
**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, 2021

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:

<u>Title of class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit

report.

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 \$105.4 million, computed by reference to the closing sales price of the common stock as reported by the Nasdaq Global Market on December 31, 2020, 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 16, 2021 was 42,859,675.

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 to be filed with the Securities and Exchange Commission on or before October 28, 2021.

APPLIED GENETIC TECHNOLOGIES CORPORATION
ANNUAL REPORT ON FORM 10-K
FOR FISCAL YEAR ENDED JUNE 30, 2021

TABLE OF CONTENTS

	Page
PART I	
Item 1. Business	1
Item 1A. Risk Factors	43
Item 1B. Unresolved Staff Comments	90
Item 2. Properties	90
Item 3. Legal Proceedings	91
Item 4. Mine Safety Disclosures	91
PART II	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	92
Item 6. Selected Financial Data	92
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	92
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	107
Item 8. Financial Statements and Supplementary Data	108
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	143
Item 9A. Controls and Procedures	143
Item 9B. Other Information	143
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	144
Item 11. Executive Compensation	144
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	144
Item 13. Certain Relationships and Related Transactions, and Director Independence	145
Item 14. Principal Accountant Fees and Services	145
PART IV	
Item 15. Exhibits and Financial Statement Schedules	146
Item 16. Form 10-K Summary	150
SIGNATURES	151

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, including results and timing of our clinical trials and planned clinical trials, 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,” “hope,” “plan,” “anticipate,” “project,” “believe,” “estimate,” “predict,” “intend,” “potential,” “might,” “would,” “continue,” “seek” 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 law, including the securities laws of the United States and the rules and regulations of the Securities and Exchange Commission, 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,” “AGTC” or the “Company” refer to Applied Genetic Technologies Corporation.

Item 1. BUSINESS

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 continue to progress clinical programs in X-linked retinitis pigmentosa (XLRP) and achromatopsia (ACHM). In addition, we have a partnered clinical-stage program in optogenetics, and preclinical programs in central nervous system (CNS), ophthalmology, and otology indications. With several important clinical milestones on the horizon, we believe that we are well positioned to advance our XLRP product candidate through our XLRP Phase 1/2 Expansion, or Skyline and XLRP Phase 2/3, or Vista, clinical trials (described below) as well as our ACHMB3 product candidate towards a pivotal trial. We will work with the United States Food and Drug Administration, or the FDA, to plan for late-stage development of our ACHM product candidate. 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. 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 preclinical 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 preclinical program in dry age-related macular degeneration, or AMD.
 - **Seek opportunities for strategic partnerships and acquisitions in ophthalmology gene therapy.** In February 2017, we entered into a collaboration agreement with Bionic Sight, LLC, or 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.
- **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 use a consistent framework to focus on diseases for which:

- the underlying genetic defect is well characterized;
- the underlying genetic defect can be addressed by approaches amenable with the use of AAV, such as gene replacement, RNA targeting sequences, or antibody delivery; and
- 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 that these markets can be served with a small, targeted commercial infrastructure. Our research in the fields of otology and CNS are examples of this strategy.

- **Extend our expertise in adeno-associated virus, or AAV, vector design, manufacturing and delivery.** We believe that our deep 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 external research collaborations to identify novel next generation capsids, develop optimized promoters to enhance product performance, and identify opportunities for continuous improvement in our manufacturing process. We are also expanding our research and discovery capabilities to further enhance our ability to develop next generation products, including the delivery of other payloads such as antibodies and RNA.

