development activities through the completion of a first in human trial for the XLRS program and all development activities through the date of Investigational New Drug Application (“IND”) and the completion of a natural history study for the XLRP program. In addition, Biogen pre-funded the Company to conduct discovery, research and development activities for additional drug candidates through the stage of clinical candidate designation for discovery programs targeting three indications (of which one indication has two development plans at contract inception), after which, Biogen had an option to continue to develop, seek regulatory approval for and commercialize the designated clinical candidate. The pre-funded research and development activities for each program are referred to as “Pre-Funded Activities”.

In February 2016, the Company announced Biogen’s selection of adrenoleukodystrophy as the non-ophthalmic indication of the discovery programs. Under the terms of the Collaboration Agreement, the Company, in part through its participation in joint committees with Biogen, would participate in overseeing the development and commercialization of these specific programs.

Pursuant to the Manufacturing Agreement, Biogen had an option to receive a manufacturing license for up to six genes for a fixed fee per gene elected. If exercised, the Company would have been eligible to receive certain event milestones and royalties.

Under the Collaboration Agreement, the Company was paid an upfront nonrefundable fee of \$94.0 million of which \$58.4 million was contractually described as relating to the Pre-Funded Activities (“Pre-Funded Amounts”) and \$35.6 million was contractually described as relating to the access of licenses. In addition, under the terms of the Equity Agreement, Biogen purchased 1,453,957 shares of the Company’s common stock at a price of \$20.63 per share, for an aggregate cash purchase price of \$30.0 million of which \$10.8 million was considered to be allocated consideration as part of the Collaboration Agreement. The shares issued to Biogen represented approximately 8.1% of the Company’s outstanding common stock on a post-issuance basis, calculated on the number of shares that were outstanding at June 30, 2015, and constituted restricted securities that could not be resold by Biogen other than in a transaction registered under, or pursuant to an exemption from the registration requirements of, the Securities Act of 1933, as amended.

The Company was also eligible to receive total payments of up to \$472.5 million based on the successful achievement of future milestones under its XLRS and XLRP programs. For XLRS, the Company was eligible to receive up to: (i) \$45.0 million in milestone payments based upon the successful achievement of clinical milestones (relating to dosing in specified trials), (ii) \$155.0 million in milestone payments based upon the achievement of regulatory approvals and first commercial sale in specified territories and (iii) \$65.0 million in milestone payments based upon the achievement of worldwide sales targets. For the XLRS program, the Company had an option to share development costs and profits after the initial clinical trial data were available instead of receiving milestone payments. For XLRP, the Company was eligible to receive up to: (i) \$42.5 million in milestone payments based upon successful achievement of clinical milestones (relating to dosing in specified trials), (ii) \$102.5 million in milestone payments based upon the achievement of regulatory approvals and first commercial sale in specified territories and (iii) \$62.5 million in milestone payments based upon the achievement of worldwide sales targets. For the XLRP program, the Company had an option to share development costs and profits after the initial clinical trial data were available instead of receiving milestone payments. In addition, the Company was eligible to receive payments of up to \$592.5 million based on the exercise of the option for and the successful achievement of future milestones under its discovery programs. Each discovery program was categorized as Category A, Category B or Category C depending on the nature of the indication it sought to address. For Category A, the Company was eligible to receive payments of up to: (i) \$20.0 million based upon the successful achievement of clinical milestones (relating to dosing in specified trials) and (ii) \$70.0 million in

[Table of Contents](#)

milestone payments based upon the achievement of regulatory approvals and first commercial sale in specified territories. For Category B, the Company was eligible to receive payments of up to: (i) \$27.5 million based upon the successful achievement of clinical milestones (relating to dosing in specified trials) and (ii) \$105.0 million in milestone payments based upon the achievement of regulatory approvals and first commercial sale in specified territories. For Category C, the Company was eligible to receive payments of up to: (i) \$40.0 million based upon the successful achievement of clinical milestones (relating to dosing in specified trials) and (ii) \$140.0 million in milestone payments based upon the achievement of regulatory approvals and first commercial sale in specified territories. Under certain limited circumstances, if there were discovery products from more than one discovery program in any of Category A, Category B or Category C, then the milestone payments under the applicable category would have been payable for the applicable discovery product from each such discovery program to achieve the specified milestones.

Prior to 2018, the Company received a \$5.0 million milestone payment related to initial dosing of a XLRS patient. In April 2018, the Company triggered a \$2.5 million milestone payment related to the initial dosing of a XLRP patient. In July 2018, the Company triggered a \$10.0 million milestone payment related to the treatment of a first patient of second cohort in a Phase 1/2 Clinical XLRP Study.

While the Company recognized additional revenue as it continued to perform under the Collaboration Agreement prior to March 8, 2019, the termination date of the agreement, the Company will not receive any milestone-based or royalty payments under the Collaboration Agreement after its termination.

Accounting Analysis

For the periods prior to July 1, 2018, the Company applied the provisions of ASC 605 in accounting for this arrangement.

Under ASC 605 and Topic 606, the Company has concluded that the Collaboration Agreement, the Manufacturing Agreement and the Equity Agreement should be accounted for as one arrangement as the agreements were with the same party and were negotiated and executed contemporaneously.

The performance obligations and the allocated transaction price as of the date of initial application of Topic 606 are as follows:

<u>In thousands</u>	<u>Allocated Transaction Price</u>
XLRS License and Pre-Funded Activities	\$ 52,060
XLRP License and Pre-Funded Activities	43,570
Pre-Funded Activities associated with the Discovery Programs	16,700
	<u>\$ 112,330</u>

The Pre-Funded Activities associated with the Discovery Programs amount is comprised of four distinct performance obligations based on the separate development plans for discovery candidates at contract inception. The Company concluded that the delivered license was not distinct from the Pre-Funded Activities as Biogen cannot obtain the benefit of the license without the related services. Further, each of the license and related Pre-Funded Activities performance obligation is considered a distinct performance obligation as each development plan is pursued independent of every other development plan.

The Company concluded that Post-Funded Activities represent customer options that are not material rights as any services requested by Biogen and provided by the Company are reimbursed at a rate that reflects the estimated standalone selling price for the services. As such, the Company will recognize revenue related to Post-Funded Activities as the services are provided. Through the date of adoption of ASC 606, the Company recognized revenue of \$4.7 million for Post-Funded Activities. The Company recorded revenue of \$2.7 million for the year ended June 30, 2019 related to Post-Funded Activities.

[Table of Contents](#)

The Company concluded that the option to receive i) commercial licenses for the Discovery Programs that achieve clinical candidate designation, as defined in the Collaboration Agreement and ii) manufacturing licenses for up to six genes pursuant to the Manufacturing Agreement represent customer options that are not material rights as the exercise price for such options reflects the estimated standalone selling price for such option. As such, the Company would account for such option if and when the options are exercised.

As of the date of the initial application of Topic 606, the total transaction price for the Biogen Agreement was \$112.3 million which included a \$5.0 million milestone payment for initiation of dosing of XLRS and a \$2.5 million milestone payment for initiation of dosing of XLRP. The Company used the most-likely method to determine the amount of variable consideration in the Biogen Agreement. The Company believes that any estimated amount of variable consideration related to clinical and regulatory milestone payments should be fully constrained as the achievement of such milestones was highly susceptible to factors outside of the Company's control. The Company determined that the commercial milestones and sales-based royalties would be recognized when the related sales occurred as they were deemed to relate predominately to the license granted and therefore were also excluded from the transaction price.

In the quarter ended September 30, 2018, the Company received a \$10.0 million milestone payment related to XLRP which increased the transaction price. Based on an understanding between the parties in the quarter ended September 30, 2018, the Company also reallocated \$1.1 million of Pre-Funded amounts to cover Post-Funded Activities which resulted in a decrease to the transaction price and deferred revenue of \$1.1 million in the quarter ended September 30, 2018. Additionally, the Company reallocated \$1.8 million of variable consideration between Pre-Funded Activities associated with Discovery Programs performance obligations based on changes to the underlying development plans of the product candidates.

The reallocation between Discovery Programs generated an insignificant cumulative catch up adjustment to revenue in the quarter ended September 30, 2018. The cumulative catch-up adjustment to revenue that relates to changes or reallocations of the transaction price are further discussed in the *Summary of Contract Assets and Liabilities* section below.

The transaction price was allocated to the performance obligations based on the relative estimated standalone selling price of each performance obligation or, in the case of certain variable consideration, to one or more performance obligations. The estimated standalone selling prices for performance obligations, that include a license and Pre-Funded Activities, were developed using the estimated selling price of the license and an estimate of the overall effort to perform the Pre-Funded Activities. The estimated selling price of the licenses were determined using a discounted cash flow valuation utilizing forecasted revenues and costs for the Company's product candidate licenses.

The Company recognized revenue related to the performance obligations which included a license and Pre-Funded Activities over the estimated period of the research and development services using a proportional performance model. The Company measured proportional performance based on the costs incurred relative to the total costs expected to be incurred to satisfy the performance obligation. Management believes that recognizing revenue on a proportional performance basis based on costs incurred faithfully depicts the transfer of goods and services to the customer because the customer consumed the Company's services as such services were performed. The Company accounted for the termination of the Collaboration Agreement upon the effective date of the termination and updated its total costs incurred to satisfy the performance obligations as of June 30, 2019; including any impact of the termination.

For the years ended June 30, 2019 and 2018, the Company recorded revenue of \$41.1 million and \$24.1 million, respectively, from its collaboration with Biogen. The Company had no accounts receivable balances as of June 30, 2019 and had \$1.7 million as of June 30, 2018, related to the Biogen Agreement. As a result of the termination of the Collaboration Agreement with Biogen effective March 8, 2019, the Company recognized the remaining deferred revenue balance as of the termination date. Therefore, at June 30, 2019, the Company had no

Table of Contents

deferred revenue related to the Biogen Agreement. For further details regarding deferred revenue, refer to Summary of Contract Assets and Liabilities section.

The Company's revenue is comprised of the following related to the Biogen Agreement:

In thousands	June 30, 2019	June 30, 2018
Collaboration revenue		
Licenses and related services	\$ 27,000	\$ 18,529
Development services	2,736	3,028
Milestone revenue	11,392	2,500
Total collaboration revenue	<u>\$ 41,128</u>	<u>\$ 24,057</u>

License and related services revenue is comprised of revenue related to the Company's completion of performance obligations that contain the delivery of licenses and Pre-Funded Activities. Development services revenue relates to the delivery of Post Funded Activities. Milestone revenue relates to the portion of milestone payments received that are recognized as revenue based on the proportional performance of the underlying performance obligation and revenue recognized due to the termination of the Collaboration Agreement.

Summary of Contract Assets and Liabilities

The following table presents changes in the balances of our contract assets and liabilities during the year ended June 30, 2019:

In thousands	June 30, 2018	Additions	Deductions	June 30, 2019
Contract assets	\$ —	\$ —	\$ —	\$ —
Contract liabilities:				
Deferred revenue	\$ 29,521	\$ 10,000	\$ 39,521	\$ —

The Company recorded an entry to increase deferred revenue and accumulated deficit for \$22.6 million as of July 1, 2018 related to the adoption of Topic 606. The impact of the adoption of Topic 606 is reflected within the beginning of period balance. Additions for the year ended June 30, 2019 include the \$10 million milestone payment received associated with the XLRP program. For the year ended June 30, 2019, the Company recognized revenue of \$29.5 million related to deferred revenue that existed as of June 30, 2018.

Bionic Sight

On February 2, 2017, the Company entered into a strategic research and development collaboration agreement with Bionic Sight, LLC ("Bionic Sight"), to develop therapies for patients with visual deficits and blindness due to retinal disease. Through the AGTC-Bionic Sight collaboration, the companies seek to develop a new optogenetic therapy that leverages AGTC's deep experience in gene therapy and ophthalmology and Bionic Sight's innovative neuro-prosthetic device and algorithm for retinal coding.

Under the agreement, AGTC made an initial \$2.0 million payment to Bionic Sight for an equity interest in that company. This initial investment represents an approximate 5% equity interest in Bionic Sight. In addition to the initial investment, AGTC is contributing ongoing research and development support costs through additional payments and other in-kind contributions (AGTC Ongoing R&D Support). The AGTC Ongoing R&D Support payments and in-kind contributions are made over time and may continue up to the date Bionic Sight receives both IND clearance from the FDA and receipt of written approval from an internal review board to conduct clinical trials from at least one clinical site for that product candidate (the "IND Trigger"). As of June 30, 2019, the Company had incurred approximately \$2.0 million in ongoing research and development support costs and in-kind contributions.

[Table of Contents](#)

If the IND Trigger is attained, AGTC will (i) receive additional equity, based on the valuation in place at the beginning of the agreement, for the AGTC Ongoing R&D Support payments and in-kind contributions, and (ii) will be obligated to purchase additional equity in Bionic Sight for \$4.0 million, at a pre-determined valuation. The Company has concluded that the AGTC Ongoing R&D Support is within the scope of ASC 606 *Revenue from Contracts with Customers*, as the services rendered represent a distinct service delivered to a counterparty that meets the definition of a customer. The Company considers these services to represent one combined performance obligation. Given that the consideration that the Company is entitled to is contingent upon achievement of the IND Trigger, the consideration is determined to be variable. The Company believes that the amount of variable consideration related to the achievement of the IND Trigger should be fully constrained as the achievement of this event is highly susceptible to factors outside of the Company's control. The Company evaluates the amount of potential receipt of the variable consideration and the likelihood that the consideration will be received. Utilizing the most likely amount method, and if it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price. The variable consideration related to Bionic Sight agreement has been fully constrained since the inception of the agreement and no amounts have been recognized as revenue to date. With regard to the obligation to purchase additional equity in Bionic Sight for \$4.0 million, the Company concluded that this represents a forward contract to be accounted for within the scope of ASC 321, *Investments—Equity Securities*. The Company assessed the fair value of this forward contract at inception of the Bionic Sight agreement and determined the value to be de minimis. As the forward contract does not have a readily determinable fair value, the Company has elected to use the measurement alternative for the subsequent measurement of this instrument. Under the measurement alternative, the forward contract will be remeasured to fair value when observable transactions involving the underlying equity securities or impairment of those securities occur. No such observable transactions or impairment involving the underlying equity securities have occurred since the inception of the arrangement.

Due to the uncertainty of achieving the IND Trigger, the Company is expensing the AGTC Ongoing R&D Support payments and in-kind contributions made under the collaboration agreement. Such amounts are included as a component of research and development expenses in the Company's financial statements.

The Company recorded its initial \$2.0 million investment in Bionic Sight using the equity method of accounting for investments, which is recorded as its own line item on the Company's balance sheet. During fiscal 2019, the Company recorded a reduction of its investment in Bionic Sight of \$35,000 and an investment loss on the statement of operations to reflect its equity interest in the net loss of this affiliate. As of June 30, 2019, the amount of the Company's underlying equity in net assets of Bionic Sight is not representative of the amount at which the investment is carried due to retained losses experienced by Bionic Sight prior to the Company's investment.

The ongoing research and development costs and contributions will be recorded as a periodic cost until such time when or if the IND Trigger is achieved.

The collaboration agreement grants to AGTC, subject to achievement by Bionic Sight of certain development milestones, an option to exclusively negotiate for a limited period of time to acquire (i) a majority equity interest in Bionic Sight, (ii) the Bionic Sight assets to which the collaboration agreement relates, or (iii) an exclusive license with respect to the product to which the collaboration agreement relates.

8. Share-based Compensation Plans

The Company uses stock options and awards of restricted stock to provide long-term incentives for its employees, non-employee directors and certain consultants. The Company has two equity compensation plans under which awards are currently authorized for issuance, the 2013 Employee Stock Purchase Plan and the 2013 Equity and Incentive Plan. No awards have been issued to date under the 2013 Employee Stock Purchase Plan and all of the 128,571 shares previously authorized under this plan remain available for issuance. As of June 30, 2019, the total number of shares available for issuance under the 2013 Equity and Incentive Plan was 1,244,754.

Table of Contents

The Compensation Committee of the Board of Directors, as the plan administrator, has the authority to select the individuals to whom share-based awards are granted and to determine the terms of each award, including (i) the number of shares of common stock subject to a stock option or restricted share award; (ii) the date on which the stock option becomes exercisable; (iii) the option exercise price, which, in the case of incentive stock options, must be at least 100% (110% in the case of incentive stock options granted to a stockholder owning in excess of 10% of the Company's stock) of the fair market value of the common stock as of the date of grant; (iv) the vesting term; and (v) the duration of the option (which, in the case of incentive stock options, may not exceed ten years). Employee options typically vest over a three- or four-year period.

A summary of the stock option activity is as follows:

(In thousands, except per share amounts)	June 30, 2019		June 30, 2018	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding , beginning of year	3,107	\$ 10.93	2,716	\$ 12.95
Granted	1,172	4.5	914	4.72
Exercised	(65)	2.4	(18)	0.35
Forfeited	(317)	7.2	(415)	9.86
Expired	(312)	12.4	(90)	15.92
Outstanding , end of year	<u>3,585</u>	<u>\$ 9.19</u>	<u>3,107</u>	<u>\$ 10.93</u>
Exercisable , end of year	<u>2,167</u>		<u>1,900</u>	
Weighted average fair value of options granted during the year		<u>\$ 2.89</u>		<u>\$ 3.37</u>

For the year ended June 30, 2019, the Company granted 24,000 restricted stock awards to employees with weighted average exercise price of \$4.54, which vested on the grant date. Therefore, the weighted average exercise price for the granted stock awards and weighted average exercise price for vested stock awards is the same, and no restricted stock awards were outstanding as of June 30, 2019.

The intrinsic value of options exercised during the years ended June 30, 2019 and 2018 was \$0.2 million and \$0.1 million, respectively. The total fair value of options that vested during the fiscal years ended June 30, 2019 and 2018 was \$3.9 million and \$5.1 million, respectively.

The following table summarizes information about stock options exercisable, and vested and expected to vest as of June 30, 2019:

(In thousands, except per share amounts)	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Contractual Life (in years)
Vested and expected to vest	3,447	\$ 9.35	\$ 518	7.07
Exercisable	2,167	\$ 11.75	\$ 505	6.02

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that were in the money as of June 30, 2019.

In accounting for stock options to non-employees, the fair value of services related to the options granted are generally recorded as an expense as these services are provided to the Company over the relating service periods. The Company re-measures any non-vested, non-employee options to fair value at the end of each reporting period using the Black-Scholes pricing model.

Share-based compensation expense related to stock options awarded to employees, non-employee directors and consultants amounted to \$3.9 million and \$5.0 million for the fiscal years ended June 30, 2019 and 2018, respectively.

Table of Contents

Share-based compensation expense related to restricted shares of common stock awarded to employees and consultants amounted to \$113,090 and \$145,600 for the fiscal years ended June 30, 2019 and 2018, respectively.

Total share-based expense associated with stock options and restricted shares of common stock was allocated as follows:

In thousands	June 30, 2019	June 30, 2018
General and administrative	\$ 2,134	\$ 2,821
Research and development	1,895	2,372
	<u>\$ 4,029</u>	<u>\$ 5,193</u>

The fair value of each option granted is estimated on the grant date using the Black-Scholes stock option pricing model. The following assumptions were made in estimating fair value:

Assumption	June 30, 2019	June 30, 2018
Dividend yield	0.00%	0.00%
Expected term	6.00 to 6.25 years	6.00 to 6.50 years
Risk-free interest rate	1.82% to 3.11%	1.83% to 2.87%
Expected volatility	69.22%	83.53%

The dividend yield is based upon the assumption that the Company will not declare a dividend over the life of the options. Since adopting ASC 718, the Company has been unable to use historical employee exercise and option expiration data to estimate the expected term assumption for the Black-Scholes grant-date valuation. The Company therefore has utilized the "simplified" method, as prescribed by the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment*, to estimate on a formula basis the expected term of our stock options considered to have "plain vanilla" characteristics. The risk-free interest rate is based on the U.S. Treasury yield curve on the date of valuation. For the year ended June 30, 2019, the expected volatility is based on the historical volatility of the company stock price. For the year ended June 30, 2018 the expected volatility was primarily based on the historical volatility of peer company data. If the Company had used peer company data for the year ended June 30, 2019, share-based compensation expense for the reporting period would have differed by an insignificant amount. Forfeitures are estimated at the time of the grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Share-based compensation expense recognized in the statements of operations for the fiscal years ended June 30, 2019 and 2018 does not reflect tax related effects on stock-based compensation given the Company's historical and anticipated operating losses and offsetting changes in its valuation allowance that fully reserves against potential deferred tax assets.

Unrecognized compensation expense related to non-vested employee stock options amounted to \$4.5 million as of June 30, 2019. Such compensation expense is expected to be recognized over a weighted-average period of 2.54 years.

9. Commitments and Contingencies

Operating Leases

Alachua, Florida

The Company's corporate headquarters are located in Alachua, Florida. In January 2016, the Company moved into a new combined-use facility consisting of approximately 21,500 square feet of laboratory and office space. The initial lease term for this facility is 12 years and the Company has options to extend the term of the lease for three additional five-year periods. The Company's prior leased facilities encompassed approximately 7,000 square feet of office and laboratory space. The operating leases associated with the prior facilities expired in December 2015.

[Table of Contents](#)

Cambridge, Massachusetts

In August 2015, the Company entered into a two-year lease to occupy approximately 3,000 square feet of office and laboratory space in Cambridge, Massachusetts. In July 2017, the Company entered into a new lease to increase our office and laboratory space in Cambridge by approximately 5,000 square feet to a total of approximately 8,000 square feet and extend the term of the lease for an additional seven years, with an option to further extend the lease for one additional three-year term. This additional facility primarily focuses on business development, pharmacology, clinical operations and basic research and development.

For the fiscal years ended June 30, 2019 and, 2018, rent expense under these operating leases amounted to \$1,109,000, and \$909,000, respectively. Future annual minimum lease payments (in thousands) under these non-cancelable operating leases are as follows:

<u>Year Ending June 30,</u>	<u>Amount</u>
2020	\$ 1,353
2021	1,376
2022	1,400
2023	1,425
2024	1,450
Thereafter	2,638
	<u>\$ 9,642</u>

License and Other Agreements

Under various agreements, the Company will be required to pay royalties and milestone payments upon the successful development and commercialization of products. The Company has entered into funding agreements with various not-for-profit organizations. The Company may become obligated to pay royalties on net product sales of any collaboration product that it successfully develops and subsequently commercializes or, if it out-licenses rights to a collaboration product, a specified percentage of certain payments it receives from its licensee. The Company is not obligated to make such payments unless and until annual sales of a collaboration product exceed a designated threshold. The Company's obligation to make such payments would end upon its payment of a specified amount.

The Company is also party to various agreements entered into in the ordinary course of its business, principally relating to licensed technology. The Company had seven license agreements with six different entities, including four with the University of Florida Research Foundation. The Company is responsible for all costs related to preparation, filing, issuance, prosecution and maintenance of the underlying patents covered in the license agreements. The Company is required to pay minimum annual royalty and license maintenance for all licenses until such time when the license is terminated by either expiration of underlying patents or voluntary termination by either party per the agreement.

These license agreements also require future payments related to milestones or royalties on future sales of specified products. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory and commercial milestones. There is uncertainty regarding the various activities and outcomes needed to reach these milestones, and they may not be achieved. The Company may terminate its license agreements with zero to ninety days written notice depending upon the terms of each specific agreement.

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners or customers, in

[Table of Contents](#)

connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. From time to time, the Company may be involved in claims and legal actions that arise in the normal course of business. Management has no reason to believe that the outcome of any such legal actions would have a significant adverse effect on the Company's financial position, results of operations or cash flows.