- **Expand our manufacturing capabilities.** We continue to invest in the development and expansion of our internal manufacturing capabilities with a particular focus on adding facilities while enhancing the productivity, scalability and purity of our manufacturing platform. Our late-stage, commercial manufacturing process has demonstrated it can produce thousands of ophthalmology doses from a 50L bioreactor with an approximately 90% full to empty capsid ratio and greater than 97% purity levels as demonstrated in multiple batches completed by our personnel as well as batches completed at a Contract Development and Manufacturing Organization (CDMO). Our process development and pilot manufacturing facility is used to manufacture early stage research materials, and we are currently expanding our in-house capabilities through the lease of a build-to-suit 21,250 square foot current Good Manufacturing Practices (“cGMP”) manufacturing and quality control facility adjacent to our current Florida facility. We plan to support the facility development through a combination of robust tenant improvement allowances and tiered rental rates during the construction and initial occupancy period. The facility will encompass manufacturing and analytical functions. This facility will be a state-of-the-art, cGMP-compliant production and testing facility for AAV-based gene medicines capable of clinical and commercial batch production. Once this facility is up and running, we expect it will further decrease our dependence on contract manufacturing and testing organizations and allowing our internal subject matter experts to fully engage in the production activities. We believe that 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. The cell and gene therapy industry, as well as the greater biotechnology field, continues to be challenged by COVID-19-related supply chain disruptions. Our ability to execute at our current and planned facilities will depend on our ability to access raw materials and other necessary supplies, such as non-human primates (NHP) for our toxicology testing in order meet programmatic needs and timing.

Our Initial Focus in Ophthalmology and Other Areas

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 Retinitis Pigmentosa GTPase Regulator, (RPGR) gene, and ACHM, caused by mutations in either the Cyclic Nucleotide Gated Channel Subunit Beta 3 (CNGB3) gene or the Cyclic Nucleotide Gated Channel Subunit Alpha 3 (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 have completed targeted enrollment of 28 patients in our Phase 1/2 clinical trials for our XLRP product candidate and, in July 2021, reported full 12-month data showing a 50% response rate in the high dose groups. We are currently executing on our Skyline and Vista trials, which are informed by end-of phase 2 feedback received from the FDA. We plan to release 3-month data from the Skyline trial in the first half of calendar year 2022 and 6-month data from the Vista trial in the fourth quarter of calendar year 2022.

[Table of Contents](#)

- **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% to 85% have the form of disease caused by mutations in the CNGB3 gene or the CNGA3 gene. We have completed planned enrollment of adult patients in our Phase 1/2 clinical trials for both our ACHM CNGB3 product candidate and our ACHM CNGA3 product candidate and, in July 2021, reported full 12-month data showing clinically meaningful improvement in ACHMB3 patients in the high and pediatric groups but weaker biologic signals in the ACHMA3 patients. Based on the improvements seen in the ACHMB3 patients, we are preparing an End of Phase 2 (EOP2) submission and request a meeting with the FDA to receive feedback on our late-stage plans for ACHMB3. We plan to release 3-month data for high dose pediatric patients, both ACHMB3 and ACHMA3 in the fourth quarter of calendar year 2021.

In addition to our most advanced ophthalmological product candidates, we have a collaboration with Bionic Sight to develop an optogenetics product candidate for patients with advanced retinal disease and a preclinical program for our Dry AMD product candidate, a gene therapy focused on Complement Factor H, or CFH.

- **Optogenetics:** In addition to these two lead ophthalmology programs, we have a collaboration with Bionic Sight to develop an optogenetic product candidate for patients with advanced retinal disease. This clinical stage program leverages a unique optogenetic protein, administered by intravitreal injection in an AAV vector, that is activated with a neural coding device using Bionic Sight's proprietary algorithm to convert what the patient is viewing into signals the brain can understand. In March 2021, Bionic Sight, which has responsibility for conducting the clinical trial, reported promising results in its first two cohorts of patients. Bionic Sight reported that these patients, all of whom have complete or near-complete blindness, can now see light and motion, and, in two cases, can detect the direction of motion. The product appears to be safe and well tolerated and Bionic Sight is continuing to enroll patients at higher doses.
- **Dry AMD:** Individuals with mutations in CFH, which is a component of the dysregulated complement pathway, have an increased risk of developing AMD that is six times greater than those who do not have such mutation (Sepp et al., 2006). Preclinical data in relevant animal models support the approach of CFH gene augmentation as a potential therapeutic strategy for AMD. Based on market research, we believe there may be as many as 600,000 patients in the United States that would benefit from a CFH gene therapy approach. The full length CFH gene is too large to fit into a single AAV and, therefore, we have re-engineered the gene and have determined that our construct retains functionality both in vitro and in vivo. The program is positioned to proceed to investigational new drug-, or IND-, enabling safety and biodistribution studies. Due to the current global shortage of NHP test subjects, the timeline remains uncertain.