10. Income Taxes

For the fiscal years ended June 30, 2019 and 2018, the Company recorded the following current and deferred income tax expense or (benefit). For the fiscal years ended June 30, 2019 and 2018, the federal and state income tax provision (benefit) summarized as follows:

In thousands	June 30,	
	2019	2018
Current provision:		
Federal	\$—	\$(790)
State	76	862
	<u>76</u>	<u>72</u>
Deferred tax liabilities:		
Federal	\$—	\$—
State	—	—
	<u>—</u>	<u>—</u>
Provision for income taxes	<u>\$ 76</u>	<u>\$ 72</u>

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets (liabilities) are comprised of the following:

In thousands	June 30,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	\$ 20,526	\$ 13,910
Tax credit carryforwards	25,501	23,567
Accruals and other	3,513	4,625
Depreciation and amortization	238	112
Gross deferred tax assets	49,778	42,214
Deferred tax asset valuation allowance	(49,778)	(42,214)
Total deferred tax assets, net of valuation allowance	<u>—</u>	<u>—</u>
Deferred tax liabilities:		
Depreciation and amortization	—	—
Total deferred tax liabilities	<u>—</u>	<u>—</u>
Net deferred tax asset (liability)	<u>\$ —</u>	<u>\$ —</u>

As of June 30, 2019, the Company had federal and state net operating losses of approximately \$24.8 million and \$5.1 million (tax effected), respectively, that may be applied against future taxable income and expire in various

Table of Contents

years ranging from 2022 to 2038 and federal net operating losses of \$53.6 million that do not expire under the Tax Act. As of June 30, 2019, the Company also had federal and state research and development tax credits of approximately \$25.5 million and \$45,000, respectively, which may provide future tax benefits and expire in various years ranging from 2027 to 2048.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on its history of operating losses, the Company has concluded that as of June 30, 2019, it is more likely than not that the benefit of its deferred tax assets will not be realized. Therefore, any tax benefits to be realized in future years as a result of the utilization of the Company's net operating loss carry forwards as of June 30, 2019, computed based on statutory federal and state rates, are completely offset by valuation allowances established because realization of the deferred tax benefits are not considered more likely than not as of that date. The valuation allowance increased by approximately \$7.6 million during the fiscal year ended June 30, 2019, due primarily to the net increase in federal net operating losses and equity adjustments as a result of ASC 606 revenue recognition standards and its impact on deferred revenue.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act (H.R. 1) (the "Tax Act"). The Act includes a number of changes in existing tax law impacting businesses including, among other things, a permanent reduction in the corporate income tax rate from 35% to 21%, effective January 1, 2018. The Company's deferred tax assets and valuation reserve decreased by \$7.6 million from the impact of the corporate tax rate change from the Tax Act.

The differences between the effective income tax rate reflected in the provision for income taxes and the amounts, which would be determined by applying a 21% rate for the year ended June 30, 2019 and a blended statutory federal income tax rate of 28% for the year ended June 30, 2018, is summarized as follows:

	<u>June 30, 2019</u>	<u>June 30, 2018</u>
Federal income tax benefit at statutory rate	21%	28%
State income tax, net of federal benefit	(3)	3
Permanent differences-incentive stock compensation	(27)	(2)
Permanent differences-transportation and travel	(9)	—
Permanent differences-research expenses	—	(7)
Research and development tax credits	100	24
Tax Act-refundable AMT credit	—	4
Rate change	14	—
Other	(9)	(2)
Change in unrecognized tax benefit	—	(3)
Remeasurement of net deferred tax assets	—	(36)
Change in valuation allowance, including remeasurement	(91)	(9)
Effective income tax rate	<u>(4)%</u>	<u>0%</u>

Under the provisions of the Internal Revenue Code, the Company's net operating loss and tax credit carry forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carry forwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Since its inception, the Company has completed several financings and sales of common stock which have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code. Subsequent ownership changes may further affect the limitation in future years. A full valuation allowance has been provided against the Company's net operating loss

Table of Contents

carryforwards and, if an adjustment were to be required, this adjustment would be offset by an adjustment to the deferred tax asset established for the net operating loss carryforwards and the valuation allowance.

For fiscal years through June 30, 2019, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development tax credit carry forwards; however, until a study is completed, and any adjustment is known, no amounts are being presented as an uncertain tax position as of June 30, 2019 or 2018. A full valuation allowance has been provided against the Company's research and development tax credits and, if an adjustment were to be required, this adjustment would be offset by an adjustment to the deferred tax asset established for the tax credit carry forwards and the valuation allowance.

The Company files income tax returns in the United States and in multiple states. The federal and state returns are generally subject to tax examinations for the tax years ended June 30, 2015 through June 30, 2019. To the extent the Company has tax attribute carry forwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service (IRS), or state authorities, to the extent such attributes are utilized in a future period. On December 28, 2015, the IRS, notified the Company of an income tax audit for the tax period ending June 30, 2014. As of June 30, 2017, the IRS audit was closed and the Company incurred no penalties or payment liabilities for its income tax positions.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination. For the year ended June 30, 2019, the Company increased the uncertain tax position reserve by \$76,000 which includes interest and penalties. A reserve of \$2,035,000 was recorded for the year ended June 30, 2019 and a reserve of \$1,959,000 was recorded for the year ended June 30, 2018. The entire amount of the reserve would reduce the annual effective tax rate if recognized. The Company does not anticipate that the amount of unrecognized tax benefits as of June 30, 2019 will significantly change within the next twelve months. The Company's practice is to recognize interest and/or penalties related to uncertain income tax positions in income tax expense. The Company had \$424,000 of interest and/or penalties accrued on the Company's balance sheets as of June 30, 2019. The Company had \$348,000 of interest and/or penalties accrued on the Company's balance sheet as of June 30, 2018. The Company recognized \$76,000 of interest and/or penalties in the statement of operations for the year ended June 30, 2019 related to uncertain tax positions. The Company recognized \$348,000 of interest and/or penalties in the statement of operations for the year ended June 30, 2018 related to uncertain tax positions. The liability for uncertain tax positions as of June 30, 2019 is included in other long-term liabilities on the balance sheet. A reconciliation of the unrecognized tax benefits, excluding interest and penalties, is summarized below:

<u>In thousands</u>	<u>June 30,</u> <u>2019</u>	<u>June 30,</u> <u>2018</u>
Balance at beginning of period	\$ 1,611	\$ 950
Additions related to current period tax positions	—	—
Additions related to prior period tax positions	—	661
Balance at end of period	<u>\$ 1,611</u>	<u>\$ 1,611</u>

11. Accrued Expenses

Accrued expenses as of June 30, 2019 and 2018 consisted of the following:

<u>In thousands</u>	<u>June 30,</u>	
	<u>2019</u>	<u>2018</u>
Research and development-related	\$4,909	\$4,164
Compensation-related	2,406	2,186
General and administrative- related	709	805
	<u>\$8,024</u>	<u>\$7,155</u>

[Table of Contents](#)**12. Defined Contribution Plan**

The Company sponsors an employee 401(k) salary deferral plan (“401(k) Plan”) that covers substantially all of its employees and is administered through its staff leasing company. Under the 401(k) Plan, employees may elect to defer up to 25% of their compensation per year (subject to a maximum limit prescribed by federal tax law) and the Company matches a portion of such employee contributions up to a maximum of 4% of the eligible salary. The Company’s matching contributions to the 401(k) Plan amounted to \$327,000 and \$302,000 for the years ended June 30, 2019 and 2018, respectively.

13. Common Stock, Preferred Stock and Stockholders’ Equity*Common Stock*

As of June 30, 2019, there were 150,000,000 shares of \$0.001 par value common stock and 5,000,000 shares of preferred stock that were authorized to be issued. As of that date, a total of 18,226,356 and 18,207,352 shares of common stock were issued and outstanding, respectively, while none of the preferred shares were issued and outstanding.

The following shares of common stock were reserved for future issuance:

<u>In thousands</u>	<u>June 30, 2019</u>
Stock options issued and outstanding	3,585,351
Authorized for future grant under the 2013 Employee Stock Purchase Plan	128,571
Authorized for future grant under the 2013 Equity and Incentive Plan	1,244,754
	<u>4,958,676</u>

14. Quarterly Financial Information (Unaudited)

Summarized quarterly information for the two fiscal years ended June 30, 2019 and 2018, respectively, is as follows:

<u>In thousands, except per share data</u>	<u>Year 2019 by Quarter:</u>			
	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>
Revenue	\$ 14,034	\$ 5,934	\$ 21,318	\$ 406
Income/loss from operations	\$ 756	\$ (4,671)	\$ 11,005	\$ (11,440)
Net income/(loss)	\$ 1,200	\$ (4,181)	\$ 11,489	\$ (10,514)
Net earnings/(loss) per common share, basic	\$ 0.07	\$ (0.23)	\$ 0.63	\$ (0.58)
Net earnings/(loss) per common share, diluted	\$ 0.07	\$ (0.23)	\$ 0.63	\$ (0.58)

<u>In thousands, except per share data</u>	<u>Year 2018 by Quarter:</u>			
	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>
Revenue	\$ 10,315	\$ 4,852	\$ 3,603	\$ 5,416
Loss from operations	\$ (1,667)	\$ (6,242)	\$ (7,696)	\$ (6,779)
Net loss	\$ (1,397)	\$ (5,190)	\$ (8,101)	\$ (6,612)
Net loss per common share, basic	\$ (0.08)	\$ (0.29)	\$ (0.45)	\$ (0.36)
Net loss per common share, diluted	\$ (0.08)	\$ (0.29)	\$ (0.45)	\$ (0.36)

[Table of Contents](#)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized and reported within the time periods specified in the rules and forms, and that such information is accumulated and communicated to us, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and we necessarily were required to apply our judgment in evaluating whether the benefits of the controls and procedures that we adopt outweigh their costs.

Our management, with the participation of the Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15e and 15d-15e under the Securities Exchange Act of 1934, as amended as of the end of the period covered by this quarterly report). Based on this evaluation the Chief Executive Officer and Chief Financial Officer concluded that these disclosure controls and procedures are effective and designed to ensure that the information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, summarized and reported within the requisite time periods.

Management’s Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate “internal control over financial reporting,” as such term is defined under Rule 13a-15(f) of the Exchange Act. We maintain internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management’s authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements would be prevented or detected on a timely basis.

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 the policies or procedures may deteriorate. Therefore, internal control over financial reporting determined to be effective provides only reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Management assessed the effectiveness of the Company’s internal control over financial reporting as of June 30, 2019. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework (2013)*. Based on this assessment, management has concluded that the Company’s internal control over financial reporting was effective as of June 30, 2019. Accordingly, our management has concluded that the financial statements included in this Annual Report on Form 10-K present fairly, in all material respects, our financial position, results of

[Table of Contents](#)

operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States.

As a non-accelerated filer, we are not required to comply with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act.

Changes in Internal Control over Financial Reporting

There was no change 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 period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information regarding directors, executive officers and corporate governance included in our definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A no later than 120 days after the end of our fiscal year in connection with our fiscal 2019 Annual Meeting of Stockholders (the "Proxy Statement") is incorporated herein by reference.

We are required under Item 405 of Regulation S-K to provide information concerning delinquent filers of reports under Section 16 of the Securities and Exchange Act of 1934, as amended. This information will be set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information regarding executive compensation included in the Proxy Statement is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information regarding security ownership of certain beneficial owners and management and related stockholder matters included in the Proxy Statement is incorporated herein by reference.

Table of Contents

We have two equity compensation plans under which awards are currently authorized for issuance, our 2013 Equity and Incentive Plan and our 2013 Employee Stock Purchase Plan. In connection with the consummation of our initial public offering in April 2014, our board of directors terminated any new offerings under our 2001 Stock Option Plan and our 2011 Stock Incentive Plan. Each of our 2013 Equity and Incentive Plan, our 2013 Employee Stock Purchase Plan, our 2001 Stock Option Plan and our 2011 Stock Incentive Plan was approved by our stockholders prior to our initial public offering in 2014. The following table provides information regarding securities authorized for issuance as of June 30, 2019 under our equity compensation plans.

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights, and vesting of outstanding restricted stock units</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
	<u>(a)</u>	<u>(b)</u>	<u>(c)</u>
Equity compensation plans approved by security holders	3,585,351	\$ 9.19	1,373,325 ⁽¹⁾
Equity compensation plans not approved by security holders	—	\$ —	—
Total	3,585,351	\$ 9.19	1,373,325

- (1) Includes 1,244,754 shares issuable under our 2013 Equity and Incentive Plan, which may be issued in the form of options, restricted stock, unrestricted stock, performance share awards or other equity-based awards, and 128,571 shares issuable under our 2013 Employee Stock Purchase Plan. This number includes the automatic increase in shares added to our 2013 Equity and Incentive Plan by its terms, added July 1 of each fiscal year and calculated as a 4% increase of the number of shares of our common stock issued and outstanding on the immediately preceding June 30 or such lesser number of shares of our common stock as determined by our compensation committee.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTORS INDEPENDENCE

The information regarding certain relationships and related transactions, and director independence included in the Proxy Statement is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information regarding principal accounting fees and services included in the Proxy Statement is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as a part of this Report:

- (1) **Financial Statements**—See Index to Financial Statements and Financial Statement Schedule at Item 8 on page 87 of this Annual Report on Form 10-K.
- (2) **Financial Statement Schedules**—See Index to Financial Statements and Financial Statement Schedule at Item 8 on page 87 of this Annual Report on Form 10-K. All other schedules are omitted because they are not applicable or not required.

Table of Contents

(3) **Index to Exhibits.**

<u>Exhibit number</u>	<u>Description</u>
3.1	<u>Fifth Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on April 1, 2014)</u>
3.2	<u>Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on April 1, 2014)</u>
4.1	<u>Specimen certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.1	<u>Lease Agreement made as of April 10, 2015, by and between Alachua Foundation Park Holding Company, LLC and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K for the year ending June 30, 2015 (File No. 001-36370))</u>
10.2*^	<u>Employment Agreement dated as of August 29, 2019 between Applied Genetic Technologies Corporation and Mark S. Shearman</u>
10.3*^	<u>Employment Agreement dated as of August 29, 2019 between Applied Genetic Technologies Corporation and Stephen W. Potter</u>
10.4*	<u>Employment Agreement dated as of September 26, 2014 between Applied Genetic Technologies Corporation and Susan B. Washer (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, event date September 26, 2014, filed on October 2, 2014 (File No. 001-36370))</u>
10.5†	<u>Collaboration and License Agreement dated as of July 1, 2015 by and between Biogen MA Inc., and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K for the year ending June 30, 2018 (File No. 001-36370))</u>
10.6	<u>Common Stock Purchase Agreement dated as of July 1, 2015 by and between Biogen MA Inc., and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ending June 30, 2015 (File No. 001-36370))</u>
10.7†	<u>Manufacturing License and Technology Transfer Agreement dated as of July 1, 2015 by and between Biogen MA Inc., and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the year ending June 30, 2018 (File No. 001-36370))</u>
10.8†	<u>Second Amendment to Non-exclusive License Agreement, made and effective as of June 29, 2015, by and between The UAB Research Foundation, Inc. and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the year ending June 30, 2015 (File No. 001-36370))</u>
10.9†	<u>Omnibus Amendment to Standard Exclusive License Agreement with Sublicensing Terms, made and effective as of July 1, 2015, by and between the University of Florida Research Foundation, Inc., the University of Florida Board of Trustees, John Hopkins University and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the year ending June 30, 2015 (File No. 001-36370))</u>

Table of Contents

<u>Exhibit number</u>	<u>Description</u>
10.10†	<u>Omnibus Amendment to Standard Exclusive License Agreement with Know How and Standard Non-Exclusive License Agreement, made and effective as of June 30, 2015, by and between the University of Florida Research Foundation, Inc. and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ending June 30, 2015 (File No. 001-36370))</u>
10.11	<u>Lease Agreement made as of September 19, 2011, by and between Thomson-Davis Enterprises, LLC and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.12†	<u>Exclusive License Agreement with Sublicensing Terms, effective as of September 25, 2001, by and between the University of Florida Research Foundation, Inc. and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.13†	<u>Restated Amendment to License Agreement made and, effective as of January 31, 2005, by and between the University of Florida Research Foundation, Inc. and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.14†	<u>First Amendment After Restated Amendment to License Agreement, made and effective as of November 28, 2007, by and between the University of Florida Research Foundation, Inc. and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.15†	<u>Standard Exclusive License Agreement with Sublicensing Terms, effective as of October 7, 2003, by and between the University of Florida Research Foundation, Inc., Johns Hopkins University and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.16†	<u>First Amendment to Standard Exclusive License Agreement with Sublicensing Terms, made as of November 2004, by and between the University of Florida Research Foundation, Inc., Johns Hopkins University and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.17†	<u>Second Amendment to Standard Exclusive License Agreement with Sublicensing Terms, made as of February 25, 2009, by and among Applied Genetic Technologies Corporation, the University of Florida Research Foundation, Inc. and Johns Hopkins University (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.18†	<u>Non-Exclusive License Agreement with Sublicensing Terms, made as of January 19, 2006, by and between The UAB Research Foundation, Inc. and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.19†	<u>Standard Non-Exclusive License Agreement, effective as of September 18, 2012, by and between the University of Florida Research Foundation, Inc. and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.20†	<u>Standard Exclusive License Agreement with Know How, effective as of November 5, 2012, by and between the University of Florida Research Foundation, Inc. and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>

Table of Contents

<u>Exhibit number</u>	<u>Description</u>
10.21	<u>Amended and Restated Investor Rights Agreement, dated as of November 15, 2012 (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.22*	<u>Applied Genetic Technologies Corporation 2001 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.23*	<u>Applied Genetic Technologies Corporation 2011 Stock Incentive Plan, as amended, and forms of Incentive Stock Option Agreement and Nonstatutory Stock Option Agreement thereunder (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.24*	<u>Applied Genetic Technologies Corporation 2013 Equity And Incentive Plan (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.25*	<u>Applied Genetic Technologies Corporation 2013 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.26	<u>Form of Indemnification Agreement for Directors Associated with an Investment Fund (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.27	<u>Form of Indemnification Agreement for Directors Not Associated with an Investment Fund (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.28†	<u>Second Amendment After Restated Amendment to License Agreement, made and effective as of January 10, 2014, by and between the University of Florida Research Foundation, Inc. and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.29†	<u>Fourth Amendment to Standard Exclusive License Agreement with Sublicensing Terms, made as of December 17, 2013 by and between the University of Florida Research Foundation, Inc., Johns Hopkins University and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1 (File No. 333-193309))</u>
10.30†	<u>First Amendment to Non-Exclusive License, made as of March 28, 2014, by and between the UAB Research Foundation, Inc. and Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1 (File No. 333-197385))</u>
10.31*	<u>Employment Letter Agreement dated as of July 26, 2017 between Applied Genetic Technologies Corporation and William A. Sullivan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 2, 2017)</u>
10.32*	<u>Employment Letter Agreement dated as of July 29, 2019 between Applied Genetic Technologies Corporation and Matthew Feinsod (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 2, 2019)</u>
10.33*^	<u>Employment Letter Agreement dated as of June 12, 2019 between Applied Genetic Technologies Corporation and Theresa Heah</u>
10.34*^	<u>Employment Agreement dated as of August 29, 2019 between Applied Genetic Technologies Corporation and Brian Krex</u>
23.1^	<u>Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm</u>
23.2^	<u>Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm</u>

Table of Contents

<u>Exhibit number</u>	<u>Description</u>
31.1 [^]	<u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2 [^]	<u>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1 [^]	<u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101.INS [^]	XBRL Instance Document
10.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

* Management contract or compensatory plan or arrangement

[^] Filed herewith

[†] We have omitted portions of this exhibit, for which confidential treatment has been granted.

ITEM 16. FORM 10-K SUMMARY

None.

SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS

In thousands	Beginning of Period	Additions		Deductions	End of Period
		Charge (Benefit) to Expenses	To (from) Other Accounts		
Deferred Tax Valuation Allowance					
Year 2019	\$ 42,214	\$ 7,564	\$ —	\$ —	\$49,778
Year 2018	\$ 40,303	\$ 1,911	\$ —	\$ —	\$42,214
Year 2017	\$ 37,412	\$ 2,891	\$ —	\$ —	\$40,303

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

APPLIED GENETIC TECHNOLOGIES CORPORATION

By: /s/ Susan B. Washer
Susan B. Washer
President and Chief Executive Officer
Date: September 26, 2019

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Susan B. Washer</u> Susan B. Washer	Chief Executive Officer, President and Director (Principal Executive Officer)	September 26, 2019
<u>/s/ William A. Sullivan</u> William A. Sullivan	Chief Financial Officer (Principal Financial and Accounting Officer)	September 26, 2019
<u>/s/ Scott Koenig</u> Scott Koenig	Director	September 26, 2019
<u>/s/ William Aliski</u> William Aliski	Director	September 26, 2019
<u>/s/ Ed Hurwitz</u> Ed Hurwitz	Director	September 26, 2019
<u>/s/ Ivana Magovcevic-Liebisch</u> Ivana Magovcevic-Liebisch	Director	September 26, 2019
<u>/s/ Anne VanLent</u> Anne VanLent	Director	September 26, 2019
<u>/s/ James Rosen</u> James Rosen	Director	September 26, 2019

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of the 29th day of August, 2019 by and between Applied Genetic Technologies Corporation, a Delaware corporation, including its successors and assigns, (the "Employer" or "Company"), and Mark S. Shearman ("Executive").

NOW, THEREFORE, in consideration of the promises and the respective undertakings of Employer and Executive set forth below, Employer and Executive hereby agree as follows:

1. Employment. Employer hereby employs Executive, and Executive hereby accepts such employment and agrees to perform services for Employer, for the period and on the other terms and subject to the conditions set forth in this Agreement. Employee's Start Date shall be and shall be considered the Effective Date of this Agreement.

2. Employment at Will. Executive is employed "at-will" which means that Executive's employment is not for any defined term and may be terminated by either Executive or the Company at any time, with or without cause, for any or no reason, subject to the notice provisions herein.

3. Position and Duties.

3.1 Service with Employer. Employer hereby employs Executive in an executive capacity with the title of Chief Scientific Officer and Executive hereby accepts such employment and undertakes and agrees to serve in such capacity. Executive shall have such powers, perform such duties and fulfill such responsibilities as are typically associated with such position in other similarly situated companies and shall report directly to the Company's President and Chief Executive Officer,

3.2 Performance of Duties. Executive agrees to: (i) devote substantially all of Executive's business time, attention and efforts to the business and affairs of Employer while employed; and (ii) adhere to all Employer's written employment policies and procedures as shall be in force from time to time.

3.3 Outside Activities. During the Term, Executive shall not: (i) except as set forth below, accept other employment; (ii) except as set forth below, render or perform services for compensation to any Person (as hereinafter defined) other than Employer; (iii) serve as an officer or on the board of directors (or similar governing body) of any entity other than Employer, whether or not for compensation; or (iv) engage in any other business, enterprise or activity that will require any effort on the part of Executive that, in the sole discretion of Employer, could reasonably be expected to materially detract from the ability of Executive to perform Executive's duties to Employer pursuant to this Agreement; provided, however, Executive may engage in the activities set forth in Schedule A hereto or described in clause (iii) or (iv) above if prior to engaging in such activity, Executive has disclosed such activity to the Board and received written approval to engage in such activity from the Board. Executive may engage in personal investments without disclosure to or written approval from the Board provided Executive is not required or expected to serve as a board member, advisor or consultant and Executive shall, at any time, own beneficially

less than 2% of the outstanding securities of any issuer and such personal investment shall not otherwise interfere with Executive's performance of duties hereunder and/or the provisions of Executive's written agreements with Employer.

3.4 Executive Representations. Executive represents that Executive is not subject to any restrictive covenant, confidentiality agreement, or any other agreement that would prevent Executive from accepting employment with Employer, and based on the information provided to Employer by Executive, Employer accepts such representation.