While our initial focus was in ophthalmology, we are also using our deep capabilities and knowledge of vector construct and design, clinical development, and manufacturing to extend our pipeline into other areas of unmet medical need where we believe an AAV gene therapy approach can potentially provide an advantage.

- **Frontotemporal dementia (FTD):** FTD is a degenerative brain disorder, second only to Alzheimer's disease in terms of prevalence and incidence in the dementia spectrum, is on the rise due to the aging population, and has no approved treatments. Mutations in the Progranulin (PGRN) gene are one of the three main genetic causes of FTD, representing approximately 20% of familial FTD, and accounting for 7,500 to 15,000 cases in the United States and European Union. We have identified a unique capsid, gene and promoter construct that we believe, based on our preclinical data to date, will be more effective in patients than other approaches and are proceeding to IND-enabling safety and biodistribution studies. Due to current global shortage of NHP test subjects, the timeline remains uncertain.

[Table of Contents](#)

- **Amyotrophic lateral sclerosis (ALS):** ALS (Lou Gehrig's disease) is an autosomal dominant, fatal adult-onset disease with no truly effective therapy. It is the most common adult-onset motor neuron disease, with approximately ~75,000 cases in the United States and European Union, and is characterized by upper and lower motor neuron degeneration. Early symptoms are muscle weakness that progresses and ultimately results in respiratory failure, with death usually occurring within 3 to 5 years of diagnosis. There are both sporadic (~90%) and familial (~10%) forms of the disease, with the most common genetic cause linked to the C9orf72 gene, representing 30-40% of cases. C9orf72 mutations are also present in FTD. We are developing a novel trivalent approach that we believe can fully address all the cellular deficits associated with the mutation and are in the process of finalizing the optimal combination of components to create a therapeutic construct that will be advanced to later stage preclinical studies.
- **Otology:** Mutations in the gap junction protein beta 2 gene (GJB2) account for approximately 30% of all genetic hearing loss cases, representing approximately 90,000 cases in the United States and European Union markets. Patients with this mutation can have severe-to-profound deafness in both ears that is identified in screening tests routinely performed in newborns. In collaboration with Otonomy, Inc. (Otonomy), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, we are developing an AAV-based gene therapy to restore hearing in patients with sensorineural hearing loss caused by a mutation in GJB2. We and Otonomy announced promising preclinical data at the American Society of Gene and Cell Therapy (ASGCT) meeting in May 2021, demonstrating the rescue of hearing loss and cochlear morphology in two independent mouse models. The companies are conducting IND-enabling activities based on pre-IND meeting feedback from the FDA, with an IND filing anticipated in the first half of calendar year 2023.

Recent Corporate Milestones

In June 2020, to address the challenges of visiting clinics as a result of the Covid-19 pandemic and to improve the experience for patients, we launched a nationwide mobile vision testing center, staffed with certified technicians and key testing equipment, for patients enrolled in our ongoing Phase 1/2 clinical trials, and we plan to offer access to similar centers for both the Skyline and Vista trials. More than 70 patient visits at mobile vision testing centers have been completed as of June 30, 2021.

In June 2020, we announced significant productivity and quality enhancements in our proprietary manufacturing platform that are currently being used to create clinical trial material for our planned pivotal XLRP clinical trials. These enhancements will also benefit future clinical trial material for all of our programs.

In July 2020, we announced the updated development plan for our XLRP clinical program and the design of our Skyline and Vista Trials.

In August 2020, we announced the formation of a Patient Advisory Council to build on our focus of incorporating the patient and caregiver voice into our culture and clinical and preclinical programs and to provide insight and recommendations to our clinical development efforts.

In November 2020, we reported additional positive data from our ongoing Phase 1/2 clinical program in patients with XLRP.

In January 2021, we provided an update on our ongoing clinical trials in patients with ACHM. We believe that the data provides the first reported quantitative evidence of improvements in visual sensitivity, supports the positive patient reported outcomes and provides a path forward to collect additional data to fully realize the potential of this treatment.

In February 2021, we closed an underwritten public offering of common stock and warrants resulting in gross proceeds of \$74.5 million, before deducting underwriting discounts, commissions and other offering expenses payable by us.

[Table of Contents](#)

In April 2021, we and TeamedOn International announced a licensing agreement to advance gene therapy to treat XLRS, an inherited disease that causes loss of vision due to degeneration of the retina in males. TeamedOn will conduct all activities to reinitiate clinical development of our previously discontinued XLRS clinical program and we will be eligible to receive milestones and royalties based on clinical progress.

In April 2021, we announced a license with SparingVision SAS whereby we enabled SparingVision to use our proprietary cone-specific promoter technology in up to three non-competing products in exchange for an upfront license fee, and the potential to receive future milestone and royalty payments.

In May 2021, we presented abstracts at ASGCT that described improvements to our manufacturing process (Abstract 806) and the validation of a novel expression assay for use in our Vista trial (Abstract 884). Additionally, Otonomy, our collaborator in genetic hearing loss, presented data hearing recovery in relevant mouse models using our product candidate.

In May 2021, we signed a 20-year lease for a build-to-suit 21,250 square foot cGMP manufacturing and quality control facility adjacent to our Florida facility to prepare for anticipated late-stage development of our XLRP and ACHM programs.

In May 2021, we amended our long-term loan agreement and received a second term loan advance of \$10.0 million. Additionally, the interest-only period and facility maturity date were extended to March 31, 2022 and April 1, 2024, respectively.

In May 2021, we announced the expansion of our leadership team with the addition of Janet Rae, RAC, as Senior Vice President, Global Regulatory Affairs and Quality, who brings extensive experience in the regulatory affairs industry specializing in drug, biologic and gene therapy products with a specialization in orphan drugs and rare disease therapy development.

In June 2021, we announced 12-month data from our on-going Phase 1/2 ACHM clinical trials showing biological activity in patients with mutations in the ACHMB3 gene.

In July 2021, we hosted a virtual Research Day that provided a review of 12-month data from the highest dose groups in our ongoing Phase 1/2 clinical trials in XLRP and an expanded analysis of the 12-month data from our ongoing Phase 1/2 clinical trials in ACHM that we reported in June 2021, including a discussion on light sensitivity and ACHM genetics.

In July 2021, The United States Adopted Name (USAN) Council notified us that it has formally assigned the USAN name laruparetigene zosaparovec for our XLRP product candidate.

Our Strengths

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

- Product candidates in clinical development, including three ongoing Phase 1/2 clinical trials, as well as a Phase 1/2 extension trial and plans for a Phase 2/3 trial, with enough capital to complete initial data analysis for these trials;
- Topline interim 12-month data from our Phase 1/2 clinical trial for our XLRP product candidate that continue to show an acceptable safety profile and evidence of increase and expansion in central visual sensitivity, encouraging improvements in visual acuity, and preliminary results from quality of life surveys that support meaningful impact on patients' lives;
- Comprehensive End-of-Phase 2 feedback from the FDA that informed our revised framework for moving the XLRP candidate into the next stages of development;

[Table of Contents](#)