4. Compensation.

4.1 Base Salary. Employer shall pay to Executive a base salary for all services to be rendered by Executive under this Agreement (the "Base Salary"), which Base Salary shall be paid in accordance with Employer's normal payroll schedule, procedures and policies (which schedule, procedures and policies may be modified from time to time) and subject to applicable deductions as required by law. Employer shall review Executive's salary on an annual basis and may, in its discretion, consider and declare from time to time increases in the Base Salary that it pays Executive. Any and all increases in Executive's salary pursuant to this section shall cause the level of Base Salary to be increased by the amount of each such increase for purposes of this Agreement. The increased level of Base Salary as provided in this section shall become the level of Base Salary for the remainder of the term of this Agreement unless there is a further increase in Base Salary as provided herein. Notwithstanding the foregoing, the Base Salary of Executive may be decreased provided it is done so in proportion to decreases in Base Salary of the entire executive team of the Company.

4.2 Annual Bonus. The Executive will be eligible to participate in the Employer's annual cash incentive compensation plan on substantially the same terms as other executive officers. Company-wide and individual performance objectives ("MBOs") will be established by the Compensation Committee. Target incentives do not constitute a promise of payment and the Executive's actual bonus, if any, will depend in part on the Employer's performance and the Compensation Committee's discretion in assessing the Executive's individual performance in relation to his or her MBOs and the overall performance and status of the Company. To qualify for the incentive bonus, the Executive must remain employed with the Company through the date that the incentive bonus is paid in accordance with the Employer's normal practice.

4.3 Participation in Benefit Plans. Executive shall be entitled to participate in all employee benefit plans or programs offered to other senior executives from time to time (to the extent that Executive meets the requirements for each such plan or program), including participation in any health insurance plan, disability insurance plan, dental plan, eye care plan, 401(k) plan, life insurance plan, or other similar plans (all such benefits, the "Benefit Plans"). Some or all of the benefits may be provided by Employer's leasing agent TriNet (or its successor(s) or assign(s)).

4.4 Expenses. Employer shall reimburse Executive for all ordinary and necessary business expenses reasonably incurred by him in the performance of Executive's duties under this Agreement, subject to the presentment and approval of appropriate itemized expense statements, receipts, vouchers or other supporting documentation in accordance with Employer's normal policies for expense verification in effect from time to time.

4.5 Paid Time Off. Executive shall be entitled to paid time off pursuant to Employer's standard paid time off policies in the same manner as the Company's other Senior Executives. Unused paid time off may be carried over from year to year, but in no case may more than 45 days (360 hours) of unused paid time off be accrued.

4.6 Total Compensation. Executive shall not receive any other compensation or benefits other than as provided in Sections 4.1 through 4.5 hereof.

5. Payments Upon Termination.

5.1 Voluntary Resignation without Good Reason. Executive may terminate Executive's employment by providing Employer with 30 days' advance written notice. If Executive terminates Executive's employment (other than for Good Reason (either prior to or within 12 months following a Change in Control) or by reason of Disability, each as defined below) (i) Employer shall pay to Executive the Accrued Obligations (as defined below), (ii) Executive's participation in the Benefit Plans shall terminate as of the Termination Date, and (iii) Employer shall have no other obligations to Executive under this Agreement, other than those provided in this Section 5.1.

(a) For purposes of this Agreement, "Accrued Obligations" means: (i) Executive's earned and unpaid Base Salary through the Termination Date; (ii) reimbursement for any reimbursable business expenses incurred by Executive through the Termination Date in accordance with Section 4.4; and (iii) Executive's accrued but unused paid time off as of the Termination Date. The amounts payable pursuant to clauses (i) and (iii) hereof shall be paid no later than sixty (60) days following Executive's Termination Date.

(b) For purposes of this Agreement, "Termination Date" means: the effective date of Executive's "separation from service" as defined in Section 409A of the Internal Revenue Code of 1986, as amended (the "Code").

5.2 Termination by Employer For Cause. If Executive is terminated for Cause: (i) Employer shall pay to Executive the Accrued Obligations, (ii) Executive's participation in the Benefit Plans shall terminate as of the Termination Date, and (iii) Employer shall have no further obligations to Executive under this Agreement, other than those provided in this Section 5.2. For purposes of this Agreement, "Cause" means: (a) Executive's failure to substantially perform Executive's duties with the Company (if Executive has not cured such failure to substantially perform, if curable, within thirty (30) days after Executive's receipt of written notice thereof from the Board that specifies the conduct constituting Cause under this clause (a)); (b) Executive's willful misconduct, or gross negligence in the performance of Executive's duties hereunder; (c) the conviction of Executive for, or the entering by Executive of a guilty plea or plea of no contest with respect to, any crime that constitutes a felony or involves fraud, dishonesty or moral turpitude; (d) Executive's commission of an act of fraud, embezzlement or misappropriation against the Company; (e) Executive's material breach of the fiduciary duty owed by Executive to the

Company; (f) Executive's engaging in any improper conduct that has or is likely to have an adverse economic or reputational impact on the Company; or (g) Executive's material breach of this Agreement.

5.3 Termination by Employer Without Cause or by Executive for Good Reason If Executive's employment is terminated (a) by Employer without Cause (other than upon Disability or death) or (b) by Executive for Good Reason either prior to a Change in Control or within twelve (12) months following a Change in Control: (i) Employer shall pay to Executive the Accrued Obligations, (ii) Executive shall be entitled to receive the Severance Benefits (as defined below in Section 5.5 and subject to the conditions described therein and in Section 5.6), and (iii) Employer shall have no further obligations to Executive under this Agreement, other than those provided in this Section 5.3. For purposes of this Agreement, "Good Reason" means the occurrence of any of the following events (without Executive's consent):

- (a) a material adverse change in Executive's functions, duties, or responsibilities with the Company which change would cause Executive's position to become one of materially lesser responsibility, importance, or scope;
- (b) a relocation of the Executive's principal workplace to a location more than 50 miles from the location of such workplace immediately prior to the Change in Control without the Executive's express written consent;
- (c) a material diminution in the Executive's compensation or benefits without the express written consent of the Executive, other than an across-the-board reduction in compensation levels that applies to all senior executives generally; or
- (d) a material breach of this Agreement by the Company.

Notwithstanding the foregoing, no such event shall constitute "Good Reason" unless (a) Executive shall have given written notice of such event to the Company within ninety (90) days after the initial occurrence thereof, (b) the Company shall have failed to cure the condition constituting Good Reason within thirty (30) days following the delivery of such notice (or such longer cure period as may be agreed upon by the parties), and (c) Executive terminates employment within thirty (30) days after expiration of such cure period.

5.4 Termination by Employer due to Executive's Death or Disability. If Executive's employment is terminated by reason of death or Disability (as defined below): (i) Employer shall pay to Executive the Accrued Obligations, (ii) Executive's participation in the Benefit Plans shall terminate as of the Termination Date (except to the extent Executive is eligible for continued disability benefits under the applicable Employer plan), and (iii) Employer shall have no further obligations to Executive under this Agreement, other than those provided in this Section 5.4. For purposes of this Agreement, "Disability" means Executive being determined to be totally disabled by the Social Security Administration or Executive's inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve months.

5.5 Severance Benefits. “Severance Benefits” means:

(a) The payment to Executive of the Severance Amount in a lump sum immediately following the Termination Date.

(b) For this purpose, “Severance Amount” means:

(i) In the event that Executive’s employment is terminated without Cause or by the Executive for Good Reason, in each case, within twelve (12) months following a Change in Control, an amount equal to the sum of (A) the product of 1.0 multiplied by Executive’s annual Base Salary plus (B), the product of 1.0 multiplied by the Executive’s target bonus in effect immediately prior to the Date of Termination.

(ii) In the event that Executive’s employment is terminated without Cause (other than within twelve (12) months of a Change in Control), an amount equal to the sum of (A) the product of 0.75 multiplied by Executive’s annual Base Salary plus (B), the product of the Executive’s target bonus in effect immediately prior to the Date of Termination multiplied by a fraction equal to the quotient of the number of days during such year on which the Executive was employed by the Company, divided by 365.

(c) The continuation of Executive’s participation in the Company’s medical, dental, and vision benefit plans at the same premium cost to Executive as charged to Executive immediately prior to the Termination Date for a period of (i) in the event that the Executive’s employment is terminated without Cause or by the Executive for Good Reason, in each case, within twelve (12) months following a Change in Control, twelve (12) months immediately following the Termination Date or (ii) in the event that the Executive’s employment is terminated without Cause (other than within twelve (12) months of a Change in Control) nine (9) months immediately following the Termination Date (in each case, the “Continuation Period”), or if earlier, until Executive obtains other employment which provides the same type of benefit; provided, however, that (i) it is understood and agreed that such continued medical, dental and vision benefits may at the election of the Company be provided by Executive electing the continuation of such coverage pursuant to COBRA with the Company reimbursing Executive for COBRA premiums to the extent required so that Executive’s premium cost for the coverage in effect for Executive prior to the Termination Date is substantially the same as immediately prior to the Termination Date, and (ii) if the Company determines, in its reasonable judgment, that providing medical, dental, and/or vision benefits in accordance with the preceding provisions of this Section 5.5(c) would result in a violation of applicable law, the imposition of any penalties under applicable law, or adverse tax consequences for participants covered by the Company’s medical, dental, and/or vision plans, the Company may terminate such

coverage (or reimbursement) with respect to Executive and instead pay to Executive taxable cash payments at the same time and in the same amounts as the Company would have paid as premiums (or as COBRA premium reimbursements) to provide such coverage.

(d) Acceleration of vesting as follows:

(i) In the event that Executive's employment is terminated by Employer without Cause or by Executive for Good Reason, in each case, within twelve (12) months following a Change in Control: each stock option, restricted stock unit, restricted stock award or other stock-based compensatory award granted by the Company to Executive that is outstanding as of the Termination Date and is not fully vested as of the date of the Termination Date (each an "Award"), shall become fully vested as of the date Executive provides the Company with the Irrevocable Release provided for in this Section 5.5 within the period prescribed therein.

(ii) In the case of any Award the vesting of which is contingent in whole or in part upon the attainment of any Company or market performance condition that has not yet been satisfied, such condition shall be deemed to have been satisfied as of the date of termination at the level that would result in vesting of 100% of the number of shares stated as the target award.

(e) For purposes of this Agreement, "Change of Control" means, and shall be deemed to have occurred, if:

(i) any Person, excluding (i) employee benefit plans of the Company or any of its Affiliates, is or becomes the "beneficial owner" (as defined in Rules 13d-3 and 13d-5 under the Exchange Act, which Rules shall apply for purposes of this clause (a) whether or not the Company is subject to the Exchange Act), directly or indirectly, of Company securities representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities ("Voting Power");

(ii) the Company consummates a merger, consolidation, share exchange, division or other reorganization or transaction of the Company (a "Fundamental Transaction") with any other corporation, other than a Fundamental Transaction that results in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) at least fifty percent (50%) of the combined Voting Power immediately after such Fundamental Transaction of (i) the Company's outstanding securities, (ii) the surviving entity's outstanding securities, or (iii) in the case of a division, the outstanding securities of each entity resulting from the division;

(iii) the stockholders of the Company approve a plan of complete liquidation or winding-up of the Company or the consummation of the sale or disposition (in one transaction or a series of transactions) of all or substantially all of the Company's assets; or

(iv) during any period of 24 consecutive months, individuals who at the beginning of such period constituted the Board (including for this purpose any new director whose election or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds (2/3) of the directors then still in office who were directors at the beginning of such period or whose appointment, election or nomination was previously so approved or recommended) cease for any reason to constitute at least a majority of the Board.

5.6 Required Delivery of Irrevocable Release: Compliance with Section 6 Obligations. Notwithstanding the provisions of Section 5.5, as a condition to entitlement to the Severance Benefits, Executive must provide to the Company an Irrevocable Release and Noncompete Affirmation not later than the sixtieth day after the Date of Termination; provided however that if the sixty day period begins in one calendar year and ends in a subsequent calendar year, any payment to be made or benefit to be provided upon receipt of the Irrevocable Release and Noncompete Affirmation shall not be made or provided until the subsequent year. In the event Executive fails to provide an Irrevocable Release and Noncompete Affirmation to the Company within such sixty day period, the Company will immediately cease to pay or provide any further Severance Benefits, no accelerated vesting of stock options or other awards pursuant to Section 5.5(d) shall occur, and Executive shall be obligated to immediately repay to the Company all previously paid or provided Severance Benefits. "Irrevocable Release and Noncompete Affirmation" means a confidential separation agreement, release of claims and affirmation of noncompete, in form and substance substantially similar to the attached Exhibit A that has been executed by Executive, delivered to the Company, and become irrevocable by Executive. In addition, in the event that Executive breaches the obligations under Section 6 of this Agreement at any time during the Continuation Period, Executive will cease to be entitled to any further Severance Benefits.

6. Promises and Covenants Regarding Confidential Information and Goodwill; Inventions and Assignment; Restrictive Covenants

6.1 Confidential Information and Goodwill. In consideration of Executive's promises and covenants contained in this Agreement, including Executive's promise and covenant not to disclose Confidential Information, Employer will provide Executive with Confidential Information. In further consideration of Executive's promises and covenants contained in this Agreement, including Executive's promise and covenant to utilize the Goodwill exclusively for the benefit of Employer, Employer will allow Executive to receive Confidential Information concerning the Company's customers, labs, vendors and employees and, to the extent required to fulfill Executive's duties, the Company will permit Executive to represent the Company on its behalf with such persons. To the extent that Executive's duties involve sales or customer relations, the Company will permit Executive to utilize the Goodwill in Executive's sales efforts and will provide sales support to Executive similar to that which it provides to its sales representatives.

6.2 Duties. While employed by Company, Executive shall perform the duties required of Executive hereunder and shall devote Executive's best efforts and exclusive business time, energy and skill to performing such duties; not make any disparaging remarks regarding Company to any person with whom Company has business relations, including any employee or vendor of Company; use the Goodwill solely for the benefit of Company; and not interfere in such Goodwill, either during or following Executive's employment with Company.

6.3 Delivery of Company Property. Executive recognizes that all documents, magnetic media and other tangible items which contain Confidential Information are the property of Company exclusively. Upon request by Company or termination of Executive's employment with Company, Executive shall promptly return to Company all Confidential Information and Company Property within Executive's possession and control, and shall refrain from taking any Confidential Information or Company Property or allowing any Confidential Information or Company Property to be taken from Company; and immediately return to Company all information pertaining to Company or Company Property in Executive's possession.

6.4 Promise and Covenant Not to Disclose. The parties acknowledge that Company is the sole and exclusive owner of Confidential Information, and that Company has legitimate business interests in protecting Confidential Information. The parties further acknowledge that Company has invested, and continues to invest, considerable amounts of time and money in obtaining, developing, and preserving the confidentiality of Confidential Information and that, by reason of the trust relationship arising between Executive and Company, Executive owes Company a fiduciary duty to preserve and protect Confidential Information from all unauthorized disclosure and unauthorized use. Executive shall not, directly or indirectly, disclose Confidential Information to any third party (except to Executive's attorneys, the Company's personnel, other persons designated in writing by the Company, or except as otherwise provided by law) or use Confidential Information for any purpose other than for the direct benefit of Company while in Company's employ and thereafter.

6.5 Inventions and Assignment. Executive agrees that he will promptly disclose to the Company any and all Company Inventions and that Executive hereby irrevocably assigns to the Company all ownership rights in and to any and all Company Inventions. During Executive's

employment or at any time thereafter, upon request of the Company, Executive will sign, execute and deliver any and all documents or instruments, including, without limitation, patent applications, declarations, invention assignments and copyright assignments, and will take any other action which the Company shall deem necessary to perfect in the Company trademark, copyright or patent rights with respect to Inventions, or to otherwise protect the Company's trade secrets and proprietary interests. The term "Inventions" means discoveries; developments; trade secrets; processes; formulas; data; lists; software programs; graphics; artwork; logos, and all other works of authorship, ideas, concepts, know-how, designs, and techniques, whether or not any of the foregoing is or are patentable, copyrightable, or registrable under any intellectual property laws or industrial property laws in the United States. The term "Company Inventions" means all Inventions that (a) relate to the business or proposed business of the Company or any of its predecessors or that are discovered, developed, created, conceived, reduced to practice, made, learned or written by Executive, either alone or jointly with others, in the course of Executive's employment; (b) utilize, incorporate or otherwise relate to Confidential Information; or (c) are discovered, developed, created, conceived, reduced to practice, made, or written by him using property or equipment of the Company or any of its predecessors. Executive agrees to promptly and fully communicate in writing to the Company (to such department or officer of the Company and in accordance with such procedures as the Company may direct from time to time) any and all Company Inventions. Executive acknowledges and agrees that any work of authorship by Executive or others comprising Company Inventions shall be deemed to be a "work made for hire," as that term is defined in the United States Copyright Act (17 U.S.C. § 101 (2000)). To the extent that any such work of authorship may not be deemed to be a work made for hire, Executive hereby irrevocably assigns any ownership rights Executive may have in and to such work to the Company. This Agreement does not apply to any Inventions Executive made before Executive's employment with the Company. To clearly establish Executive's rights, Executive has listed on Exhibit B any Inventions, whether or not patentable or copyrightable and whether or not reduced to practice, made by him prior to Executive's employment with the Company that are owned by Executive ("*Prior Inventions*"), together with the approximate dates of their creation. If no such list is attached, Executive represents that there are no Prior Inventions.

6.6 Other Promises and Covenants. In consideration for the benefits specifically provided for in this Section 6.6 and that may otherwise be provided pursuant to this Agreement, including but not limited to the benefits payable pursuant to Section 5.5, Executive hereby promises and covenants as follows.

(a) In consideration of payment to Executive of \$500.00, less applicable withholdings, Executive agrees that during Executive's employment with Company and, unless this Section 6.6(a) is waived by the Company in writing, for a period of one year following termination of employment for any reason other than the Company's termination of Executive's employment without Cause (the "Non-Competition Period"), Executive shall not either directly or indirectly, on Executive's own or another's behalf, engage in or assist others in any of the following activities (except on behalf of Company):

(i) (whether as principal, agent, partner or otherwise) engage in, own, manage, operate, control, finance, invest in, participate in, or otherwise carry on, or be employed by, associated with, or in any manner

connected with, lend such Executive's name to, lend Executive's credit to, or render services or advice to a Competing Business anywhere in the Geographic Area; or

(ii) provide or develop any products, technology or services that are the same or Substantially Similar to the products, technology and services provided or developed by the Company or any of its Affiliates.

(b) Unless Section 6.6(a) is waived by the Company in writing, as mutually-agreed upon consideration for the post-employment restriction described herein, the Company will pay Executive \$10,000.00 within one month of Executive's date of termination. Notwithstanding the foregoing, in the event that Executive has breached his or her fiduciary duty to the Company or has unlawfully taken, physically or electronically, property belong to the Company, then the Non-Competition Period shall be extended for an additional period of one year.

(c) During Executive's employment with Company and for a period of two years following termination of employment for any reason (the "Non-Solicitation Period"), Executive shall not either directly or indirectly, on Executive's own or another's behalf, engage in or assist others in any of the following activities:

(i) induce or attempt to induce any customer, agent, supplier, licensee, or business relation of the Company or any of its Affiliates to cease doing business with the Company or any of its Affiliates, or in any way interfere with the relationship between any customer, supplier, licensee, or business relation of the Company or any of its Affiliates; or

(ii) on behalf of a Competing Business, solicit or attempt to solicit the business or patronage of any Person who is a customer or agent of the Company or any of its Affiliates, whether or not Executive had personal contact with such Person.

(iii) solicit, encourage, or take any other action which is intended to induce any employee, independent contractor or agent of the Company or any of its Affiliates to terminate Executive's employment or other business relationship with the Company or such Affiliate;

(iv) in any way interfere in any manner with the employment or other business relationship between the Company and/or any of its Affiliates, on the one hand, and any employee, independent contractor or agent of the Company or such Affiliate, on the other hand; or

(v) employ, or otherwise engage as an employee, independent contractor or otherwise, any individual who was an employee, independent contractor, agent or was otherwise affiliated with the Company or any of its Affiliates from the period beginning one year prior to the date on which Executive became employed and continuing through the expiration of the Non-Solicitation Period.

provided, however, that nothing set forth in this Section 6 shall prohibit Executive from owning, as a passive investment, not in excess of five percent (5%) in the aggregate of any class of capital stock of any corporation if such stock is publicly traded and listed on any national or regional stock exchange or reported on the Nasdaq Stock Market.

6.7 Definitions. For purposes hereof:

(a) “*Affiliate*” means, with respect to any Entity, any Entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or under common control with, such Entity.

(b) “*Agreement*” means this Employment Agreement.

(c) “*Company Business*” means (i) any business related to providing services related to, manufacturing, selling or distributing gene therapy products using adeno-associated virus technology for the treatment of inherited and acquired diseases or conducting research or development with regard thereto; and (ii) any other business that the Company is actively engaged in researching, developing or marketing at the time of the termination of Executive’s employment, provided that this clause (ii) shall only apply if Executive is involved with the research, development, or marketing of that other business.

(d) “*Company Property*” means all physical materials, documents, information, keys, computer software and hardware, including laptop computers and mobile or handheld scheduling computers, manuals, data bases, product samples, tapes, magnetic media, technical notes and any other equipment or items which Company provides for or to Executive or which otherwise belongs to the Company, and those documents and items which Executive may develop or help develop while in Company’s employ, whether or not developed during regular working hours or on Company’s premises. The term “*Company Property*” shall include the original of such materials, any copies thereof, any notes derived from such materials, and any derivative work of such materials.

(e) “*Competing Business*” means any other Entity engaged in the Company Business, other than the Company and its Affiliates.

(f) “*Confidential Information*” means the trade secrets and other information of Company, including but not limited to (i) the customer lists, customer contact information, customer purchase information, pricing information, strategic and marketing plans, compilations of customer information, names of employees, contracts with third parties, training, financial and marketing books, sales projections, internal employer databases, reports, manuals and information including information related to Company, its Affiliates or its customers, including those documents and items which any employee may develop or help develop while

in the employ of the Company or any of its Affiliates, whether or not developed during regular working hours or on the premises of the Company or such Affiliate; (ii) the identity, skills, personnel file information, performance appraisals and compensation of job applicants, employees, contractors, and consultants; (iii) specialized training; (iv) source code, scripts, user screens, reports or any other information pertaining to the internal information technology or network of the Company and/or its Affiliates; and (v) information related to inventions owned by the Company or any of its Affiliates or licensed from third parties; and unless the context requires otherwise, the term “Confidential Information” includes the original of such materials, any copies thereof, any notes derived from such materials, and any derivative work of such materials. The term “Confidential Information” does not include (1) information that was or becomes generally available publicly other than through disclosure by Executive, or (2) is required to be disclosed to any governmental agency or self-regulatory body or is otherwise required to be disclosed by law. Unless the context requires otherwise, the term “Confidential Information” shall include the original of such materials, any copies thereof, any notes derived from such materials, and any derivative work of such materials.

(g) “*Entity*” means and includes any person, partnership, association, corporation, limited liability company, trust, unincorporated organization or any other business entity or enterprise.

(h) “*Geographic Area*” means those states in which the Company or any of its subsidiaries conducts business or in which its products are being sold or marketed at the time of the termination of Executive’s employment.

(i) “*Goodwill*” means the value of the relationships between the Company and its agents, customers, vendors, labs, and employees.

(j) “*Substantially Similar*” means substantially similar in function or capability or otherwise competitive to the products or services being developed, manufactured or sold by the Company during and/or at the end of Executive’s employment, or are marketed to substantially the same type of user or customer as that to which the products and services of the Company are marketed or proposed to be marketed.

6.8 Acknowledgements Regarding Other Promises and Covenants. With regard to the promises and covenants set forth herein, Executive acknowledges and agrees that:

(a) the restrictions are ancillary to an otherwise enforceable agreement including the provisions of this Agreement regarding the disclosure, ownership and use of the Confidential Information and Goodwill of Company;

(b) the limitations as to time, geographical area, and scope of activity to be restricted are reasonable and acceptable to Executive, and do not impose any greater restraint than is reasonably necessary to protect the Goodwill and other legitimate business interests of Company;

(c) the performance by Executive, and the enforcement by Company, of such promises and covenants will cause no undue hardship on Executive;

(d) the time periods covered by the promises and covenants will not include any period(s) of violation of, or any period(s) of time required for litigation brought by Company to enforce any such promise or covenant, it being understood that the extension of time provided in this paragraph may not exceed two (2) years.

6.9 Duty to Give Notice of Agreement. During employment by Company and the period of any post-employment obligation applicable hereunder, Executive shall provide written notice to any prospective employer of Executive's obligations under this Agreement, and shall provide a true copy hereof to such prospective employer at the outset of any communications about employment.

6.10 Independent Elements. The parties acknowledge that the promises and covenants contained in Section 6 above are essential independent elements of this Agreement and that, but for Executive agreeing to comply with them, Company would not employ Executive. Accordingly, the existence or assertion of any claim by Executive against Company, whether based on this Agreement or otherwise, shall not operate as a defense to Company's enforcement of the promises and covenants in Section 6. An alleged or actual breach of the Agreement by Company will not be a defense to enforcement of any such promise or covenant, or other obligations of Executive to Company. The promises and covenants in Section 6 will remain in full force and effect whether Executive is terminated by Company or voluntarily resigns.

6.11 Remedies for Breach of Agreement. Executive acknowledges that Executive's breach of any promise or covenant contained in Section 6 will result in irreparable injury to Company and that Company's remedies at law for such a breach will be inadequate. Accordingly, Executive agrees and consents that Company, in addition to all other remedies available at law and in equity, shall be entitled to both preliminary and permanent injunctions to prevent and/or halt a breach or threatened breach by Executive of any such promise or covenant, and Executive waives the requirement of the posting of any bond in connection with such injunctive relief. Executive further acknowledges and agrees that the promises and covenants contained in Section 6 are enforceable, reasonable, and valid.

7. Miscellaneous.

7.1 Governing Law; Arbitration

(a) This Agreement is made under and shall be governed by and construed in accordance with the laws of Florida, without regard to its conflicts of law principles.

(b) With respect to claims by the Company against Executive related to Executive's threatened or actual breach of Section 6 of this Agreement, each Party hereby irrevocably agrees that all actions or proceedings concerning such disputes

may be brought by the Company in (a) the United States District Court for the Northern District of Florida; or (b) in any court of the State of Florida sitting in Alachua County, provided that the United States District Court lacks subject matter jurisdiction over such action or proceeding. Executive consents to jurisdiction of and venue in the courts in the State of Florida set forth in this Section, and hereby waives to the maximum extent permitted by applicable law any objection which Executive may have based on improper venue or forum non conveniens.

(c) Except to the extent provided for in subsection (b) above, the Company and Executive agree that any claim, dispute or controversy arising under or in connection with this Agreement, or otherwise in connection with Executive's employment by the Company or termination of his employment (including, without limitation, any such claim, dispute or controversy arising under any federal, state or local statute, regulation or ordinance or any of the Company's employee benefit plans, policies or programs) shall be resolved solely and exclusively by binding, confidential, arbitration. The arbitration shall be held in Gainesville, Florida (or at such other location as shall be mutually agreed by the parties). The arbitration shall be conducted in accordance with the Commercial Rules of the American Arbitration Association (the "AAA") in effect at the time of the arbitration, including the Expedited Procedures. All fees and expenses of the arbitration, including a transcript if either requests, shall be borne equally by the parties. Each party is responsible for the fees and expenses of its own attorneys, experts, witnesses, and preparation and presentation of proofs and post-hearing briefs (unless the party prevails on a claim for which attorney's fees are recoverable under law). In rendering a decision, the arbitrator shall apply all legal principles and standards that would govern if the dispute were being heard in court. This includes the availability of all remedies that the parties could obtain in court. In addition, all statutes of limitation and defenses that would be applicable in court, will apply to the arbitration proceeding. The decision of the arbitrator shall be set forth in writing, and be binding and conclusive on all parties. Any action to enforce or vacate the arbitrator's award shall be governed by the Federal Arbitration Act, if applicable, and otherwise by applicable state law. If either the Company or Executive improperly pursues any claim, dispute or controversy against the other in a proceeding other than the arbitration provided for herein, the responding party shall be entitled to dismissal or injunctive relief regarding such action and recovery of all costs, losses and attorney's fees related to such action.

7.2 Entire Agreement. This Agreement and the documents referenced herein contain the entire agreement of the parties relating to the employment of Executive by Employer and the ancillary matters discussed herein and supersedes all prior agreements, negotiations and understandings with respect to such matters, including, without limitation, any term sheet between the parties hereto with respect to such matters, and the parties hereto have made no agreements, representations or warranties relating to such employment or ancillary matters which are not set forth herein.

7.3 Withholding Taxes. Employer may withhold from any compensation and Benefits payable under this Agreement all federal, state, city or other taxes as shall be required pursuant to any law or governmental regulation or ruling.

7.4 Golden Parachute Limit. Notwithstanding any other provision of this Agreement, in the event that any portion of the Severance Benefits or any other payment or benefit received or to be received by Executive (whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement) (collectively, the "Total Benefits") would be subject to the excise tax imposed under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code") (the "Excise Tax"), the Total Benefits shall be reduced to the extent necessary so that no portion of the Total Benefits is subject to the Excise Tax; provided, however, that no such reduction in the Total Benefits shall be made if by not making such reduction, Executive's Retained Amount (as hereinafter defined) would be greater than Executive's Retained Amount if the Total Benefits are so reduced. All determinations required to be made under this Section 7.4 shall be made by tax counsel selected by the Company and reasonably acceptable to Executive ("Tax Counsel"), which determinations shall be conclusive and binding on Executive and the Company absent manifest error. All fees and expenses of Tax Counsel shall be borne solely by the Company. Prior to any reduction in Executive's Total Benefits pursuant to this Section 7.4, Tax Counsel shall provide Executive and the Company with a report setting forth its calculations and containing related supporting information. In the event any such reduction is required, the Total Benefits shall be reduced in the following order: (i) the Severance Amount (in reverse order of payment), (ii) any portion of the Total Benefits that are not subject to Section 409A of the Code (other than Total Benefits resulting from any accelerated vesting of equity awards), (iv) other Total Benefits that are subject to Section 409A of the Code in reverse order of payment, and (v) Total Benefits that are not subject to Section 409A and arise from any accelerated vesting of any equity awards. "Retained Amount" shall mean the present value (as determined in accordance with sections 280G(b)(2)(A)(ii) and 280G(d)(4) of the Code) of the Total Benefits net of all federal, state and local taxes imposed on Executive with respect thereto.

7.5 Compliance With Section 409A. This Agreement is intended to comply with the requirements of Section 409A of the Code (including the exceptions thereto), to the extent applicable, and shall be interpreted and administered accordingly. If any provision contained in this Agreement conflicts with the requirements of Section 409A of the Code (or the exemptions intended to apply under this Agreement), this Agreement shall be deemed to be reformed to comply with the requirements of Section 409A of the Code (or applicable exemptions thereto). Notwithstanding anything to the contrary herein, for purposes of determining Executive's entitlement to the Severance Benefits under Section 5 hereof, (a) Executive's employment shall not be deemed to have terminated unless and until Executive incurs a "separation from service" as defined in Section 409A of the Code, and (b) the effective date of any termination or resignation of employment (or any similar term) shall be the effective date of Executive's separation from service. Reimbursement of any expenses provided for in this Agreement shall be made in accordance with the Company's policies (as applicable) with respect thereto as in effect from time to time (but in no event later than the end of calendar year following the year such expenses were incurred) and in no event shall (i) the amount of expenses eligible for reimbursement hereunder during a taxable year affect the expenses eligible for reimbursement in any other taxable year or (ii) the right to reimbursement be subject to liquidation or exchange for another benefit. Notwithstanding anything to the contrary herein, if a payment or benefit under this Agreement is

due to a “separation from service” for purposes of the rules under Treas. Reg. § 1.409A-3(i)(2) (payments to specified employees upon a separation from service) and Executive is determined to be a “specified employee” (as determined under Treas. Reg. § 1.409A-1(i)), such payment shall, to the extent necessary to comply with the requirements of Section 409A of the Code, be made on the later of (x) the date specified by the foregoing provisions of this Agreement or (y) the date that is six (6) months after the date of Executive’s separation from service (or, if earlier, the date of Executive’s death). Any installment payments that are delayed pursuant to the provisions of this section shall be accumulated and paid in a lump sum on the first day of the seventh month following Executive’s separation from service (or, if earlier, upon Executive’s death) and the remaining installment payments shall begin on such date in accordance with the schedule provided in this Agreement. To the extent permitted by Section 409A, each payment hereunder shall be deemed to be a separate payment for purposes of Section 409A of the Code.

7.6 Amendments. No amendment or modification of the terms of this Agreement shall be valid unless made in writing and signed by both Executive and Employer.

7.7 Severability; Reformation. Whenever possible, each provision of this Agreement shall be interpreted in such a manner as to be effective and valid under applicable Law but if any provision of this Agreement is held to be invalid, illegal or unenforceable under any applicable Law or rule, the validity, legality and enforceability of the other provisions of this Agreement will not be affected or impaired thereby. If any provision of this Agreement is found invalid, illegal or unenforceable because it is too broad in scope, too lengthy in duration or violates any Law or regulation, it shall be reformed by limiting its scope, limiting its duration or construing it to avoid such violation (as the case may be) while giving the greatest effect to the intent of the parties as is legally permissible.

7.8 No Waiver. No waiver of any provision of this Agreement shall in any event be effective unless the same shall be in writing and signed by the party against whom such waiver is sought to be enforced, and any such waiver shall be effective only in the specific instance and for the specific purpose for which given.

7.9 Assignment; No Third Party Beneficiary. This Agreement is a personal service contract, and shall not be assignable by Executive. This Agreement shall be assignable by Employer to any successor to the business of Employer, without the written consent of Executive; provided, however, that the assignee or transferee is the successor to all or substantially all of the business assets of Employer and such assignee or transferee expressly assumes all the obligations, duties, and liabilities of Employer set forth in this Agreement. Any purported assignment of this Agreement in violation of this Section 7.9 shall be null and void. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns, and no other Person shall have any right, benefit or obligation hereunder.

7.10 Counterparts; Facsimile Signatures. This Agreement may be executed in separate counterparts, each of which will be an original and all of which taken together shall constitute one and the same agreement, and any party hereto may execute this Agreement by signing any such counterpart. A facsimile signature by any party on a counterpart of this Agreement shall be binding and effective for all purposes. Such party shall subsequently deliver to the other party an original, executed copy of this Agreement; provided, however, that a failure of such party to deliver an original, executed copy shall not invalidate Executive’s or its signature.

7.11 Notices. All notices, instructions and other communications given hereunder or in connection herewith shall be in writing. Any such notice, instruction or communication shall be sent either (i) by registered or certified mail, return receipt requested, postage prepaid, or (ii) prepaid via a reputable nationwide overnight courier service, in each case addressed as follows:

If to the Company, to: AGTC
14193 NW 119th Terrace
Alachua, FL 32615
Attention: Director of Human Resources
Attention: General Counsel

If to the Executive, to: Mark S. Shearman

or to such other address as either the Company or the Executive may have furnished to the other in writing in accordance herewith). Any such notice, instruction or communication shall be deemed to have been delivered five business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, or one business day after it is sent via a reputable nationwide overnight courier service. Either party may give any notice, instruction or other communication hereunder using any other means, but no such notice, instruction or other communication shall be deemed to have been duly delivered unless and until it actually is received by the party for whom it is intended.

7.12 Interpretation. The headings contained in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

7.13 Cumulative Remedies. The rights and remedies of the parties hereunder are cumulative and not exclusive of any rights or remedies any party hereto may otherwise have.

7.14 Expenses Relating to this Agreement. Each party shall pay its or Executive's own expenses incident to the negotiation, preparation and execution of this Agreement.

7.15 Acknowledgement. Executive acknowledges that Executive has been advised to and has been given the opportunity to consult with legal counsel for the purposes of reviewing this Agreement, including the non-competition and non-solicitation covenants contained herein. Executive further acknowledges that he or she has been given 10 business days to consider the terms of this Agreement. If Executive executes this Agreement prior to the end of the 10 business day period, he or she agrees and acknowledges that such execution was a knowing and voluntary waiver of his or her right to consider this Agreement for the full 10 business day period.

IN WITNESS WHEREOF, Executive and Employer have executed this Employment Agreement as of the date set forth in the first paragraph.

APPLIED GENETIC TECHNOLOGIES
CORPORATION

By: /s/ Susan B. Washer
Name: Susan B. Washer
Title: President and CEO

Date: August 29, 2019

EXECUTIVE

/s/ Mark S. Shearman
Name: Mark S. Shearman

Date: August 26, 2019

Schedule A - Permitted Outside Activities

Pursuant to Section 3.3 of the Employment Agreement, Executive has disclosed and the Board has approved his participation in the following outside activities:

Exhibit A

GENERAL RELEASE AND WAIVER OF ALL CLAIMS
(INCLUDING OLDER WORKER BENEFITS PROTECTION ACT CLAIMS AND
AFFIRMATION OF NONCOMPETE)

For good and valuable consideration, including without limitation the compensation and benefits set forth in the Employment Agreement dated 2019 (the "Agreement") between the undersigned and Applied Genetic Technologies Corporation (the "Company"), to which this General Release and Waiver of All Claims is attached, the terms of which Agreement shall survive this General Release and Waiver of Claims, the undersigned, on behalf of and for himself or herself and his or her heirs, administrators, executors, representatives, estates, attorneys, insurers, successors and assigns (hereafter referred to separately and collectively as the "Releasor"), hereby voluntarily releases and forever discharges the Company, and its subsidiaries (direct and indirect), affiliates, related companies, divisions, predecessor and successor companies, and each of its and their present, former, and future shareholders, officers, directors, employees, agents, representatives, attorneys, insurers and assigns (collectively as "Releasees"), jointly and individually, from any and all actions, causes of action, claims, suits, charges, complaints, contracts, covenants, agreements, promises, debts, accounts, damages, losses, sums of money, obligations, demands, and judgments all of any kind whatsoever, known or unknown, at law or in equity, in tort, contract, by statute, or on any other basis, for contractual, compensatory, punitive or other damages, expenses (including attorney's fees and cost), reimbursements, or costs of any kind, which the undersigned employee ever had, now has, or may have, from the beginning of the world to the date of this Release, known or unknown, in law or equity, whether statutory or common law, whether federal, state, local or otherwise, including but not limited to any and all claims arising out of or in any way related to the undersigned's engagement by the Company (including the hiring or termination of that engagement), or any related matters including, but not limited to claims, if any arising under the Age Discrimination in Employment Act of 1967, as amended by the Older Worker Benefits Protection Act; the Civil Rights Act of 1964, as amended; the Civil Rights Act of 1991, as amended; the Family and Medical Leave Act of 1993, as amended; the Immigration Reform and Control Act of 1986; the Americans with Disabilities Act of 1990, as amended; the Employee Retirement Income Security Act (ERISA), as amended; the Florida Civil Rights Act, FLA. STAT. Sections 760.01 - 760.11; FLA STAT. Sections 448.01 et seq.; Mass. Gen. L. c. 151B, section 1 et seq.; Mass. Gen. L. c. 149, section 1 et seq.; Mass. Gen. L. c. 151, section 1A et seq.; and federal, state or local common law, laws, statutes, ordinances or regulations. Notwithstanding the foregoing, nothing contained in this General Release and Waiver of Claims shall be construed to bar any claim by the undersigned to enforce the terms of the Agreement.

Releasor represents and acknowledges the following:

- (a) that Releasor understands the various claims Releasor could have asserted under federal or state law, including but not limited to the Age Discrimination in Employment Act and other similar laws;

-
- (b) that Releasor has read this General Release carefully and understands all of its provisions;
 - (c) that Releasor understands that Releasor has the right to and is advised to consult an attorney concerning this General Release and in particular the waiver of rights Releasor might have under the laws described herein and that to the extent, if any, that Releasor desired, Releasor availed himself or herself of this right;
 - (d) that Releasor has been provided at least forty-five (45) days to consider whether to sign this General Release and that to the extent Releasor has signed this General Release before the expiration of such forty-five (45) day period Releasor has done so knowingly and willingly;
 - (e) that Releasor enters into this General Release and waives any claims knowingly and willingly; and

that this General Release shall become effective seven (7) business days after it is signed. Releasor may revoke this General Release within seven (7) business days after it is signed by delivering a written notice of rescission to Scott Koenig, Chair of AGTC, c/o MacroGenics, Inc., 1500 East Gude Drive, Rockville, MD 20850. To be effective, the notice of rescission must be hand delivered, or postmarked within the seven (7) business day period and sent by certified mail, return receipt requested, to the referenced address.

A. Executive acknowledges that Executive remains bound by Executive's obligations set forth in Sections 6.1, 6.2, 6.3, 6.4, 6.5, 6.6(a), 6.6(c), 6.7, 6.8, 6.9, 6.10 and 6.11 of the Agreement. Executive confirms that for a period of one year following the termination of Executive's employment with the Company, Executive shall not either directly or indirectly, on Executive's own or another's behalf, engage in or assist others in any of the following activities (except on behalf of Company):

- (i) (whether as principal, agent, partner or otherwise) engage in, own, manage, operate, control, finance, invest in, participate in, or otherwise carry on, or be employed by, associated with, or in any manner connected with, lend such Executive's name to, lend Executive's credit to, or render services or advice to a Competing Business anywhere in the Geographic Area; or
- (ii) provide or develop any products, technology or services that are the same or Substantially Similar to the products, technology and services provided or developed by the Company or any of its Affiliates.

The capitalized terms herein have the meanings set forth in section 6.7 of the Agreement.

Executive agrees that Executive will not disparage or encourage or induce others to disparage any of the Company, its subsidiaries and affiliates, together with all of their respective past and present directors and officers and each of their successors and assigns. Nothing herein is intended to or shall prevent Executive from providing limiting testimony in response to a valid subpoena, court

order, regulatory request or other judicial, administrative or legal process or otherwise as required by law.

Signed and sealed this day of , 20 .

Signed: _____

Name (print): Mark S. Shearman

EXHIBIT B
LIST OF PRIOR INVENTIONS

Title

Date

Brief Description

No Inventions.

Additional sheets attached.

Date:

Signature /s/ Mark S. Shearman

Name Mark S. Shearman

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of the 29th day of August, 2019 by and between Applied Genetic Technologies Corporation, a Delaware corporation, including its successors and assigns, (the "Employer" or "Company"), and Stephen W. Potter ("Executive").

NOW, THEREFORE, in consideration of the promises and the respective undertakings of Employer and Executive set forth below, Employer and Executive hereby agree as follows:

1. Employment. Employer hereby employs Executive, and Executive hereby accepts such employment and agrees to perform services for Employer, for the period and on the other terms and subject to the conditions set forth in this Agreement. Employee's Start Date shall be and shall be considered the Effective Date of this Agreement.

2. Employment at Will. Executive is employed "at-will" which means that Executive's employment is not for any defined term and may be terminated by either Executive or the Company at any time, with or without cause, for any or no reason, subject to the notice provisions herein.

3. Position and Duties.

3.1 Service with Employer. Employer hereby employs Executive in an executive capacity with the title of Chief Business Officer and Executive hereby accepts such employment and undertakes and agrees to serve in such capacity. Executive shall have such powers, perform such duties and fulfill such responsibilities as are typically associated with such position in other similarly situated companies and shall report directly to the Company's President and Chief Executive Officer,

3.2 Performance of Duties. Executive agrees to: (i) devote substantially all of Executive's business time, attention and efforts to the business and affairs of Employer while employed; and (ii) adhere to all Employer's written employment policies and procedures as shall be in force from time to time.

3.3 Outside Activities. During the Term, Executive shall not: (i) except as set forth below, accept other employment; (ii) except as set forth below, render or perform services for compensation to any Person (as hereinafter defined) other than Employer; (iii) serve as an officer or on the board of directors (or similar governing body) of any entity other than Employer, whether or not for compensation; or (iv) engage in any other business, enterprise or activity that will require any effort on the part of Executive that, in the sole discretion of Employer, could reasonably be expected to materially detract from the ability of Executive to perform Executive's duties to Employer pursuant to this Agreement; provided, however, Executive may engage in the activities set forth in Schedule A hereto or described in clause (iii) or (iv) above if prior to engaging in such activity, Executive has disclosed such activity to the Board and received written approval to engage in such activity from the Board. Executive may engage in personal investments without disclosure to or written approval from the Board provided Executive is not required or expected to serve as a board member, advisor or consultant and Executive shall, at any time, own beneficially

less than 2% of the outstanding securities of any issuer and such personal investment shall not otherwise interfere with Executive's performance of duties hereunder and/or the provisions of Executive's written agreements with Employer.

3.4 Executive Representations. Executive represents that Executive is not subject to any restrictive covenant, confidentiality agreement, or any other agreement that would prevent Executive from accepting employment with Employer, and based on the information provided to Employer by Executive, Employer accepts such representation.

4. Compensation.

4.1 Base Salary. Employer shall pay to Executive a base salary for all services to be rendered by Executive under this Agreement (the "Base Salary"), which Base Salary shall be paid in accordance with Employer's normal payroll schedule, procedures and policies (which schedule, procedures and policies may be modified from time to time) and subject to applicable deductions as required by law. Employer shall review Executive's salary on an annual basis and may, in its discretion, consider and declare from time to time increases in the Base Salary that it pays Executive. Any and all increases in Executive's salary pursuant to this section shall cause the level of Base Salary to be increased by the amount of each such increase for purposes of this Agreement. The increased level of Base Salary as provided in this section shall become the level of Base Salary for the remainder of the term of this Agreement unless there is a further increase in Base Salary as provided herein. Notwithstanding the foregoing, the Base Salary of Executive may be decreased provided it is done so in proportion to decreases in Base Salary of the entire executive team of the Company.

4.2 Annual Bonus. The Executive will be eligible to participate in the Employer's annual cash incentive compensation plan on substantially the same terms as other executive officers. Company-wide and individual performance objectives ("MBOs") will be established by the Compensation Committee. Target incentives do not constitute a promise of payment and the Executive's actual bonus, if any, will depend in part on the Employer's performance and the Compensation Committee's discretion in assessing the Executive's individual performance in relation to his or her MBOs and the overall performance and status of the Company. To qualify for the incentive bonus, the Executive must remain employed with the Company through the date that the incentive bonus is paid in accordance with the Employer's normal practice.

4.3 Participation in Benefit Plans. Executive shall be entitled to participate in all employee benefit plans or programs offered to other senior executives from time to time (to the extent that Executive meets the requirements for each such plan or program), including participation in any health insurance plan, disability insurance plan, dental plan, eye care plan, 401(k) plan, life insurance plan, or other similar plans (all such benefits, the "Benefit Plans"). Some or all of the benefits may be provided by Employer's leasing agent TriNet (or its successor(s) or assign(s)).

4.4 Expenses. Employer shall reimburse Executive for all ordinary and necessary business expenses reasonably incurred by him in the performance of Executive's duties under this Agreement, subject to the presentment and approval of appropriate itemized expense statements, receipts, vouchers or other supporting documentation in accordance with Employer's normal policies for expense verification in effect from time to time.

4.5 Paid Time Off. Executive shall be entitled to paid time off pursuant to Employer's standard paid time off policies in the same manner as the Company's other Senior Executives. Unused paid time off may be carried over from year to year, but in no case may more than 45 days (360 hours) of unused paid time off be accrued.