- 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;
- A partnership with Otonomy, a company with deep expertise in neurotology, for the development of our joint otology program;
- Proprietary gene therapy manufacturing system, including a leased build-to-suit cGMP manufacturing and quality control facility that is under construction, capable of making significant quantities of high quality viral vectors in accordance with Good Manufacturing Practice, or GMP, standards as successfully demonstrated in seven different clinical trials, and has demonstrated a 10-fold increase in productivity as a result of our internal development efforts, which means that we can produce thousands of ophthalmology doses from a 50L bioreactor with greater than 90% full capsids and 97% purity at a cost of goods that is potentially as much as a 90-fold improvement over other methods;
- Product candidates, using our AAV vector technology platform, that have demonstrated they are generally safe and well tolerated for the indications we are developing;
- Technical expertise in analytical techniques, synthetic promoter development, engineered and 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 19 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 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;
- AAV vectors can deliver 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

[Table of Contents](#)

- 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 conducted internal and external research to design promoters that optimize therapeutic constructs for maximum expression with a smaller size, and increased cell specificity. We expect to perform this same type of work for each new indication we pursue.
- **Capsid:** after the promoter and gene of interest are selected, these elements must be packaged into an AAV capsid. There are 10⁸ 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 built an rAAV manufacturing platform agnostic to indication, dosing requirements or market size, with demonstrated ability to generate thousands of ocular doses in modest scale stirred tank bioreactors. This scalable, proprietary, high-yield vector manufacturing process can address the most demanding material needs with minimized scaling needs. The system is turnkey, employing robust cell lines that are well characterized and have been vetted by regulatory authorities in the United States, Canada and Europe. The upstream process consistently generates vectors characterized by greater than 50% of all capsids containing full-length, target gene sequences while the downstream process further enhances this resulting in excess of 90% full capsids. The companion analytical platform for process and material characterization is comprised of over 35 product-specific assays developed and transferred to vendors, consistent with regulatory requirements for clinical development. The full suite of characterization assays has transitioned to validation activities to support regulatory approval of the production and characterization platforms. Large biotech partners have successfully transferred our technology into their facilities, and even transferred the process themselves to third party CDMOs, demonstrating an unparalleled robustness. We are augmenting our aggressive risk mitigation approach to manufacturing activities for our internal pipeline, by building our own cGMP facility as a strategic approach to our transition to late-phase clinical development and manufacturing while we continue to support our previous platform technology transfer efforts at multiple redundant CDMOs. Recent process improvements advance our upstream productivity over ten-fold relative to earlier versions of the process (figure below), and over 50-fold relative to traditional transient transfection, employing all scalable operations which have been optimized to provide a final product substantially free of process residuals, often below the quantification limits of our sensitive assays.

Our manufacturing process has been reviewed by the United States Food and Drug Administration, or the FDA, Health Canada, the Irish Medicines Board and the Israeli Ministry of Health and has been authorized for

[Table of Contents](#)

production of clinical trial material for use in clinical trials in the United States, Canada, Europe and Israel. We have successfully manufactured clinical trial material for seven different indications using three different CDMOs. Our staff have utilized our state-of-the-art process development facility to adapt our process across multiple bioreactor platforms and scales, demonstrating a robust and flexible platform capable of integrating into diverse partner, manufacturing and commercial facility environments.