4.6 Total Compensation. Executive shall not receive any other compensation or benefits other than as provided in Sections 4.1 through 4.5 hereof.

5. Payments Upon Termination.

5.1 Voluntary Resignation without Good Reason. Executive may terminate Executive's employment by providing Employer with 30 days' advance written notice. If Executive terminates Executive's employment (other than for Good Reason (either prior to or within 12 months following a Change in Control) or by reason of Disability, each as defined below) (i) Employer shall pay to Executive the Accrued Obligations (as defined below), (ii) Executive's participation in the Benefit Plans shall terminate as of the Termination Date, and (iii) Employer shall have no other obligations to Executive under this Agreement, other than those provided in this Section 5.1.

(a) For purposes of this Agreement, "Accrued Obligations" means: (i) Executive's earned and unpaid Base Salary through the Termination Date; (ii) reimbursement for any reimbursable business expenses incurred by Executive through the Termination Date in accordance with Section 4.4; and (iii) Executive's accrued but unused paid time off as of the Termination Date. The amounts payable pursuant to clauses (i) and (iii) hereof shall be paid no later than sixty (60) days following Executive's Termination Date.

(b) For purposes of this Agreement, "Termination Date" means: the effective date of Executive's "separation from service" as defined in Section 409A of the Internal Revenue Code of 1986, as amended (the "Code").

5.2 Termination by Employer For Cause. If Executive is terminated for Cause: (i) Employer shall pay to Executive the Accrued Obligations, (ii) Executive's participation in the Benefit Plans shall terminate as of the Termination Date, and (iii) Employer shall have no further obligations to Executive under this Agreement, other than those provided in this Section 5.2. For purposes of this Agreement, "Cause" means: (a) Executive's failure to substantially perform Executive's duties with the Company (if Executive has not cured such failure to substantially perform, if curable, within thirty (30) days after Executive's receipt of written notice thereof from the Board that specifies the conduct constituting Cause under this clause (a)); (b) Executive's willful misconduct, or gross negligence in the performance of Executive's duties hereunder; (c) the conviction of Executive for, or the entering by Executive of a guilty plea or plea of no contest with respect to, any crime that constitutes a felony or involves fraud, dishonesty or moral turpitude; (d) Executive's commission of an act of fraud, embezzlement or misappropriation against the Company; (e) Executive's material breach of the fiduciary duty owed by Executive to the

Company; (f) Executive's engaging in any improper conduct that has or is likely to have an adverse economic or reputational impact on the Company; or (g) Executive's material breach of this Agreement.

5.3 Termination by Employer Without Cause or by Executive for Good Reason If Executive's employment is terminated (a) by Employer without Cause (other than upon Disability or death) or (b) by Executive for Good Reason either prior to a Change in Control or within twelve (12) months following a Change in Control: (i) Employer shall pay to Executive the Accrued Obligations, (ii) Executive shall be entitled to receive the Severance Benefits (as defined below in Section 5.5 and subject to the conditions described therein and in Section 5.6), and (iii) Employer shall have no further obligations to Executive under this Agreement, other than those provided in this Section 5.3. For purposes of this Agreement, "Good Reason" means the occurrence of any of the following events (without Executive's consent):

- (a) a material adverse change in Executive's functions, duties, or responsibilities with the Company which change would cause Executive's position to become one of materially lesser responsibility, importance, or scope;
- (b) a relocation of the Executive's principal workplace to a location more than 50 miles from the location of such workplace immediately prior to the Change in Control without the Executive's express written consent;
- (c) a material diminution in the Executive's compensation or benefits without the express written consent of the Executive, other than an across-the-board reduction in compensation levels that applies to all senior executives generally; or
- (d) a material breach of this Agreement by the Company.

Notwithstanding the foregoing, no such event shall constitute "Good Reason" unless (a) Executive shall have given written notice of such event to the Company within ninety (90) days after the initial occurrence thereof, (b) the Company shall have failed to cure the condition constituting Good Reason within thirty (30) days following the delivery of such notice (or such longer cure period as may be agreed upon by the parties), and (c) Executive terminates employment within thirty (30) days after expiration of such cure period.

5.4 Termination by Employer due to Executive's Death or Disability. If Executive's employment is terminated by reason of death or Disability (as defined below): (i) Employer shall pay to Executive the Accrued Obligations, (ii) Executive's participation in the Benefit Plans shall terminate as of the Termination Date (except to the extent Executive is eligible for continued disability benefits under the applicable Employer plan), and (iii) Employer shall have no further obligations to Executive under this Agreement, other than those provided in this Section 5.4. For purposes of this Agreement, "Disability" means Executive being determined to be totally disabled by the Social Security Administration or Executive's inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve months.

5.5 Severance Benefits. “Severance Benefits” means:

(a) The payment to Executive of the Severance Amount in a lump sum immediately following the Termination Date.

(b) For this purpose, “Severance Amount” means:

(i) In the event that Executive’s employment is terminated without Cause or by the Executive for Good Reason, in each case, within twelve (12) months following a Change in Control, an amount equal to the sum of (A) the product of 1.0 multiplied by Executive’s annual Base Salary plus (B), the product of 1.0 multiplied by the Executive’s target bonus in effect immediately prior to the Date of Termination.

(ii) In the event that Executive’s employment is terminated without Cause (other than within twelve (12) months of a Change in Control), an amount equal to the sum of (A) the product of 0.75 multiplied by Executive’s annual Base Salary plus (B), the product of the Executive’s target bonus in effect immediately prior to the Date of Termination multiplied by a fraction equal to the quotient of the number of days during such year on which the Executive was employed by the Company, divided by 365.

(c) The continuation of Executive’s participation in the Company’s medical, dental, and vision benefit plans at the same premium cost to Executive as charged to Executive immediately prior to the Termination Date for a period of (i) in the event that the Executive’s employment is terminated without Cause or by the Executive for Good Reason, in each case, within twelve (12) months following a Change in Control, twelve (12) months immediately following the Termination Date or (ii) in the event that the Executive’s employment is terminated without Cause (other than within twelve (12) months of a Change in Control) nine (9) months immediately following the Termination Date (in each case, the “Continuation Period”), or if earlier, until Executive obtains other employment which provides the same type of benefit; provided, however, that (i) it is understood and agreed that such continued medical, dental and vision benefits may at the election of the Company be provided by Executive electing the continuation of such coverage pursuant to COBRA with the Company reimbursing Executive for COBRA premiums to the extent required so that Executive’s premium cost for the coverage in effect for Executive prior to the Termination Date is substantially the same as immediately prior to the Termination Date, and (ii) if the Company determines, in its reasonable judgment, that providing medical, dental, and/or vision benefits in accordance with the preceding provisions of this Section 5.5(c) would result in a violation of applicable law, the imposition of any penalties under applicable law, or adverse tax consequences for participants covered by the Company’s medical, dental, and/or vision plans, the Company may terminate such

coverage (or reimbursement) with respect to Executive and instead pay to Executive taxable cash payments at the same time and in the same amounts as the Company would have paid as premiums (or as COBRA premium reimbursements) to provide such coverage.

(d) Acceleration of vesting as follows:

(i) In the event that Executive's employment is terminated by Employer without Cause or by Executive for Good Reason, in each case, within twelve (12) months following a Change in Control: each stock option, restricted stock unit, restricted stock award or other stock-based compensatory award granted by the Company to Executive that is outstanding as of the Termination Date and is not fully vested as of the date of the Termination Date (each an "Award"), shall become fully vested as of the date Executive provides the Company with the Irrevocable Release provided for in this Section 5.5 within the period prescribed therein.

(ii) In the case of any Award the vesting of which is contingent in whole or in part upon the attainment of any Company or market performance condition that has not yet been satisfied, such condition shall be deemed to have been satisfied as of the date of termination at the level that would result in vesting of 100% of the number of shares stated as the target award.

(e) For purposes of this Agreement, "Change of Control" means, and shall be deemed to have occurred, if:

(i) any Person, excluding (i) employee benefit plans of the Company or any of its Affiliates, is or becomes the "beneficial owner" (as defined in Rules 13d-3 and 13d-5 under the Exchange Act, which Rules shall apply for purposes of this clause (a) whether or not the Company is subject to the Exchange Act), directly or indirectly, of Company securities representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities ("Voting Power");

(ii) the Company consummates a merger, consolidation, share exchange, division or other reorganization or transaction of the Company (a "Fundamental Transaction") with any other corporation, other than a Fundamental Transaction that results in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) at least fifty percent (50%) of the combined Voting Power immediately after such Fundamental Transaction of (i) the Company's outstanding securities, (ii) the surviving entity's outstanding securities, or (iii) in the case of a division, the outstanding securities of each entity resulting from the division;

(iii) the stockholders of the Company approve a plan of complete liquidation or winding-up of the Company or the consummation of the sale or disposition (in one transaction or a series of transactions) of all or substantially all of the Company's assets; or

(iv) during any period of 24 consecutive months, individuals who at the beginning of such period constituted the Board (including for this purpose any new director whose election or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds (2/3) of the directors then still in office who were directors at the beginning of such period or whose appointment, election or nomination was previously so approved or recommended) cease for any reason to constitute at least a majority of the Board.

5.6 Required Delivery of Irrevocable Release: Compliance with Section 6 Obligations. Notwithstanding the provisions of Section 5.5, as a condition to entitlement to the Severance Benefits, Executive must provide to the Company an Irrevocable Release and Noncompete Affirmation not later than the sixtieth day after the Date of Termination; provided however that if the sixty day period begins in one calendar year and ends in a subsequent calendar year, any payment to be made or benefit to be provided upon receipt of the Irrevocable Release and Noncompete Affirmation shall not be made or provided until the subsequent year. In the event Executive fails to provide an Irrevocable Release and Noncompete Affirmation to the Company within such sixty day period, the Company will immediately cease to pay or provide any further Severance Benefits, no accelerated vesting of stock options or other awards pursuant to Section 5.5(d) shall occur, and Executive shall be obligated to immediately repay to the Company all previously paid or provided Severance Benefits. "Irrevocable Release and Noncompete Affirmation" means a confidential separation agreement, release of claims and affirmation of noncompete, in form and substance substantially similar to the attached Exhibit A that has been executed by Executive, delivered to the Company, and become irrevocable by Executive. In addition, in the event that Executive breaches the obligations under Section 6 of this Agreement at any time during the Continuation Period, Executive will cease to be entitled to any further Severance Benefits.

6. Promises and Covenants Regarding Confidential Information and Goodwill; Inventions and Assignment; Restrictive Covenants

6.1 Confidential Information and Goodwill. In consideration of Executive's promises and covenants contained in this Agreement, including Executive's promise and covenant not to disclose Confidential Information, Employer will provide Executive with Confidential Information. In further consideration of Executive's promises and covenants contained in this Agreement, including Executive's promise and covenant to utilize the Goodwill exclusively for the benefit of Employer, Employer will allow Executive to receive Confidential Information concerning the Company's customers, labs, vendors and employees and, to the extent required to fulfill Executive's duties, the Company will permit Executive to represent the Company on its behalf with such persons. To the extent that Executive's duties involve sales or customer relations, the Company will permit Executive to utilize the Goodwill in Executive's sales efforts and will provide sales support to Executive similar to that which it provides to its sales representatives.

6.2 Duties. While employed by Company, Executive shall perform the duties required of Executive hereunder and shall devote Executive's best efforts and exclusive business time, energy and skill to performing such duties; not make any disparaging remarks regarding Company to any person with whom Company has business relations, including any employee or vendor of Company; use the Goodwill solely for the benefit of Company; and not interfere in such Goodwill, either during or following Executive's employment with Company.

6.3 Delivery of Company Property. Executive recognizes that all documents, magnetic media and other tangible items which contain Confidential Information are the property of Company exclusively. Upon request by Company or termination of Executive's employment with Company, Executive shall promptly return to Company all Confidential Information and Company Property within Executive's possession and control, and shall refrain from taking any Confidential Information or Company Property or allowing any Confidential Information or Company Property to be taken from Company; and immediately return to Company all information pertaining to Company or Company Property in Executive's possession.

6.4 Promise and Covenant Not to Disclose. The parties acknowledge that Company is the sole and exclusive owner of Confidential Information, and that Company has legitimate business interests in protecting Confidential Information. The parties further acknowledge that Company has invested, and continues to invest, considerable amounts of time and money in obtaining, developing, and preserving the confidentiality of Confidential Information and that, by reason of the trust relationship arising between Executive and Company, Executive owes Company a fiduciary duty to preserve and protect Confidential Information from all unauthorized disclosure and unauthorized use. Executive shall not, directly or indirectly, disclose Confidential Information to any third party (except to Executive's attorneys, the Company's personnel, other persons designated in writing by the Company, or except as otherwise provided by law) or use Confidential Information for any purpose other than for the direct benefit of Company while in Company's employ and thereafter.

6.5 Inventions and Assignment. Executive agrees that he will promptly disclose to the Company any and all Company Inventions and that Executive hereby irrevocably assigns to the Company all ownership rights in and to any and all Company Inventions. During Executive's

employment or at any time thereafter, upon request of the Company, Executive will sign, execute and deliver any and all documents or instruments, including, without limitation, patent applications, declarations, invention assignments and copyright assignments, and will take any other action which the Company shall deem necessary to perfect in the Company trademark, copyright or patent rights with respect to Inventions, or to otherwise protect the Company's trade secrets and proprietary interests. The term "Inventions" means discoveries; developments; trade secrets; processes; formulas; data; lists; software programs; graphics; artwork; logos, and all other works of authorship, ideas, concepts, know-how, designs, and techniques, whether or not any of the foregoing is or are patentable, copyrightable, or registrable under any intellectual property laws or industrial property laws in the United States. The term "Company Inventions" means all Inventions that (a) relate to the business or proposed business of the Company or any of its predecessors or that are discovered, developed, created, conceived, reduced to practice, made, learned or written by Executive, either alone or jointly with others, in the course of Executive's employment; (b) utilize, incorporate or otherwise relate to Confidential Information; or (c) are discovered, developed, created, conceived, reduced to practice, made, or written by him using property or equipment of the Company or any of its predecessors. Executive agrees to promptly and fully communicate in writing to the Company (to such department or officer of the Company and in accordance with such procedures as the Company may direct from time to time) any and all Company Inventions. Executive acknowledges and agrees that any work of authorship by Executive or others comprising Company Inventions shall be deemed to be a "work made for hire," as that term is defined in the United States Copyright Act (17 U.S.C. § 101 (2000)). To the extent that any such work of authorship may not be deemed to be a work made for hire, Executive hereby irrevocably assigns any ownership rights Executive may have in and to such work to the Company. This Agreement does not apply to any Inventions Executive made before Executive's employment with the Company. To clearly establish Executive's rights, Executive has listed on Exhibit B any Inventions, whether or not patentable or copyrightable and whether or not reduced to practice, made by him prior to Executive's employment with the Company that are owned by Executive ("*Prior Inventions*"), together with the approximate dates of their creation. If no such list is attached, Executive represents that there are no Prior Inventions.

6.6 Other Promises and Covenants. In consideration for the benefits specifically provided for in this Section 6.6 and that may otherwise be provided pursuant to this Agreement, including but not limited to the benefits payable pursuant to Section 5.5, Executive hereby promises and covenants as follows.

(a) In consideration of payment to Executive of \$500.00, less applicable withholdings, Executive agrees that during Executive's employment with Company and, unless this Section 6.6(a) is waived by the Company in writing, for a period of one year following termination of employment for any reason other than the Company's termination of Executive's employment without Cause (the "Non-Competition Period"), Executive shall not either directly or indirectly, on Executive's own or another's behalf, engage in or assist others in any of the following activities (except on behalf of Company):

(i) (whether as principal, agent, partner or otherwise) engage in, own, manage, operate, control, finance, invest in, participate in, or otherwise carry on, or be employed by, associated with, or in any manner

connected with, lend such Executive's name to, lend Executive's credit to, or render services or advice to a Competing Business anywhere in the Geographic Area; or

(ii) provide or develop any products, technology or services that are the same or Substantially Similar to the products, technology and services provided or developed by the Company or any of its Affiliates.

(b) Unless Section 6.6(a) is waived by the Company in writing, as mutually-agreed upon consideration for the post-employment restriction described herein, the Company will pay Executive \$10,000.00 within one month of Executive's date of termination. Notwithstanding the foregoing, in the event that Executive has breached his or her fiduciary duty to the Company or has unlawfully taken, physically or electronically, property belong to the Company, then the Non-Competition Period shall be extended for an additional period of one year.

(c) During Executive's employment with Company and for a period of two years following termination of employment for any reason (the "Non-Solicitation Period"), Executive shall not either directly or indirectly, on Executive's own or another's behalf, engage in or assist others in any of the following activities:

(i) induce or attempt to induce any customer, agent, supplier, licensee, or business relation of the Company or any of its Affiliates to cease doing business with the Company or any of its Affiliates, or in any way interfere with the relationship between any customer, supplier, licensee, or business relation of the Company or any of its Affiliates; or

(ii) on behalf of a Competing Business, solicit or attempt to solicit the business or patronage of any Person who is a customer or agent of the Company or any of its Affiliates, whether or not Executive had personal contact with such Person.

(iii) solicit, encourage, or take any other action which is intended to induce any employee, independent contractor or agent of the Company or any of its Affiliates to terminate Executive's employment or other business relationship with the Company or such Affiliate;

(iv) in any way interfere in any manner with the employment or other business relationship between the Company and/or any of its Affiliates, on the one hand, and any employee, independent contractor or agent of the Company or such Affiliate, on the other hand; or

(v) employ, or otherwise engage as an employee, independent contractor or otherwise, any individual who was an employee, independent contractor, agent or was otherwise affiliated with the Company or any of its Affiliates from the period beginning one year prior to the date on which Executive became employed and continuing through the expiration of the Non-Solicitation Period.

provided, however, that nothing set forth in this Section 6 shall prohibit Executive from owning, as a passive investment, not in excess of five percent (5%) in the aggregate of any class of capital stock of any corporation if such stock is publicly traded and listed on any national or regional stock exchange or reported on the Nasdaq Stock Market.

6.7 Definitions. For purposes hereof:

(a) “*Affiliate*” means, with respect to any Entity, any Entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or under common control with, such Entity.

(b) “*Agreement*” means this Employment Agreement.

(c) “*Company Business*” means (i) any business related to providing services related to, manufacturing, selling or distributing gene therapy products using adeno-associated virus technology for the treatment of inherited and acquired diseases or conducting research or development with regard thereto; and (ii) any other business that the Company is actively engaged in researching, developing or marketing at the time of the termination of Executive’s employment, provided that this clause (ii) shall only apply if Executive is involved with the research, development, or marketing of that other business.

(d) “*Company Property*” means all physical materials, documents, information, keys, computer software and hardware, including laptop computers and mobile or handheld scheduling computers, manuals, data bases, product samples, tapes, magnetic media, technical notes and any other equipment or items which Company provides for or to Executive or which otherwise belongs to the Company, and those documents and items which Executive may develop or help develop while in Company’s employ, whether or not developed during regular working hours or on Company’s premises. The term “*Company Property*” shall include the original of such materials, any copies thereof, any notes derived from such materials, and any derivative work of such materials.

(e) “*Competing Business*” means any other Entity engaged in the Company Business, other than the Company and its Affiliates.

(f) “*Confidential Information*” means the trade secrets and other information of Company, including but not limited to (i) the customer lists, customer contact information, customer purchase information, pricing information, strategic and marketing plans, compilations of customer information, names of employees, contracts with third parties, training, financial and marketing books, sales projections, internal employer databases, reports, manuals and information including information related to Company, its Affiliates or its customers, including those documents and items which any employee may develop or help develop while

in the employ of the Company or any of its Affiliates, whether or not developed during regular working hours or on the premises of the Company or such Affiliate; (ii) the identity, skills, personnel file information, performance appraisals and compensation of job applicants, employees, contractors, and consultants; (iii) specialized training; (iv) source code, scripts, user screens, reports or any other information pertaining to the internal information technology or network of the Company and/or its Affiliates; and (v) information related to inventions owned by the Company or any of its Affiliates or licensed from third parties; and unless the context requires otherwise, the term “Confidential Information” includes the original of such materials, any copies thereof, any notes derived from such materials, and any derivative work of such materials. The term “Confidential Information” does not include (1) information that was or becomes generally available publicly other than through disclosure by Executive, or (2) is required to be disclosed to any governmental agency or self-regulatory body or is otherwise required to be disclosed by law. Unless the context requires otherwise, the term “Confidential Information” shall include the original of such materials, any copies thereof, any notes derived from such materials, and any derivative work of such materials.

(g) “*Entity*” means and includes any person, partnership, association, corporation, limited liability company, trust, unincorporated organization or any other business entity or enterprise.

(h) “*Geographic Area*” means those states in which the Company or any of its subsidiaries conducts business or in which its products are being sold or marketed at the time of the termination of Executive’s employment.

(i) “*Goodwill*” means the value of the relationships between the Company and its agents, customers, vendors, labs, and employees.

(j) “*Substantially Similar*” means substantially similar in function or capability or otherwise competitive to the products or services being developed, manufactured or sold by the Company during and/or at the end of Executive’s employment, or are marketed to substantially the same type of user or customer as that to which the products and services of the Company are marketed or proposed to be marketed.

6.8 Acknowledgements Regarding Other Promises and Covenants. With regard to the promises and covenants set forth herein, Executive acknowledges and agrees that:

(a) the restrictions are ancillary to an otherwise enforceable agreement including the provisions of this Agreement regarding the disclosure, ownership and use of the Confidential Information and Goodwill of Company;

(b) the limitations as to time, geographical area, and scope of activity to be restricted are reasonable and acceptable to Executive, and do not impose any greater restraint than is reasonably necessary to protect the Goodwill and other legitimate business interests of Company;

(c) the performance by Executive, and the enforcement by Company, of such promises and covenants will cause no undue hardship on Executive;

(d) the time periods covered by the promises and covenants will not include any period(s) of violation of, or any period(s) of time required for litigation brought by Company to enforce any such promise or covenant, it being understood that the extension of time provided in this paragraph may not exceed two (2) years.

6.9 Duty to Give Notice of Agreement. During employment by Company and the period of any post-employment obligation applicable hereunder, Executive shall provide written notice to any prospective employer of Executive's obligations under this Agreement, and shall provide a true copy hereof to such prospective employer at the outset of any communications about employment.

6.10 Independent Elements. The parties acknowledge that the promises and covenants contained in Section 6 above are essential independent elements of this Agreement and that, but for Executive agreeing to comply with them, Company would not employ Executive. Accordingly, the existence or assertion of any claim by Executive against Company, whether based on this Agreement or otherwise, shall not operate as a defense to Company's enforcement of the promises and covenants in Section 6. An alleged or actual breach of the Agreement by Company will not be a defense to enforcement of any such promise or covenant, or other obligations of Executive to Company. The promises and covenants in Section 6 will remain in full force and effect whether Executive is terminated by Company or voluntarily resigns.

6.11 Remedies for Breach of Agreement. Executive acknowledges that Executive's breach of any promise or covenant contained in Section 6 will result in irreparable injury to Company and that Company's remedies at law for such a breach will be inadequate. Accordingly, Executive agrees and consents that Company, in addition to all other remedies available at law and in equity, shall be entitled to both preliminary and permanent injunctions to prevent and/or halt a breach or threatened breach by Executive of any such promise or covenant, and Executive waives the requirement of the posting of any bond in connection with such injunctive relief. Executive further acknowledges and agrees that the promises and covenants contained in Section 6 are enforceable, reasonable, and valid.

7. Miscellaneous.

7.1 Governing Law; Arbitration

(a) This Agreement is made under and shall be governed by and construed in accordance with the laws of Florida, without regard to its conflicts of law principles.

(b) With respect to claims by the Company against Executive related to Executive's threatened or actual breach of Section 6 of this Agreement, each Party hereby irrevocably agrees that all actions or proceedings concerning such disputes

may be brought by the Company in (a) the United States District Court for the Northern District of Florida; or (b) in any court of the State of Florida sitting in Alachua County, provided that the United States District Court lacks subject matter jurisdiction over such action or proceeding. Executive consents to jurisdiction of and venue in the courts in the State of Florida set forth in this Section, and hereby waives to the maximum extent permitted by applicable law any objection which Executive may have based on improper venue or forum non conveniens.

(c) Except to the extent provided for in subsection (b) above, the Company and Executive agree that any claim, dispute or controversy arising under or in connection with this Agreement, or otherwise in connection with Executive's employment by the Company or termination of his employment (including, without limitation, any such claim, dispute or controversy arising under any federal, state or local statute, regulation or ordinance or any of the Company's employee benefit plans, policies or programs) shall be resolved solely and exclusively by binding, confidential, arbitration. The arbitration shall be held in Gainesville, Florida (or at such other location as shall be mutually agreed by the parties). The arbitration shall be conducted in accordance with the Commercial Rules of the American Arbitration Association (the "AAA") in effect at the time of the arbitration, including the Expedited Procedures. All fees and expenses of the arbitration, including a transcript if either requests, shall be borne equally by the parties. Each party is responsible for the fees and expenses of its own attorneys, experts, witnesses, and preparation and presentation of proofs and post-hearing briefs (unless the party prevails on a claim for which attorney's fees are recoverable under law). In rendering a decision, the arbitrator shall apply all legal principles and standards that would govern if the dispute were being heard in court. This includes the availability of all remedies that the parties could obtain in court. In addition, all statutes of limitation and defenses that would be applicable in court, will apply to the arbitration proceeding. The decision of the arbitrator shall be set forth in writing, and be binding and conclusive on all parties. Any action to enforce or vacate the arbitrator's award shall be governed by the Federal Arbitration Act, if applicable, and otherwise by applicable state law. If either the Company or Executive improperly pursues any claim, dispute or controversy against the other in a proceeding other than the arbitration provided for herein, the responding party shall be entitled to dismissal or injunctive relief regarding such action and recovery of all costs, losses and attorney's fees related to such action.

7.2 Entire Agreement. This Agreement and the documents referenced herein contain the entire agreement of the parties relating to the employment of Executive by Employer and the ancillary matters discussed herein and supersedes all prior agreements, negotiations and understandings with respect to such matters, including, without limitation, any term sheet between the parties hereto with respect to such matters, and the parties hereto have made no agreements, representations or warranties relating to such employment or ancillary matters which are not set forth herein.

7.3 Withholding Taxes. Employer may withhold from any compensation and Benefits payable under this Agreement all federal, state, city or other taxes as shall be required pursuant to any law or governmental regulation or ruling.

7.4 Golden Parachute Limit. Notwithstanding any other provision of this Agreement, in the event that any portion of the Severance Benefits or any other payment or benefit received or to be received by Executive (whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement) (collectively, the "Total Benefits") would be subject to the excise tax imposed under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code") (the "Excise Tax"), the Total Benefits shall be reduced to the extent necessary so that no portion of the Total Benefits is subject to the Excise Tax; provided, however, that no such reduction in the Total Benefits shall be made if by not making such reduction, Executive's Retained Amount (as hereinafter defined) would be greater than Executive's Retained Amount if the Total Benefits are so reduced. All determinations required to be made under this Section 7.4 shall be made by tax counsel selected by the Company and reasonably acceptable to Executive ("Tax Counsel"), which determinations shall be conclusive and binding on Executive and the Company absent manifest error. All fees and expenses of Tax Counsel shall be borne solely by the Company. Prior to any reduction in Executive's Total Benefits pursuant to this Section 7.4, Tax Counsel shall provide Executive and the Company with a report setting forth its calculations and containing related supporting information. In the event any such reduction is required, the Total Benefits shall be reduced in the following order: (i) the Severance Amount (in reverse order of payment), (ii) any portion of the Total Benefits that are not subject to Section 409A of the Code (other than Total Benefits resulting from any accelerated vesting of equity awards), (iv) other Total Benefits that are subject to Section 409A of the Code in reverse order of payment, and (v) Total Benefits that are not subject to Section 409A and arise from any accelerated vesting of any equity awards. "Retained Amount" shall mean the present value (as determined in accordance with sections 280G(b)(2)(A)(ii) and 280G(d)(4) of the Code) of the Total Benefits net of all federal, state and local taxes imposed on Executive with respect thereto.

7.5 Compliance With Section 409A. This Agreement is intended to comply with the requirements of Section 409A of the Code (including the exceptions thereto), to the extent applicable, and shall be interpreted and administered accordingly. If any provision contained in this Agreement conflicts with the requirements of Section 409A of the Code (or the exemptions intended to apply under this Agreement), this Agreement shall be deemed to be reformed to comply with the requirements of Section 409A of the Code (or applicable exemptions thereto). Notwithstanding anything to the contrary herein, for purposes of determining Executive's entitlement to the Severance Benefits under Section 5 hereof, (a) Executive's employment shall not be deemed to have terminated unless and until Executive incurs a "separation from service" as defined in Section 409A of the Code, and (b) the effective date of any termination or resignation of employment (or any similar term) shall be the effective date of Executive's separation from service. Reimbursement of any expenses provided for in this Agreement shall be made in accordance with the Company's policies (as applicable) with respect thereto as in effect from time to time (but in no event later than the end of calendar year following the year such expenses were incurred) and in no event shall (i) the amount of expenses eligible for reimbursement hereunder during a taxable year affect the expenses eligible for reimbursement in any other taxable year or (ii) the right to reimbursement be subject to liquidation or exchange for another benefit. Notwithstanding anything to the contrary herein, if a payment or benefit under this Agreement is

due to a “separation from service” for purposes of the rules under Treas. Reg. § 1.409A-3(i)(2) (payments to specified employees upon a separation from service) and Executive is determined to be a “specified employee” (as determined under Treas. Reg. § 1.409A-1(i)), such payment shall, to the extent necessary to comply with the requirements of Section 409A of the Code, be made on the later of (x) the date specified by the foregoing provisions of this Agreement or (y) the date that is six (6) months after the date of Executive’s separation from service (or, if earlier, the date of Executive’s death). Any installment payments that are delayed pursuant to the provisions of this section shall be accumulated and paid in a lump sum on the first day of the seventh month following Executive’s separation from service (or, if earlier, upon Executive’s death) and the remaining installment payments shall begin on such date in accordance with the schedule provided in this Agreement. To the extent permitted by Section 409A, each payment hereunder shall be deemed to be a separate payment for purposes of Section 409A of the Code.

7.6 Amendments. No amendment or modification of the terms of this Agreement shall be valid unless made in writing and signed by both Executive and Employer.

7.7 Severability; Reformation. Whenever possible, each provision of this Agreement shall be interpreted in such a manner as to be effective and valid under applicable Law but if any provision of this Agreement is held to be invalid, illegal or unenforceable under any applicable Law or rule, the validity, legality and enforceability of the other provisions of this Agreement will not be affected or impaired thereby. If any provision of this Agreement is found invalid, illegal or unenforceable because it is too broad in scope, too lengthy in duration or violates any Law or regulation, it shall be reformed by limiting its scope, limiting its duration or construing it to avoid such violation (as the case may be) while giving the greatest effect to the intent of the parties as is legally permissible.

7.8 No Waiver. No waiver of any provision of this Agreement shall in any event be effective unless the same shall be in writing and signed by the party against whom such waiver is sought to be enforced, and any such waiver shall be effective only in the specific instance and for the specific purpose for which given.

7.9 Assignment; No Third Party Beneficiary. This Agreement is a personal service contract, and shall not be assignable by Executive. This Agreement shall be assignable by Employer to any successor to the business of Employer, without the written consent of Executive; provided, however, that the assignee or transferee is the successor to all or substantially all of the business assets of Employer and such assignee or transferee expressly assumes all the obligations, duties, and liabilities of Employer set forth in this Agreement. Any purported assignment of this Agreement in violation of this Section 7.9 shall be null and void. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns, and no other Person shall have any right, benefit or obligation hereunder.

7.10 Counterparts; Facsimile Signatures. This Agreement may be executed in separate counterparts, each of which will be an original and all of which taken together shall constitute one and the same agreement, and any party hereto may execute this Agreement by signing any such counterpart. A facsimile signature by any party on a counterpart of this Agreement shall be binding and effective for all purposes. Such party shall subsequently deliver to the other party an original, executed copy of this Agreement; provided, however, that a failure of such party to deliver an original, executed copy shall not invalidate Executive’s or its signature.

7.11 Notices. All notices, instructions and other communications given hereunder or in connection herewith shall be in writing. Any such notice, instruction or communication shall be sent either (i) by registered or certified mail, return receipt requested, postage prepaid, or (ii) prepaid via a reputable nationwide overnight courier service, in each case addressed as follows:

If to the Company, to: AGTC
 14193 NW 119th Terrace
 Alachua, FL 32615
 Attention: Director of Human Resources
 Attention: General Counsel

If to the Executive, to: Stephen W. Potter

or to such other address as either the Company or the Executive may have furnished to the other in writing in accordance herewith). Any such notice, instruction or communication shall be deemed to have been delivered five business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, or one business day after it is sent via a reputable nationwide overnight courier service. Either party may give any notice, instruction or other communication hereunder using any other means, but no such notice, instruction or other communication shall be deemed to have been duly delivered unless and until it actually is received by the party for whom it is intended.

7.12 Interpretation. The headings contained in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

7.13 Cumulative Remedies. The rights and remedies of the parties hereunder are cumulative and not exclusive of any rights or remedies any party hereto may otherwise have.

7.14 Expenses Relating to this Agreement. Each party shall pay its or Executive's own expenses incident to the negotiation, preparation and execution of this Agreement.

7.15 Acknowledgement. Executive acknowledges that Executive has been advised to and has been given the opportunity to consult with legal counsel for the purposes of reviewing this Agreement, including the non-competition and non-solicitation covenants contained herein. Executive further acknowledges that he or she has been given 10 business days to consider the terms of this Agreement. If Executive executes this Agreement prior to the end of the 10 business day period, he or she agrees and acknowledges that such execution was a knowing and voluntary waiver of his or her right to consider this Agreement for the full 10 business day period.

IN WITNESS WHEREOF, Executive and Employer have executed this Employment Agreement as of the date set forth in the first paragraph.

APPLIED GENETIC TECHNOLOGIES CORPORATION

By: /s/ Susan B. Washer
Name: Susan B. Washer
Title: President and CEO

Date: August 29, 2019

EXECUTIVE

/s/ Stephen W. Potter
Name: Stephen W. Potter

Date: August 26, 2019

Schedule A - Permitted Outside Activities

Pursuant to Section 3.3 of the Employment Agreement, Executive has disclosed and the Board has approved his participation in the following outside activities:

Exhibit A

GENERAL RELEASE AND WAIVER OF ALL CLAIMS
(INCLUDING OLDER WORKER BENEFITS PROTECTION ACT CLAIMS AND
AFFIRMATION OF NONCOMPETE)

For good and valuable consideration, including without limitation the compensation and benefits set forth in the Employment Agreement dated 2019 (the "Agreement") between the undersigned and Applied Genetic Technologies Corporation (the "Company"), to which this General Release and Waiver of All Claims is attached, the terms of which Agreement shall survive this General Release and Waiver of Claims, the undersigned, on behalf of and for himself or herself and his or her heirs, administrators, executors, representatives, estates, attorneys, insurers, successors and assigns (hereafter referred to separately and collectively as the "Releasor"), hereby voluntarily releases and forever discharges the Company, and its subsidiaries (direct and indirect), affiliates, related companies, divisions, predecessor and successor companies, and each of its and their present, former, and future shareholders, officers, directors, employees, agents, representatives, attorneys, insurers and assigns (collectively as "Releasees"), jointly and individually, from any and all actions, causes of action, claims, suits, charges, complaints, contracts, covenants, agreements, promises, debts, accounts, damages, losses, sums of money, obligations, demands, and judgments all of any kind whatsoever, known or unknown, at law or in equity, in tort, contract, by statute, or on any other basis, for contractual, compensatory, punitive or other damages, expenses (including attorney's fees and cost), reimbursements, or costs of any kind, which the undersigned employee ever had, now has, or may have, from the beginning of the world to the date of this Release, known or unknown, in law or equity, whether statutory or common law, whether federal, state, local or otherwise, including but not limited to any and all claims arising out of or in any way related to the undersigned's engagement by the Company (including the hiring or termination of that engagement), or any related matters including, but not limited to claims, if any arising under the Age Discrimination in Employment Act of 1967, as amended by the Older Worker Benefits Protection Act; the Civil Rights Act of 1964, as amended; the Civil Rights Act of 1991, as amended; the Family and Medical Leave Act of 1993, as amended; the Immigration Reform and Control Act of 1986; the Americans with Disabilities Act of 1990, as amended; the Employee Retirement Income Security Act (ERISA), as amended; the Florida Civil Rights Act, FLA. STAT. Sections 760.01 - 760.11; FLA STAT. Sections 448.01 et seq.; Mass. Gen. L. c. 151B, section 1 et seq.; Mass. Gen. L. c. 149, section 1 et seq.; Mass. Gen. L. c. 151, section 1A et seq.; and federal, state or local common law, laws, statutes, ordinances or regulations. Notwithstanding the foregoing, nothing contained in this General Release and Waiver of Claims shall be construed to bar any claim by the undersigned to enforce the terms of the Agreement.

Releasor represents and acknowledges the following:

- (a) that Releasor understands the various claims Releasor could have asserted under federal or state law, including but not limited to the Age Discrimination in Employment Act and other similar laws;

-
- (b) that Releasor has read this General Release carefully and understands all of its provisions;
 - (c) that Releasor understands that Releasor has the right to and is advised to consult an attorney concerning this General Release and in particular the waiver of rights Releasor might have under the laws described herein and that to the extent, if any, that Releasor desired, Releasor availed himself or herself of this right;
 - (d) that Releasor has been provided at least forty-five (45) days to consider whether to sign this General Release and that to the extent Releasor has signed this General Release before the expiration of such forty-five (45) day period Releasor has done so knowingly and willingly;
 - (e) that Releasor enters into this General Release and waives any claims knowingly and willingly; and

that this General Release shall become effective seven (7) business days after it is signed. Releasor may revoke this General Release within seven (7) business days after it is signed by delivering a written notice of rescission to Scott Koenig, Chair of AGTC, c/o MacroGenics, Inc., 1500 East Gude Drive, Rockville, MD 20850. To be effective, the notice of rescission must be hand delivered, or postmarked within the seven (7) business day period and sent by certified mail, return receipt requested, to the referenced address.

A. Executive acknowledges that Executive remains bound by Executive's obligations set forth in Sections 6.1, 6.2, 6.3, 6.4, 6.5, 6.6(a), 6.6(c), 6.7, 6.8, 6.9, 6.10 and 6.11 of the Agreement. Executive confirms that for a period of one year following the termination of Executive's employment with the Company, Executive shall not either directly or indirectly, on Executive's own or another's behalf, engage in or assist others in any of the following activities (except on behalf of Company):

- (i) (whether as principal, agent, partner or otherwise) engage in, own, manage, operate, control, finance, invest in, participate in, or otherwise carry on, or be employed by, associated with, or in any manner connected with, lend such Executive's name to, lend Executive's credit to, or render services or advice to a Competing Business anywhere in the Geographic Area; or
- (ii) provide or develop any products, technology or services that are the same or Substantially Similar to the products, technology and services provided or developed by the Company or any of its Affiliates.

The capitalized terms herein have the meanings set forth in section 6.7 of the Agreement.

Executive agrees that Executive will not disparage or encourage or induce others to disparage any of the Company, its subsidiaries and affiliates, together with all of their respective past and present directors and officers and each of their successors and assigns. Nothing herein is intended to or shall prevent Executive from providing limiting testimony in response to a valid subpoena, court

order, regulatory request or other judicial, administrative or legal process or otherwise as required by law.

Signed and sealed this day of , 20 .

Signed: _____

Name (print): Stephen W. Potter

EXHIBIT B
LIST OF PRIOR INVENTIONS

Title

Date

Brief Description

No Inventions.

Additional sheets attached.

Date:

Signature /s/ Stephen W. Potter

Name Stephen W. Potter



Visionary science for
life changing cures.

June 12, 2019

Theresa Heah, MD, MBA

Dear Theresa,

Thank you for managing your way through the rather comprehensive interview process here at Applied Genetic Technologies Corporation (the “Company” or “AGTC”). Throughout that process, you have demonstrated the professional competence and collaborative spirit that we look for in every employee. As a result, I am very pleased to offer you a position as our **Chief Medical Officer**. The terms of our offer are as follows:

Start Date and Responsibilities:

It is anticipated that your employment will commence at a time mutually agreed upon by you and the Company. As Chief Medical Officer you will be responsible for (i) providing leadership to ensure establishment of the conditions essential for determining the safety, efficacy, medical usefulness, and marketability of the company’s product candidates, (ii) oversee the creation, execution and reporting of clinical trial activities required to achieve approval by FDA, European, and Japanese regulatory agencies of new and experimental products and technologies in accordance with Good Clinical Practices, (iii) working with the management team to establish strategic direction for the company, and (vi) providing such other duties as the Company may reasonably designate. All your duties are to be performed and discharged, faithfully, diligently and to the best of your ability and in compliance with all applicable laws and regulations.

Compensation:

As a full-time, exempt employee, you will receive an annualized salary of \$467,000.00 to be paid in accordance with AGTC’s standard payroll practice. Currently, our payroll is paid on a semi-monthly basis.

We are also pleased to offer you \$109,000 as a sign-on bonus. Your bonus, paid with your 1st payroll disbursement, will be less applicable deductions, taxes, and other amounts required by federal and state laws. If you voluntarily terminate your employment with the Company or the Company terminates your employment with Cause at any time prior to one (1) year after the commencement of your employment with the Company (your “Hire Date”) you will be obligated to repay to the Company, the **entire amount** of the signing bonus. If you voluntarily terminate your employment with the Company or the Company terminates your employment with Cause at any time prior to two (2) years after the commencement of your employment with the Company (your “Hire Date”) you will be obligated to repay to the Company, 50% of the amount of the signing bonus. In furtherance of this condition and as a condition to your employment with the Company, you will be required to execute a Promissory Note in favor of the Company in an amount equal to the signing bonus.

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In addition to your base salary, you will be eligible for an annual bonus targeted at 35 percent (35%) of your base salary. Bonus eligibility and amounts are discretionary and determined based upon periodic assessments of operational and behavioral performance and the achievement of specific individual and corporate objectives. Furthermore, please note that (i) you must be an employee at the time of the scheduled bonus payment to receive the bonus, and (ii) the determination of whether a bonus is paid in any given year is subject to the approval of the Compensation Committee of the Board of Directors.

Stock Options:

Effective as of the first day of your employment, the Company will grant you stock option to purchase 100,000 shares of AGTC common stock at a purchase price equal to the closing price of AGTC's common stock on your start date. The option will be subject to the provisions of AGTC's 2013 Equity and Incentive Plan and the Stock Option Award Agreement to be entered into by you and AGTC following the grant, which in relevant part will require that such option (i) vests over a period of four years, with an initial one-year cliff; (ii) expires 10 years from the grant date; and (iii) may be exercised (as to the vested portion) for ninety (90) days following the termination of your employment.

Working Remotely, Relocation and Reimbursement:

We have agreed that you may maintain your current residence in New Jersey and perform most of your day-to-day responsibilities as a "remote employee" subject to the following conditions:

- (i) you may work from home for up to 2 days per week and will travel routinely for the remaining days to the Company's offices in Alachua, Florida and Cambridge Massachusetts, or to other locations as necessary or appropriate in connection with the performance of your duties;
- (ii) as long as you remain a "remote employee" you will be subject to the Company's Remote Employee Policy; and
- (iii) on or before your first 90 days, you will negotiate with the CEO on future requirements for travel to the Company's offices in Alachua, Florida and Cambridge Massachusetts, or to other locations as necessary or appropriate in connection with the performance of your duties.

Benefits:

You will be eligible to participate in AGTC's employee benefits in the same manner provided generally to AGTC's full-time employees, which includes options for health, dental, vision, disability and life insurance as well as a 401(k) savings plan (with a Company match of up to 4% of base salary).

The Company's benefit program is managed by our leasing agent Insuperity. For your medical benefits there is an initial waiting period thirty days, at which point elected benefits become effective. A package describing these benefits will be provided to you on or before your start date.

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The Company will reimburse you for all reasonable and necessary traveling expenses and other disbursements actually incurred by you for or on behalf of the Company in the performance of your duties during your employment. This includes qualified transportation reimbursement for a transit pass and/or qualified parking up to the allowable IRS monthly limit. As with other employees, you shall be required to submit to the Company every two weeks reports of claims of such expenses and disbursements for approval and reimbursement by the Company.

Paid Time Off:

Initially, you will be entitled to twenty (20) days of Paid Time Off (“PTO”). The time will be accrued on a semi-monthly basis and may be used as soon as it is earned. You will receive one additional day per year for each full year of employment based on your anniversary date, up to a maximum of thirty (30) days. This time is for you to use as needed for vacation, family business, sick days or other necessary time away from work. Such leave may be accumulated over three years but in no event shall your leave be accrued in excess of forty-five (45) days per year. If your employment terminates for any reason whatsoever, you shall be entitled to receive, in addition to any unpaid salary, any unused PTO accrued to the date of your termination of employment but not to exceed forty-five (45) days.

Termination:

This letter agreement is not intended to, and it does not create any employment contract for any specified term or duration between you and the Company. Your employment with the Company is terminable at any time, by yourself upon two weeks written notice, or by the Company upon two weeks written notice or payment of salary in lieu thereof. Your employment may also be terminated for cause by the Company at any time without advance written notice. “Cause” is defined for purposes of your employment as including (but it is not limited to) any of the following:

- Your failure to effectively carry out your duties and responsibilities, as evaluated and determined by the Company in its absolute discretion;
- Violation of requirements of this letter, the Employee Manual, or any provision of an applicable code of conduct or ethics;
- Conduct which, in the Company’s determination, causes embarrassment or loss of credibility to the Company, its employees, products or services, or the position that you hold, or which causes the Board to lose confidence in you.
- Conduct which, in the Company’s determination, violates the Nondisclosure, Inventions and Non- Competition Agreement, or which involves dishonesty, moral turpitude, or misrepresentation.

For purposes of this letter agreement, “Good Reason” shall mean:

- Either before or after a Change in Control, a requirement that you either (i) perform the majority of your services to the Company in any location beyond a fifty (50) mile radius of Cambridge, Massachusetts; and/or (ii) relocate your residence beyond a fifty (50) mile radius of Hoboken, NJ;

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-
- Upon the sale of all or substantially all of the stock or assets of the Company, whether by merger, acquisition or otherwise the successor company does not offer you a position with substantially equivalent responsibilities; and/or
 - Upon the sale of all or substantially all of the stock or assets of the Company, whether by merger, acquisition or otherwise, the successor company does not offer you a position with total compensation and benefits at least equivalent to those you received from the Company immediately prior to such sale.

Assuming that you have effectively worked in your new position for a period of at least six months, then if your employment is terminated because either (A) the Company terminates your employment without Cause or (B) you terminate your employment for Good Reason (and provided that you execute and do not revoke a Release and Settlement Agreement in the form reasonably acceptable to the Company and you), you will be entitled to receive an amount equal to nine (9) months' of your then-base salary; to include base salary and bonus earned (less all applicable deductions), plus the Company's payment of the Company portion of the premium for benefits that you continue pursuant to the Consolidated Omnibus Benefits Reconciliation Act of 1984, as amended, payable in a lump sum or as otherwise agreed to by you and the Company.