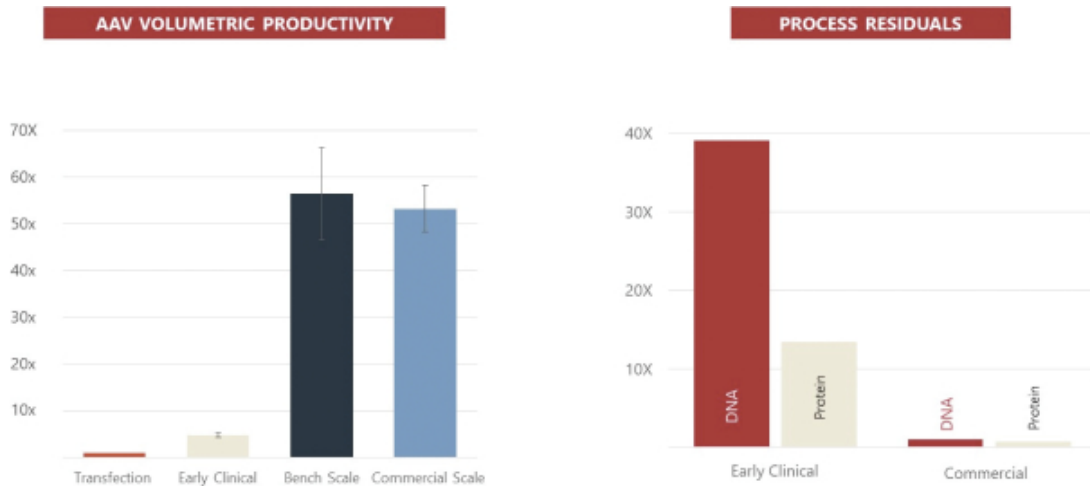
We own or have licensed 38 patents and pending patent applications covering our manufacturing technology. We believe that our core competency and intellectual property estate in vector manufacturing provide a key differentiating element of our gene therapy platform.

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. Our focus is to develop an integrated production and testing platform capable of meeting both clinical and commercial needs and we are committing substantial resources in this area. Important features of our capabilities are set forth below.

- 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 achieved more than 10-fold improvement in productivity compared to other manufacturing formats.
- We have adapted our herpes simplex virus, or HSV, helper manufacturing system to multiple vendors' single use bioreactors, demonstrating robustness and flexibility while 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 35 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 U.S., 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.

[Table of Contents](#)

Taken together, we believe that the efficiency, productivity, scalability, characterization and regulatory definition of our proprietary rAAV manufacturing platform uniquely position us to quickly transition from early phase human clinical trials to late phase, Biologics License Applications (BLA) enabling data in all our clinical programs. We are currently at commercial scale for our orphan ophthalmology programs due to our high productivity that enables us to achieve thousands of doses from a small bioreactor. Productivity (below, left) has increased 55-fold between early clinical and commercial processes at scale, while process residuals (below, right) have decreased nearly 40-fold (DNA) or greater than 10-fold (protein).



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, a 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 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. Bionic Sight is using an intravitreal injection as the method of delivery for the 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.

For each product candidate identified in our CNS preclinical programs, we will determine the optimal delivery approach to safely administer the product candidate and ensure optimal therapeutic effect.

Our Product Candidate Pipeline

Our most advanced product candidates address ophthalmology indications XLRP, ACHMB3 and ACHMA3, which are orphan diseases of the eye that are caused by mutations in single genes, significantly affect visual function starting at birth and which 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 combined. 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.

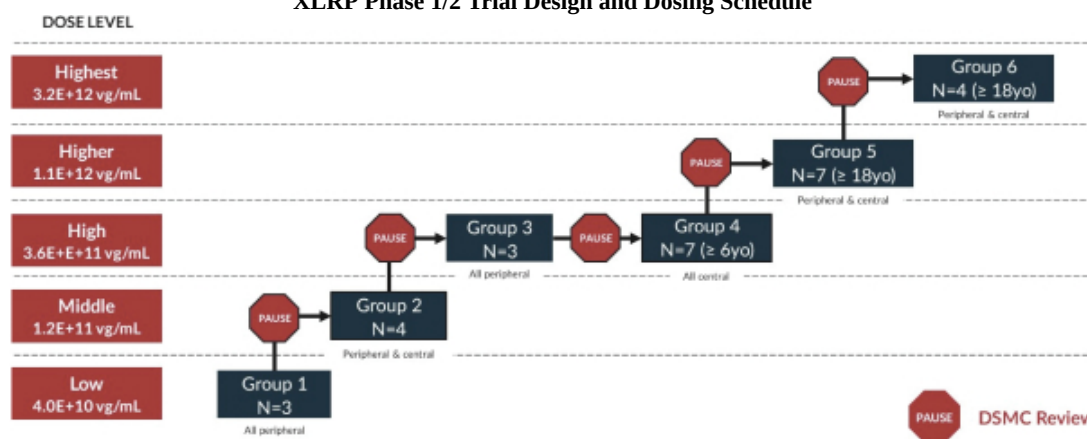
Our XLRP product candidate

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 (laruparetigene zosaparvovec) 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 maintain photoreceptor function and delay disease progression in dog and mouse models of XLRP. In addition, published NHP studies have demonstrated that our proprietary AAV capsid has as much as twice the transfection efficiency in photoreceptors as is shown by capsids used in competing programs.

Clinical development

On July 22, 2021, we updated data from our on-going XLRP Phase 1/2 dose escalation trial, conducted at multiple clinical sites in the U.S. that specialize in inherited retinal diseases. The clinical protocol was designed as a dose escalation trial to evaluate our product candidate in XLRP patients at five dose levels, spanning a 100-fold range, and included targeted enrollment of 28 patients in the dose escalation and expansion portions of the trial. This design is intended to provide us with a robust set of safety and biologic activity data with which to inform our next stage of clinical development. The primary endpoint of this clinical trial is safety, and interim data have shown that the XLRP product candidate thus far continues to show a favorable safety profile and is well tolerated. In addition to safety, this trial is measuring biologic activity by assessing changes in several measures of visual function and quality of life. Durable and meaningful improvements in central visual sensitivity and encouraging improvements in visual acuity were reported through Month 12 in all patients and through month 24 in isolated patients.

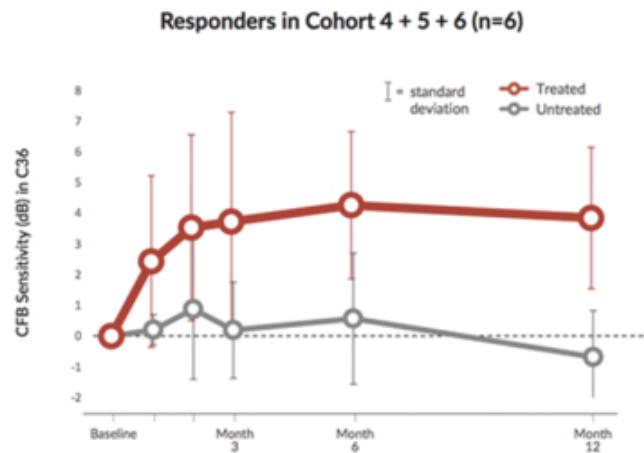
XLRP Phase 1/2 Trial Design and Dosing Schedule



Safety data through month 12 in the XLRP Phase 1/2 dose escalation trial continues to show a favorable safety profile. There are no serious adverse events (SAEs) related to the use of the study agent. Early in the trial there were four ocular SAEs of persistent subretinal fluid (coded as “retinal detachment”), that were related to the study injection procedure and required second surgeries to resolve; corrective measures were implemented to mitigate this risk and they have not recurred. All adverse events (AEs) related to the use of the study agent were mild to moderate in severity and have resolved.