Proprietary Information and Inventions:

You will be required to sign a Proprietary Information, Inventions and Non-Competition and Non-Solicitation Agreement ("PIIA") on or before your first day of work. The PIIA obligates you not to disclose confidential or proprietary information you may learn during your employment with AGTC, to assign to AGTC rights in inventions or other intellectual property developed in the course of your employment and not to solicit employees or business away from, or engage in competition against, AGTC for a period of one year following any termination of your employment.

Additional Company Policies:

Upon joining AGTC as an employee, you will become subject to all of the Company's policies and procedures, which will be presented to you during your onboarding process. These policies include AGTC's Code of Ethics and its Insider Trading Policy. Any failure by you to abide by the Company's internal policies shall be considered material misconduct.

AGTC is a drug free workplace and therefore, you will also be required to submit to a drug screening prior to your start date. Authorization for this screening will be sent to you separately.

Acknowledgement:

This offer is contingent upon satisfactory completion of reference and background checks. In accepting this offer, you give us your assurance that you have not relied on any agreements, promises or representations, express or implied, with respect to your employment that are not set forth expressly in this letter. You also acknowledge that the Company reserves the right to modify, amend or terminate the Company policies, plans and programs described in this letter at any time at its sole discretion. This letter sets forth the entire

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agreement and understanding between you and AGTC with respect to the subject matter hereof, will supersede all prior oral or written agreements relating to such matters. If this letter correctly sets forth our agreement on the subject matter hereof, kindly sign and return to AGTC the enclosed copy of this letter.

This offer is valid through June 18, 2019.

Again, it is with great pleasure that I offer you this position at AGTC. The Company is delighted with the prospect of your joining our team and hopes that you accept this offer. We have exciting and challenging work ahead of us . . . and I believe that you will be an excellent addition to our team!

Sincerely,

/s/ Susan B. Washer

Susan Washer
President and CEO

Consented to and Agreed:

/s/ Theresa Heah

Theresa Heah

Date

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EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of the 29th day of August, 2019 by and between Applied Genetic Technologies Corporation, a Delaware corporation, including its successors and assigns, (the "Employer" or "Company"), and Brian Krex ("Executive").

NOW, THEREFORE, in consideration of the promises and the respective undertakings of Employer and Executive set forth below, Employer and Executive hereby agree as follows:

1. Employment. Employer hereby employs Executive, and Executive hereby accepts such employment and agrees to perform services for Employer, for the period and on the other terms and subject to the conditions set forth in this Agreement. Employee's Start Date shall be and shall be considered the Effective Date of this Agreement.

2. Employment at Will. Executive is employed "at-will" which means that Executive's employment is not for any defined term and may be terminated by either Executive or the Company at any time, with or without cause, for any or no reason, subject to the notice provisions herein.

3. Position and Duties.

3.1 Service with Employer. Employer hereby employs Executive in an executive capacity with the title of General Counsel and Executive hereby accepts such employment and undertakes and agrees to serve in such capacity. Executive shall have such powers, perform such duties and fulfill such responsibilities as are typically associated with such position in other similarly situated companies and shall report directly to the Company's President and Chief Executive Officer,

3.2 Performance of Duties. Executive agrees to: (i) devote substantially all of Executive's business time, attention and efforts to the business and affairs of Employer while employed; and (ii) adhere to all Employer's written employment policies and procedures as shall be in force from time to time.

3.3 Outside Activities. During the Term, Executive shall not: (i) except as set forth below, accept other employment; (ii) except as set forth below, render or perform services for compensation to any Person (as hereinafter defined) other than Employer; (iii) serve as an officer or on the board of directors (or similar governing body) of any entity other than Employer, whether or not for compensation; or (iv) engage in any other business, enterprise or activity that will require any effort on the part of Executive that, in the sole discretion of Employer, could reasonably be expected to materially detract from the ability of Executive to perform Executive's duties to Employer pursuant to this Agreement; provided, however, Executive may engage in the activities set forth in Schedule A hereto or described in clause (iii) or (iv) above if prior to engaging in such activity, Executive has disclosed such activity to the Board and received written approval to engage in such activity from the Board. Executive may engage in personal investments without disclosure to or written approval from the Board provided Executive is not required or expected to serve as a board member, advisor or consultant and Executive shall, at any time, own beneficially

less than 2% of the outstanding securities of any issuer and such personal investment shall not otherwise interfere with Executive's performance of duties hereunder and/or the provisions of Executive's written agreements with Employer.

3.4 Executive Representations. Executive represents that Executive is not subject to any restrictive covenant, confidentiality agreement, or any other agreement that would prevent Executive from accepting employment with Employer, and based on the information provided to Employer by Executive, Employer accepts such representation.

4. Compensation.

4.1 Base Salary. Employer shall pay to Executive a base salary for all services to be rendered by Executive under this Agreement (the "Base Salary"), which Base Salary shall be paid in accordance with Employer's normal payroll schedule, procedures and policies (which schedule, procedures and policies may be modified from time to time) and subject to applicable deductions as required by law. Employer shall review Executive's salary on an annual basis and may, in its discretion, consider and declare from time to time increases in the Base Salary that it pays Executive. Any and all increases in Executive's salary pursuant to this section shall cause the level of Base Salary to be increased by the amount of each such increase for purposes of this Agreement. The increased level of Base Salary as provided in this section shall become the level of Base Salary for the remainder of the term of this Agreement unless there is a further increase in Base Salary as provided herein. Notwithstanding the foregoing, the Base Salary of Executive may be decreased provided it is done so in proportion to decreases in Base Salary of the entire executive team of the Company.

4.2 Annual Bonus. The Executive will be eligible to participate in the Employer's annual cash incentive compensation plan on substantially the same terms as other executive officers. Company-wide and individual performance objectives ("MBOs") will be established by the Compensation Committee. Target incentives do not constitute a promise of payment and the Executive's actual bonus, if any, will depend in part on the Employer's performance and the Compensation Committee's discretion in assessing the Executive's individual performance in relation to his or her MBOs and the overall performance and status of the Company. To qualify for the incentive bonus, the Executive must remain employed with the Company through the date that the incentive bonus is paid in accordance with the Employer's normal practice.

4.3 Participation in Benefit Plans. Executive shall be entitled to participate in all employee benefit plans or programs offered to other senior executives from time to time (to the extent that Executive meets the requirements for each such plan or program), including participation in any health insurance plan, disability insurance plan, dental plan, eye care plan, 401(k) plan, life insurance plan, or other similar plans (all such benefits, the "Benefit Plans"). Some or all of the benefits may be provided by Employer's leasing agent TriNet (or its successor(s) or assign(s)).

4.4 Expenses. Employer shall reimburse Executive for all ordinary and necessary business expenses reasonably incurred by him in the performance of Executive's duties under this Agreement, subject to the presentment and approval of appropriate itemized expense statements, receipts, vouchers or other supporting documentation in accordance with Employer's normal policies for expense verification in effect from time to time.

4.5 Paid Time Off. Executive shall be entitled to paid time off pursuant to Employer's standard paid time off policies in the same manner as the Company's other Senior Executives. Unused paid time off may be carried over from year to year, but in no case may more than 45 days (360 hours) of unused paid time off be accrued.

4.6 Total Compensation. Executive shall not receive any other compensation or benefits other than as provided in Sections 4.1 through 4.5 hereof.

5. Payments Upon Termination.

5.1 Voluntary Resignation without Good Reason. Executive may terminate Executive's employment by providing Employer with 30 days' advance written notice. If Executive terminates Executive's employment (other than for Good Reason (either prior to or within 12 months following a Change in Control) or by reason of Disability, each as defined below) (i) Employer shall pay to Executive the Accrued Obligations (as defined below), (ii) Executive's participation in the Benefit Plans shall terminate as of the Termination Date, and (iii) Employer shall have no other obligations to Executive under this Agreement, other than those provided in this Section 5.1.

(a) For purposes of this Agreement, "Accrued Obligations" means: (i) Executive's earned and unpaid Base Salary through the Termination Date; (ii) reimbursement for any reimbursable business expenses incurred by Executive through the Termination Date in accordance with Section 4.4; and (iii) Executive's accrued but unused paid time off as of the Termination Date. The amounts payable pursuant to clauses (i) and (iii) hereof shall be paid no later than sixty (60) days following Executive's Termination Date.

(b) For purposes of this Agreement, "Termination Date" means: the effective date of Executive's "separation from service" as defined in Section 409A of the Internal Revenue Code of 1986, as amended (the "Code").

5.2 Termination by Employer For Cause. If Executive is terminated for Cause: (i) Employer shall pay to Executive the Accrued Obligations, (ii) Executive's participation in the Benefit Plans shall terminate as of the Termination Date, and (iii) Employer shall have no further obligations to Executive under this Agreement, other than those provided in this Section 5.2. For purposes of this Agreement, "Cause" means: (a) Executive's failure to substantially perform Executive's duties with the Company (if Executive has not cured such failure to substantially perform, if curable, within thirty (30) days after Executive's receipt of written notice thereof from the Board that specifies the conduct constituting Cause under this clause (a)); (b) Executive's willful misconduct, or gross negligence in the performance of Executive's duties hereunder; (c) the conviction of Executive for, or the entering by Executive of a guilty plea or plea of no contest with respect to, any crime that constitutes a felony or involves fraud, dishonesty or moral turpitude; (d) Executive's commission of an act of fraud, embezzlement or misappropriation against the Company; (e) Executive's material breach of the fiduciary duty owed by Executive to the

Company; (f) Executive's engaging in any improper conduct that has or is likely to have an adverse economic or reputational impact on the Company; or (g) Executive's material breach of this Agreement.

5.3 Termination by Employer Without Cause or by Executive for Good Reason If Executive's employment is terminated (a) by Employer without Cause (other than upon Disability or death) or (b) by Executive for Good Reason either prior to a Change in Control or within twelve (12) months following a Change in Control: (i) Employer shall pay to Executive the Accrued Obligations, (ii) Executive shall be entitled to receive the Severance Benefits (as defined below in Section 5.5 and subject to the conditions described therein and in Section 5.6), and (iii) Employer shall have no further obligations to Executive under this Agreement, other than those provided in this Section 5.3. For purposes of this Agreement, "Good Reason" means the occurrence of any of the following events (without Executive's consent):

- (a) a material adverse change in Executive's functions, duties, or responsibilities with the Company which change would cause Executive's position to become one of materially lesser responsibility, importance, or scope;
- (b) a relocation of the Executive's principal workplace to a location more than 50 miles from the location of such workplace immediately prior to the Change in Control without the Executive's express written consent;
- (c) a material diminution in the Executive's compensation or benefits without the express written consent of the Executive, other than an across-the-board reduction in compensation levels that applies to all senior executives generally; or
- (d) a material breach of this Agreement by the Company.

Notwithstanding the foregoing, no such event shall constitute "Good Reason" unless (a) Executive shall have given written notice of such event to the Company within ninety (90) days after the initial occurrence thereof, (b) the Company shall have failed to cure the condition constituting Good Reason within thirty (30) days following the delivery of such notice (or such longer cure period as may be agreed upon by the parties), and (c) Executive terminates employment within thirty (30) days after expiration of such cure period.

5.4 Termination by Employer due to Executive's Death or Disability. If Executive's employment is terminated by reason of death or Disability (as defined below): (i) Employer shall pay to Executive the Accrued Obligations, (ii) Executive's participation in the Benefit Plans shall terminate as of the Termination Date (except to the extent Executive is eligible for continued disability benefits under the applicable Employer plan), and (iii) Employer shall have no further obligations to Executive under this Agreement, other than those provided in this Section 5.4. For purposes of this Agreement, "Disability" means Executive being determined to be totally disabled by the Social Security Administration or Executive's inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve months.

5.5 Severance Benefits. “Severance Benefits” means:

(a) The payment to Executive of the Severance Amount in a lump sum immediately following the Termination Date.

(b) For this purpose, “Severance Amount” means:

(i) In the event that Executive’s employment is terminated without Cause or by the Executive for Good Reason, in each case, within twelve (12) months following a Change in Control, an amount equal to the sum of (A) the product of 1.0 multiplied by Executive’s annual Base Salary plus (B), the product of 1.0 multiplied by the Executive’s target bonus in effect immediately prior to the Date of Termination.

(ii) In the event that Executive’s employment is terminated without Cause (other than within twelve (12) months of a Change in Control), an amount equal to the sum of (A) the product of 0.75 multiplied by Executive’s annual Base Salary plus (B), the product of the Executive’s target bonus in effect immediately prior to the Date of Termination multiplied by a fraction equal to the quotient of the number of days during such year on which the Executive was employed by the Company, divided by 365.

(c) The continuation of Executive’s participation in the Company’s medical, dental, and vision benefit plans at the same premium cost to Executive as charged to Executive immediately prior to the Termination Date for a period of (i) in the event that the Executive’s employment is terminated without Cause or by the Executive for Good Reason, in each case, within twelve (12) months following a Change in Control, twelve (12) months immediately following the Termination Date or (ii) in the event that the Executive’s employment is terminated without Cause (other than within twelve (12) months of a Change in Control) nine (9) months immediately following the Termination Date (in each case, the “Continuation Period”), or if earlier, until Executive obtains other employment which provides the same type of benefit; provided, however, that (i) it is understood and agreed that such continued medical, dental and vision benefits may at the election of the Company be provided by Executive electing the continuation of such coverage pursuant to COBRA with the Company reimbursing Executive for COBRA premiums to the extent required so that Executive’s premium cost for the coverage in effect for Executive prior to the Termination Date is substantially the same as immediately prior to the Termination Date, and (ii) if the Company determines, in its reasonable judgment, that providing medical, dental, and/or vision benefits in accordance with the preceding provisions of this Section 5.5(c) would result in a violation of applicable law, the imposition of any penalties under applicable law, or adverse tax consequences for participants covered by the Company’s medical, dental, and/or vision plans, the Company may terminate such

coverage (or reimbursement) with respect to Executive and instead pay to Executive taxable cash payments at the same time and in the same amounts as the Company would have paid as premiums (or as COBRA premium reimbursements) to provide such coverage.

(d) Acceleration of vesting as follows:

(i) In the event that Executive's employment is terminated by Employer without Cause or by Executive for Good Reason, in each case, within twelve (12) months following a Change in Control: each stock option, restricted stock unit, restricted stock award or other stock-based compensatory award granted by the Company to Executive that is outstanding as of the Termination Date and is not fully vested as of the date of the Termination Date (each an "Award"), shall become fully vested as of the date Executive provides the Company with the Irrevocable Release provided for in this Section 5.5 within the period prescribed therein.

(ii) In the case of any Award the vesting of which is contingent in whole or in part upon the attainment of any Company or market performance condition that has not yet been satisfied, such condition shall be deemed to have been satisfied as of the date of termination at the level that would result in vesting of 100% of the number of shares stated as the target award.

(e) For purposes of this Agreement, "Change of Control" means, and shall be deemed to have occurred, if:

(i) any Person, excluding (i) employee benefit plans of the Company or any of its Affiliates, is or becomes the "beneficial owner" (as defined in Rules 13d-3 and 13d-5 under the Exchange Act, which Rules shall apply for purposes of this clause (a) whether or not the Company is subject to the Exchange Act), directly or indirectly, of Company securities representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities ("Voting Power");

(ii) the Company consummates a merger, consolidation, share exchange, division or other reorganization or transaction of the Company (a "Fundamental Transaction") with any other corporation, other than a Fundamental Transaction that results in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) at least fifty percent (50%) of the combined Voting Power immediately after such Fundamental Transaction of (i) the Company's outstanding securities, (ii) the surviving entity's outstanding securities, or (iii) in the case of a division, the outstanding securities of each entity resulting from the division;

(iii) the stockholders of the Company approve a plan of complete liquidation or winding-up of the Company or the consummation of the sale or disposition (in one transaction or a series of transactions) of all or substantially all of the Company's assets; or

(iv) during any period of 24 consecutive months, individuals who at the beginning of such period constituted the Board (including for this purpose any new director whose election or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds (2/3) of the directors then still in office who were directors at the beginning of such period or whose appointment, election or nomination was previously so approved or recommended) cease for any reason to constitute at least a majority of the Board.

5.6 Required Delivery of Irrevocable Release: Compliance with Section 6 Obligations. Notwithstanding the provisions of Section 5.5, as a condition to entitlement to the Severance Benefits, Executive must provide to the Company an Irrevocable Release and Noncompete Affirmation not later than the sixtieth day after the Date of Termination; provided however that if the sixty day period begins in one calendar year and ends in a subsequent calendar year, any payment to be made or benefit to be provided upon receipt of the Irrevocable Release and Noncompete Affirmation shall not be made or provided until the subsequent year. In the event Executive fails to provide an Irrevocable Release and Noncompete Affirmation to the Company within such sixty day period, the Company will immediately cease to pay or provide any further Severance Benefits, no accelerated vesting of stock options or other awards pursuant to Section 5.5(d) shall occur, and Executive shall be obligated to immediately repay to the Company all previously paid or provided Severance Benefits. "Irrevocable Release and Noncompete Affirmation" means a confidential separation agreement, release of claims and affirmation of noncompete, in form and substance substantially similar to the attached Exhibit A that has been executed by Executive, delivered to the Company, and become irrevocable by Executive. In addition, in the event that Executive breaches the obligations under Section 6 of this Agreement at any time during the Continuation Period, Executive will cease to be entitled to any further Severance Benefits.

6. Promises and Covenants Regarding Confidential Information and Goodwill; Inventions and Assignment; Restrictive Covenants

6.1 Confidential Information and Goodwill. In consideration of Executive's promises and covenants contained in this Agreement, including Executive's promise and covenant not to disclose Confidential Information, Employer will provide Executive with Confidential Information. In further consideration of Executive's promises and covenants contained in this Agreement, including Executive's promise and covenant to utilize the Goodwill exclusively for the benefit of Employer, Employer will allow Executive to receive Confidential Information concerning the Company's customers, labs, vendors and employees and, to the extent required to fulfill Executive's duties, the Company will permit Executive to represent the Company on its behalf with such persons. To the extent that Executive's duties involve sales or customer relations, the Company will permit Executive to utilize the Goodwill in Executive's sales efforts and will provide sales support to Executive similar to that which it provides to its sales representatives.

6.2 Duties. While employed by Company, Executive shall perform the duties required of Executive hereunder and shall devote Executive's best efforts and exclusive business time, energy and skill to performing such duties; not make any disparaging remarks regarding Company to any person with whom Company has business relations, including any employee or vendor of Company; use the Goodwill solely for the benefit of Company; and not interfere in such Goodwill, either during or following Executive's employment with Company.

6.3 Delivery of Company Property. Executive recognizes that all documents, magnetic media and other tangible items which contain Confidential Information are the property of Company exclusively. Upon request by Company or termination of Executive's employment with Company, Executive shall promptly return to Company all Confidential Information and Company Property within Executive's possession and control, and shall refrain from taking any Confidential Information or Company Property or allowing any Confidential Information or Company Property to be taken from Company; and immediately return to Company all information pertaining to Company or Company Property in Executive's possession.

6.4 Promise and Covenant Not to Disclose. The parties acknowledge that Company is the sole and exclusive owner of Confidential Information, and that Company has legitimate business interests in protecting Confidential Information. The parties further acknowledge that Company has invested, and continues to invest, considerable amounts of time and money in obtaining, developing, and preserving the confidentiality of Confidential Information and that, by reason of the trust relationship arising between Executive and Company, Executive owes Company a fiduciary duty to preserve and protect Confidential Information from all unauthorized disclosure and unauthorized use. Executive shall not, directly or indirectly, disclose Confidential Information to any third party (except to Executive's attorneys, the Company's personnel, other persons designated in writing by the Company, or except as otherwise provided by law) or use Confidential Information for any purpose other than for the direct benefit of Company while in Company's employ and thereafter.

6.5 Inventions and Assignment. Executive agrees that he will promptly disclose to the Company any and all Company Inventions and that Executive hereby irrevocably assigns to the Company all ownership rights in and to any and all Company Inventions. During Executive's

employment or at any time thereafter, upon request of the Company, Executive will sign, execute and deliver any and all documents or instruments, including, without limitation, patent applications, declarations, invention assignments and copyright assignments, and will take any other action which the Company shall deem necessary to perfect in the Company trademark, copyright or patent rights with respect to Inventions, or to otherwise protect the Company's trade secrets and proprietary interests. The term "Inventions" means discoveries; developments; trade secrets; processes; formulas; data; lists; software programs; graphics; artwork; logos, and all other works of authorship, ideas, concepts, know-how, designs, and techniques, whether or not any of the foregoing is or are patentable, copyrightable, or registrable under any intellectual property laws or industrial property laws in the United States. The term "Company Inventions" means all Inventions that (a) relate to the business or proposed business of the Company or any of its predecessors or that are discovered, developed, created, conceived, reduced to practice, made, learned or written by Executive, either alone or jointly with others, in the course of Executive's employment; (b) utilize, incorporate or otherwise relate to Confidential Information; or (c) are discovered, developed, created, conceived, reduced to practice, made, or written by him using property or equipment of the Company or any of its predecessors. Executive agrees to promptly and fully communicate in writing to the Company (to such department or officer of the Company and in accordance with such procedures as the Company may direct from time to time) any and all Company Inventions. Executive acknowledges and agrees that any work of authorship by Executive or others comprising Company Inventions shall be deemed to be a "work made for hire," as that term is defined in the United States Copyright Act (17 U.S.C. § 101 (2000)). To the extent that any such work of authorship may not be deemed to be a work made for hire, Executive hereby irrevocably assigns any ownership rights Executive may have in and to such work to the Company. This Agreement does not apply to any Inventions Executive made before Executive's employment with the Company. To clearly establish Executive's rights, Executive has listed on Exhibit B any Inventions, whether or not patentable or copyrightable and whether or not reduced to practice, made by him prior to Executive's employment with the Company that are owned by Executive ("*Prior Inventions*"), together with the approximate dates of their creation. If no such list is attached, Executive represents that there are no Prior Inventions.

6.6 Other Promises and Covenants. In consideration for the benefits specifically provided for in this Section 6.6 and that may otherwise be provided pursuant to this Agreement, including but not limited to the benefits payable pursuant to Section 5.5, Executive hereby promises and covenants as follows.

(a) In consideration of payment to Executive of \$500.00, less applicable withholdings, Executive agrees that during Executive's employment with Company and, unless this Section 6.6(a) is waived by the Company in writing, for a period of one year following termination of employment for any reason other than the Company's termination of Executive's employment without Cause (the "Non-Competition Period"), Executive shall not either directly or indirectly, on Executive's own or another's behalf, engage in or assist others in any of the following activities (except on behalf of Company):

(i) (whether as principal, agent, partner or otherwise) engage in, own, manage, operate, control, finance, invest in, participate in, or otherwise carry on, or be employed by, associated with, or in any manner

connected with, lend such Executive's name to, lend Executive's credit to, or render services or advice to a Competing Business anywhere in the Geographic Area; or

(ii) provide or develop any products, technology or services that are the same or Substantially Similar to the products, technology and services provided or developed by the Company or any of its Affiliates.

(b) Unless Section 6.6(a) is waived by the Company in writing, as mutually-agreed upon consideration for the post-employment restriction described herein, the Company will pay Executive \$10,000.00 within one month of Executive's date of termination. Notwithstanding the foregoing, in the event that Executive has breached his or her fiduciary duty to the Company or has unlawfully taken, physically or electronically, property belong to the Company, then the Non-Competition Period shall be extended for an additional period of one year.

(c) During Executive's employment with Company and for a period of two years following termination of employment for any reason (the "Non-Solicitation Period"), Executive shall not either directly or indirectly, on Executive's own or another's behalf, engage in or assist others in any of the following activities:

(i) induce or attempt to induce any customer, agent, supplier, licensee, or business relation of the Company or any of its Affiliates to cease doing business with the Company or any of its Affiliates, or in any way interfere with the relationship between any customer, supplier, licensee, or business relation of the Company or any of its Affiliates; or

(ii) on behalf of a Competing Business, solicit or attempt to solicit the business or patronage of any Person who is a customer or agent of the Company or any of its Affiliates, whether or not Executive had personal contact with such Person.

(iii) solicit, encourage, or take any other action which is intended to induce any employee, independent contractor or agent of the Company or any of its Affiliates to terminate Executive's employment or other business relationship with the Company or such Affiliate;

(iv) in any way interfere in any manner with the employment or other business relationship between the Company and/or any of its Affiliates, on the one hand, and any employee, independent contractor or agent of the Company or such Affiliate, on the other hand; or

(v) employ, or otherwise engage as an employee, independent contractor or otherwise, any individual who was an employee, independent contractor, agent or was otherwise affiliated with the Company or any of its Affiliates from the period beginning one year prior to the date on which Executive became employed and continuing through the expiration of the Non-Solicitation Period.

provided, however, that nothing set forth in this Section 6 shall prohibit Executive from owning, as a passive investment, not in excess of five percent (5%) in the aggregate of any class of capital stock of any corporation if such stock is publicly traded and listed on any national or regional stock exchange or reported on the Nasdaq Stock Market.

6.7 Definitions. For purposes hereof:

(a) “*Affiliate*” means, with respect to any Entity, any Entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or under common control with, such Entity.

(b) “*Agreement*” means this Employment Agreement.

(c) “*Company Business*” means (i) any business related to providing services related to, manufacturing, selling or distributing gene therapy products using adeno-associated virus technology for the treatment of inherited and acquired diseases or conducting research or development with regard thereto; and (ii) any other business that the Company is actively engaged in researching, developing or marketing at the time of the termination of Executive’s employment, provided that this clause (ii) shall only apply if Executive is involved with the research, development, or marketing of that other business.

(d) “*Company Property*” means all physical materials, documents, information, keys, computer software and hardware, including laptop computers and mobile or handheld scheduling computers, manuals, data bases, product samples, tapes, magnetic media, technical notes and any other equipment or items which Company provides for or to Executive or which otherwise belongs to the Company, and those documents and items which Executive may develop or help develop while in Company’s employ, whether or not developed during regular working hours or on Company’s premises. The term “*Company Property*” shall include the original of such materials, any copies thereof, any notes derived from such materials, and any derivative work of such materials.

(e) “*Competing Business*” means any other Entity engaged in the Company Business, other than the Company and its Affiliates.

(f) “*Confidential Information*” means the trade secrets and other information of Company, including but not limited to (i) the customer lists, customer contact information, customer purchase information, pricing information, strategic and marketing plans, compilations of customer information, names of employees, contracts with third parties, training, financial and marketing books, sales projections, internal employer databases, reports, manuals and information including information related to Company, its Affiliates or its customers, including those documents and items which any employee may develop or help develop while

in the employ of the Company or any of its Affiliates, whether or not developed during regular working hours or on the premises of the Company or such Affiliate; (ii) the identity, skills, personnel file information, performance appraisals and compensation of job applicants, employees, contractors, and consultants; (iii) specialized training; (iv) source code, scripts, user screens, reports or any other information pertaining to the internal information technology or network of the Company and/or its Affiliates; and (v) information related to inventions owned by the Company or any of its Affiliates or licensed from third parties; and unless the context requires otherwise, the term “Confidential Information” includes the original of such materials, any copies thereof, any notes derived from such materials, and any derivative work of such materials. The term “Confidential Information” does not include (1) information that was or becomes generally available publicly other than through disclosure by Executive, or (2) is required to be disclosed to any governmental agency or self-regulatory body or is otherwise required to be disclosed by law. Unless the context requires otherwise, the term “Confidential Information” shall include the original of such materials, any copies thereof, any notes derived from such materials, and any derivative work of such materials.

(g) “*Entity*” means and includes any person, partnership, association, corporation, limited liability company, trust, unincorporated organization or any other business entity or enterprise.

(h) “*Geographic Area*” means those states in which the Company or any of its subsidiaries conducts business or in which its products are being sold or marketed at the time of the termination of Executive’s employment.

(i) “*Goodwill*” means the value of the relationships between the Company and its agents, customers, vendors, labs, and employees.

(j) “*Substantially Similar*” means substantially similar in function or capability or otherwise competitive to the products or services being developed, manufactured or sold by the Company during and/or at the end of Executive’s employment, or are marketed to substantially the same type of user or customer as that to which the products and services of the Company are marketed or proposed to be marketed.

6.8 Acknowledgements Regarding Other Promises and Covenants. With regard to the promises and covenants set forth herein, Executive acknowledges and agrees that:

(a) the restrictions are ancillary to an otherwise enforceable agreement including the provisions of this Agreement regarding the disclosure, ownership and use of the Confidential Information and Goodwill of Company;

(b) the limitations as to time, geographical area, and scope of activity to be restricted are reasonable and acceptable to Executive, and do not impose any greater restraint than is reasonably necessary to protect the Goodwill and other legitimate business interests of Company;

(c) the performance by Executive, and the enforcement by Company, of such promises and covenants will cause no undue hardship on Executive;

(d) the time periods covered by the promises and covenants will not include any period(s) of violation of, or any period(s) of time required for litigation brought by Company to enforce any such promise or covenant, it being understood that the extension of time provided in this paragraph may not exceed two (2) years.

6.9 Duty to Give Notice of Agreement. During employment by Company and the period of any post-employment obligation applicable hereunder, Executive shall provide written notice to any prospective employer of Executive's obligations under this Agreement, and shall provide a true copy hereof to such prospective employer at the outset of any communications about employment.

6.10 Independent Elements. The parties acknowledge that the promises and covenants contained in Section 6 above are essential independent elements of this Agreement and that, but for Executive agreeing to comply with them, Company would not employ Executive. Accordingly, the existence or assertion of any claim by Executive against Company, whether based on this Agreement or otherwise, shall not operate as a defense to Company's enforcement of the promises and covenants in Section 6. An alleged or actual breach of the Agreement by Company will not be a defense to enforcement of any such promise or covenant, or other obligations of Executive to Company. The promises and covenants in Section 6 will remain in full force and effect whether Executive is terminated by Company or voluntarily resigns.

6.11 Remedies for Breach of Agreement. Executive acknowledges that Executive's breach of any promise or covenant contained in Section 6 will result in irreparable injury to Company and that Company's remedies at law for such a breach will be inadequate. Accordingly, Executive agrees and consents that Company, in addition to all other remedies available at law and in equity, shall be entitled to both preliminary and permanent injunctions to prevent and/or halt a breach or threatened breach by Executive of any such promise or covenant, and Executive waives the requirement of the posting of any bond in connection with such injunctive relief. Executive further acknowledges and agrees that the promises and covenants contained in Section 6 are enforceable, reasonable, and valid.

7. Miscellaneous.

7.1 Governing Law; Arbitration

(a) This Agreement is made under and shall be governed by and construed in accordance with the laws of Florida, without regard to its conflicts of law principles.

(b) With respect to claims by the Company against Executive related to Executive's threatened or actual breach of Section 6 of this Agreement, each Party hereby irrevocably agrees that all actions or proceedings concerning such disputes

may be brought by the Company in (a) the United States District Court for the Northern District of Florida; or (b) in any court of the State of Florida sitting in Alachua County, provided that the United States District Court lacks subject matter jurisdiction over such action or proceeding. Executive consents to jurisdiction of and venue in the courts in the State of Florida set forth in this Section, and hereby waives to the maximum extent permitted by applicable law any objection which Executive may have based on improper venue or forum non conveniens.

(c) Except to the extent provided for in subsection (b) above, the Company and Executive agree that any claim, dispute or controversy arising under or in connection with this Agreement, or otherwise in connection with Executive's employment by the Company or termination of his employment (including, without limitation, any such claim, dispute or controversy arising under any federal, state or local statute, regulation or ordinance or any of the Company's employee benefit plans, policies or programs) shall be resolved solely and exclusively by binding, confidential, arbitration. The arbitration shall be held in Gainesville, Florida (or at such other location as shall be mutually agreed by the parties). The arbitration shall be conducted in accordance with the Commercial Rules of the American Arbitration Association (the "AAA") in effect at the time of the arbitration, including the Expedited Procedures. All fees and expenses of the arbitration, including a transcript if either requests, shall be borne equally by the parties. Each party is responsible for the fees and expenses of its own attorneys, experts, witnesses, and preparation and presentation of proofs and post-hearing briefs (unless the party prevails on a claim for which attorney's fees are recoverable under law). In rendering a decision, the arbitrator shall apply all legal principles and standards that would govern if the dispute were being heard in court. This includes the availability of all remedies that the parties could obtain in court. In addition, all statutes of limitation and defenses that would be applicable in court, will apply to the arbitration proceeding. The decision of the arbitrator shall be set forth in writing, and be binding and conclusive on all parties. Any action to enforce or vacate the arbitrator's award shall be governed by the Federal Arbitration Act, if applicable, and otherwise by applicable state law. If either the Company or Executive improperly pursues any claim, dispute or controversy against the other in a proceeding other than the arbitration provided for herein, the responding party shall be entitled to dismissal or injunctive relief regarding such action and recovery of all costs, losses and attorney's fees related to such action.

7.2 Entire Agreement. This Agreement and the documents referenced herein contain the entire agreement of the parties relating to the employment of Executive by Employer and the ancillary matters discussed herein and supersedes all prior agreements, negotiations and understandings with respect to such matters, including, without limitation, any term sheet between the parties hereto with respect to such matters, and the parties hereto have made no agreements, representations or warranties relating to such employment or ancillary matters which are not set forth herein.

7.3 Withholding Taxes. Employer may withhold from any compensation and Benefits payable under this Agreement all federal, state, city or other taxes as shall be required pursuant to any law or governmental regulation or ruling.

7.4 Golden Parachute Limit. Notwithstanding any other provision of this Agreement, in the event that any portion of the Severance Benefits or any other payment or benefit received or to be received by Executive (whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement) (collectively, the "Total Benefits") would be subject to the excise tax imposed under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code") (the "Excise Tax"), the Total Benefits shall be reduced to the extent necessary so that no portion of the Total Benefits is subject to the Excise Tax; provided, however, that no such reduction in the Total Benefits shall be made if by not making such reduction, Executive's Retained Amount (as hereinafter defined) would be greater than Executive's Retained Amount if the Total Benefits are so reduced. All determinations required to be made under this Section 7.4 shall be made by tax counsel selected by the Company and reasonably acceptable to Executive ("Tax Counsel"), which determinations shall be conclusive and binding on Executive and the Company absent manifest error. All fees and expenses of Tax Counsel shall be borne solely by the Company. Prior to any reduction in Executive's Total Benefits pursuant to this Section 7.4, Tax Counsel shall provide Executive and the Company with a report setting forth its calculations and containing related supporting information. In the event any such reduction is required, the Total Benefits shall be reduced in the following order: (i) the Severance Amount (in reverse order of payment), (ii) any portion of the Total Benefits that are not subject to Section 409A of the Code (other than Total Benefits resulting from any accelerated vesting of equity awards), (iv) other Total Benefits that are subject to Section 409A of the Code in reverse order of payment, and (v) Total Benefits that are not subject to Section 409A and arise from any accelerated vesting of any equity awards. "Retained Amount" shall mean the present value (as determined in accordance with sections 280G(b)(2)(A)(ii) and 280G(d)(4) of the Code) of the Total Benefits net of all federal, state and local taxes imposed on Executive with respect thereto.

7.5 Compliance With Section 409A. This Agreement is intended to comply with the requirements of Section 409A of the Code (including the exceptions thereto), to the extent applicable, and shall be interpreted and administered accordingly. If any provision contained in this Agreement conflicts with the requirements of Section 409A of the Code (or the exemptions intended to apply under this Agreement), this Agreement shall be deemed to be reformed to comply with the requirements of Section 409A of the Code (or applicable exemptions thereto). Notwithstanding anything to the contrary herein, for purposes of determining Executive's entitlement to the Severance Benefits under Section 5 hereof, (a) Executive's employment shall not be deemed to have terminated unless and until Executive incurs a "separation from service" as defined in Section 409A of the Code, and (b) the effective date of any termination or resignation of employment (or any similar term) shall be the effective date of Executive's separation from service. Reimbursement of any expenses provided for in this Agreement shall be made in accordance with the Company's policies (as applicable) with respect thereto as in effect from time to time (but in no event later than the end of calendar year following the year such expenses were incurred) and in no event shall (i) the amount of expenses eligible for reimbursement hereunder during a taxable year affect the expenses eligible for reimbursement in any other taxable year or (ii) the right to reimbursement be subject to liquidation or exchange for another benefit. Notwithstanding anything to the contrary herein, if a payment or benefit under this Agreement is

due to a “separation from service” for purposes of the rules under Treas. Reg. § 1.409A-3(i)(2) (payments to specified employees upon a separation from service) and Executive is determined to be a “specified employee” (as determined under Treas. Reg. § 1.409A-1(i)), such payment shall, to the extent necessary to comply with the requirements of Section 409A of the Code, be made on the later of (x) the date specified by the foregoing provisions of this Agreement or (y) the date that is six (6) months after the date of Executive’s separation from service (or, if earlier, the date of Executive’s death). Any installment payments that are delayed pursuant to the provisions of this section shall be accumulated and paid in a lump sum on the first day of the seventh month following Executive’s separation from service (or, if earlier, upon Executive’s death) and the remaining installment payments shall begin on such date in accordance with the schedule provided in this Agreement. To the extent permitted by Section 409A, each payment hereunder shall be deemed to be a separate payment for purposes of Section 409A of the Code.

7.6 Amendments. No amendment or modification of the terms of this Agreement shall be valid unless made in writing and signed by both Executive and Employer.

7.7 Severability; Reformation. Whenever possible, each provision of this Agreement shall be interpreted in such a manner as to be effective and valid under applicable Law but if any provision of this Agreement is held to be invalid, illegal or unenforceable under any applicable Law or rule, the validity, legality and enforceability of the other provisions of this Agreement will not be affected or impaired thereby. If any provision of this Agreement is found invalid, illegal or unenforceable because it is too broad in scope, too lengthy in duration or violates any Law or regulation, it shall be reformed by limiting its scope, limiting its duration or construing it to avoid such violation (as the case may be) while giving the greatest effect to the intent of the parties as is legally permissible.

7.8 No Waiver. No waiver of any provision of this Agreement shall in any event be effective unless the same shall be in writing and signed by the party against whom such waiver is sought to be enforced, and any such waiver shall be effective only in the specific instance and for the specific purpose for which given.

7.9 Assignment; No Third Party Beneficiary. This Agreement is a personal service contract, and shall not be assignable by Executive. This Agreement shall be assignable by Employer to any successor to the business of Employer, without the written consent of Executive; provided, however, that the assignee or transferee is the successor to all or substantially all of the business assets of Employer and such assignee or transferee expressly assumes all the obligations, duties, and liabilities of Employer set forth in this Agreement. Any purported assignment of this Agreement in violation of this Section 7.9 shall be null and void. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns, and no other Person shall have any right, benefit or obligation hereunder.

7.10 Counterparts; Facsimile Signatures. This Agreement may be executed in separate counterparts, each of which will be an original and all of which taken together shall constitute one and the same agreement, and any party hereto may execute this Agreement by signing any such counterpart. A facsimile signature by any party on a counterpart of this Agreement shall be binding and effective for all purposes. Such party shall subsequently deliver to the other party an original, executed copy of this Agreement; provided, however, that a failure of such party to deliver an original, executed copy shall not invalidate Executive’s or its signature.

IN WITNESS WHEREOF, Executive and Employer have executed this Employment Agreement as of the date set forth in the first paragraph.

APPLIED GENETIC TECHNOLOGIES
CORPORATION

By: /s/ Susan B. Washer
Name: Susan B. Washer
Title: President and CEO

Date: August 29, 2019

EXECUTIVE

/s/ Brian Krex
Name: Brian Krex

Date: August 26, 2019

Schedule A - Permitted Outside Activities

Pursuant to Section 3.3 of the Employment Agreement, Executive has disclosed and the Board has approved his participation in the following outside activities:

Exhibit A

**GENERAL RELEASE AND WAIVER OF ALL CLAIMS
(INCLUDING OLDER WORKER BENEFITS PROTECTION ACT CLAIMS AND
AFFIRMATION OF NONCOMPETE)**

For good and valuable consideration, including without limitation the compensation and benefits set forth in the Employment Agreement dated _____, 2019 (the "Agreement") between the undersigned and Applied Genetic Technologies Corporation (the "Company"), to which this General Release and Waiver of All Claims is attached, the terms of which Agreement shall survive this General Release and Waiver of Claims, the undersigned, on behalf of and for himself or herself and his or her heirs, administrators, executors, representatives, estates, attorneys, insurers, successors and assigns (hereafter referred to separately and collectively as the "Releasor"), hereby voluntarily releases and forever discharges the Company, and its subsidiaries (direct and indirect), affiliates, related companies, divisions, predecessor and successor companies, and each of its and their present, former, and future shareholders, officers, directors, employees, agents, representatives, attorneys, insurers and assigns (collectively as "Releasees"), jointly and individually, from any and all actions, causes of action, claims, suits, charges, complaints, contracts, covenants, agreements, promises, debts, accounts, damages, losses, sums of money, obligations, demands, and judgments all of any kind whatsoever, known or unknown, at law or in equity, in tort, contract, by statute, or on any other basis, for contractual, compensatory, punitive or other damages, expenses (including attorney's fees and cost), reimbursements, or costs of any kind, which the undersigned employee ever had, now has, or may have, from the beginning of the world to the date of this Release, known or unknown, in law or equity, whether statutory or common law, whether federal, state, local or otherwise, including but not limited to any and all claims arising out of or in any way related to the undersigned's engagement by the Company (including the hiring or termination of that engagement), or any related matters including, but not limited to claims, if any arising under the Age Discrimination in Employment Act of 1967, as amended by the Older Worker Benefits Protection Act; the Civil Rights Act of 1964, as amended; the Civil Rights Act of 1991, as amended; the Family and Medical Leave Act of 1993, as amended; the Immigration Reform and Control Act of 1986; the Americans with Disabilities Act of 1990, as amended; the Employee Retirement Income Security Act (ERISA), as amended; the Florida Civil Rights Act, FLA. STAT. Sections 760.01 - 760.11; FLA STAT. Sections 448.01 et seq.; Mass. Gen. L. c. 151B, section 1 et seq.; Mass. Gen. L. c. 149, section 1 et seq.; Mass. Gen. L. c. 151, section 1A et seq.; and federal, state or local common law, laws, statutes, ordinances or regulations. Notwithstanding the foregoing, nothing contained in this General Release and Waiver of Claims shall be construed to bar any claim by the undersigned to enforce the terms of the Agreement.

Releasor represents and acknowledges the following:

- (a) that Releasor understands the various claims Releasor could have asserted under federal or state law, including but not limited to the Age Discrimination in Employment Act and other similar laws;

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- (b) that Releasor has read this General Release carefully and understands all of its provisions;
 - (c) that Releasor understands that Releasor has the right to and is advised to consult an attorney concerning this General Release and in particular the waiver of rights Releasor might have under the laws described herein and that to the extent, if any, that Releasor desired, Releasor availed himself or herself of this right;
 - (d) that Releasor has been provided at least forty-five (45) days to consider whether to sign this General Release and that to the extent Releasor has signed this General Release before the expiration of such forty-five (45) day period Releasor has done so knowingly and willingly;
 - (e) that Releasor enters into this General Release and waives any claims knowingly and willingly; and

that this General Release shall become effective seven (7) business days after it is signed. Releasor may revoke this General Release within seven (7) business days after it is signed by delivering a written notice of rescission to Scott Koenig, Chair of AGTC, c/o MacroGenics, Inc., 1500 East Gude Drive, Rockville, MD 20850. To be effective, the notice of rescission must be hand delivered, or postmarked within the seven (7) business day period and sent by certified mail, return receipt requested, to the referenced address.

A. Executive acknowledges that Executive remains bound by Executive's obligations set forth in Sections 6.1, 6.2, 6.3, 6.4, 6.5, 6.6(a), 6.6(c), 6.7, 6.8, 6.9, 6.10 and 6.11 of the Agreement. Executive confirms that for a period of one year following the termination of Executive's employment with the Company, Executive shall not either directly or indirectly, on Executive's own or another's behalf, engage in or assist others in any of the following activities (except on behalf of Company):

- (i) (whether as principal, agent, partner or otherwise) engage in, own, manage, operate, control, finance, invest in, participate in, or otherwise carry on, or be employed by, associated with, or in any manner connected with, lend such Executive's name to, lend Executive's credit to, or render services or advice to a Competing Business anywhere in the Geographic Area; or
- (ii) provide or develop any products, technology or services that are the same or Substantially Similar to the products, technology and services provided or developed by the Company or any of its Affiliates.

The capitalized terms herein have the meanings set forth in section 6.7 of the Agreement.

Executive agrees that Executive will not disparage or encourage or induce others to disparage any of the Company, its subsidiaries and affiliates, together with all of their respective past and present directors and officers and each of their successors and assigns. Nothing herein is intended to or shall prevent Executive from providing limiting testimony in response to a valid subpoena, court

order, regulatory request or other judicial, administrative or legal process or otherwise as required by law.

Signed and sealed this day of , 20 .

Signed: _____

Name (print): Brian Krex

EXHIBIT B
LIST OF PRIOR INVENTIONS

Title

Date

Brief Description

No Inventions.

Additional sheets attached.

Date:

Signature /s/ Brian Krex

Name Brian Krex

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-198979) of Applied Genetic Technologies Corporation pertaining to the Applied Genetic Technologies Corporation 2011 Stock Incentive Plan, 2013 Equity and Incentive Plan and the 2013 Employee Stock Purchase Plan, and
- (2) Registration Statement (Form S-3 No. 333-225286) of Applied Genetic Technologies Corporation

of our report dated September 26, 2019, with respect to the financial statements and financial statement schedule of Applied Genetic Technologies Corporation included in this Annual Report (Form 10-K) of Applied Genetic Technologies Corporation for the year ended June 30, 2019.

/s/ Ernst & Young LLP

Tampa, Florida
September 26, 2019

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-198979) of Applied Genetic Technologies Corporation pertaining to the Applied Genetic Technologies Corporation 2011 Stock Incentive Plan, 2013 Equity and Incentive Plan and the 2013 Employee Stock Purchase Plan, and
- (2) Registration Statement (Form S-3 No. 333-225286) of Applied Genetic Technologies Corporation

of our report dated September 10, 2018, with respect to the financial statements and schedule of Applied Genetic Technologies Corporation included in this Annual Report (Form 10-K) of Applied Genetic Technologies Corporation for the year ended June 30, 2018.

/s/ Ernst & Young LLP

Tampa, Florida
September 10, 2018

CERTIFICATIONS

I, Susan B. Washer, certify that:

1. I have reviewed this Annual Report on Form 10-K of Applied Genetic Technologies Corporation;
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.
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: September 26, 2019

By: /s/ Susan B. Washer
Susan B. Washer
Chief Executive Officer and President
(Principal Executive Officer)

CERTIFICATIONS

I, William A. Sullivan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Applied Genetic Technologies Corporation;
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.
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: September 26, 2019

By: /s/ William A. Sullivan
William A. Sullivan
Chief Financial Officer
(Principal Financial Officer)

**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 Applied Genetic Technologies Corporation (the "Company") for the year ended June 30, 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 18 U.S.C. Section 1350, that to his or her 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: September 26, 2019

By: /s/ Susan B. Washer

Susan B. Washer
Chief Executive Officer and President
(Principal Executive Officer)

Date: September 26, 2019

By: /s/ William A. Sullivan

William A. Sullivan
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Applied Genetic Technologies Corporation and will be retained by Applied Genetic Technologies Corporation and furnished to the Securities and Exchange Commission or its staff upon request.