The study agent continues to demonstrate biologic activity as assessed by several measures of visual function, including visual sensitivity measured by microperimetry. There are many ways to evaluate improvements in visual sensitivity including a mean change over time in the treated area, an analysis of detailed changes in the treated area represented by a heat map and a pointwise analysis looking at changes in individual loci within the treated area. Based on FDA feedback, we are now defining a responder as a patient with a change from baseline in visual sensitivity of at least 7 dB in at least 5 loci. These 5 loci are pre-specified at baseline for the ongoing trials based on three repetitions of microperimetry testing. Using this definition retrospectively for the Phase 1/2 patients, looking at loci within the central area closest to the fovea, four of 11 centrally treated patients in the high dose groups meet the definition of responder at Month 12, compared with five of 11 in high dose groups at Month 6. Additionally, there were two of seven responders in dose group 4 at both Month 12 and Month 6. The mean sensitivity change for these patients is shown in the graph below. As described and shown in the table below, one patient each from Groups 2 and 5 are no longer responders by this definition at Month 12; however, these two patients show increased mean sensitivity from baseline in the treated eyes compared with untreated fellow eyes. Of note, during our virtual Research Day in July 2021, retina surgeon and Study Investigator Robert Sisk, M.D., Associate Professor, University of Cincinnati’s Department of Ophthalmology, described other ways of showing clinical benefit besides the above definition of responder. He showed examples of clinical benefit evidenced by visual field expansion (widening), as well as by increased sensitivity in the very central region of the field in study patients who otherwise did not meet the above the definition of responder.

Mean sensitivity change from baseline in responder sub-group at Month 12



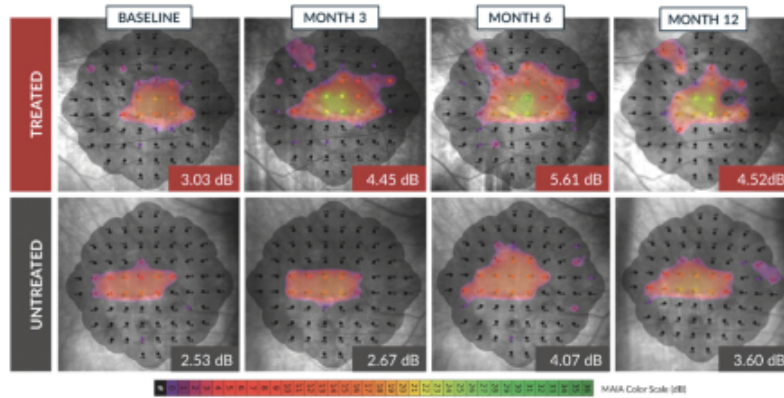
Pointwise change from baseline in responder sub-group at Month 6 and Month 12

<u>Dose Group</u>	<u>C36 Change ³⁷db @ ³⁵ Loci at Month 6</u>	<u>Number of Responders</u>	<u>C36 Change ³⁷db @ ³⁵ Loci at Month 12</u>	<u>Number of Responders</u>
2#	Yes	1/1	No	0/1
4	No	2/7	No	2/7
	Yes			
	No			
	No			
	Yes			
	No			
	No			
5	No	3/7	No	2/7
	Yes			
	No**			
	No			
	Yes			
6	No**	2/4	No**	2/4
	No**			
	Yes			
	Yes			

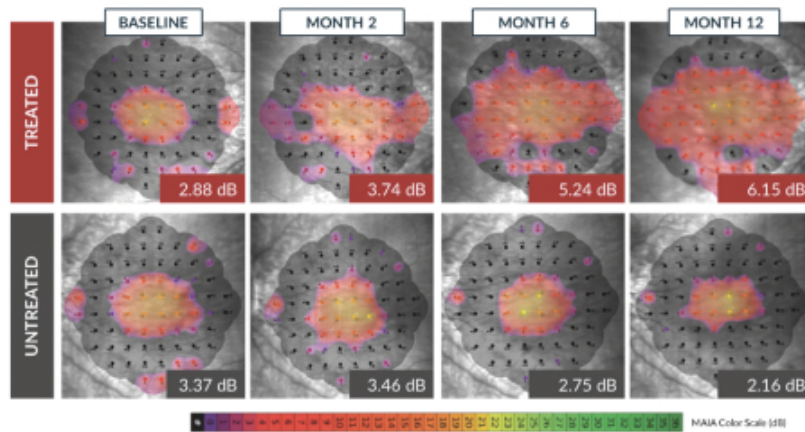
[Table of Contents](#)

In addition to presenting the summary data for mean sensitivity and pointwise analysis, we also reviewed individual heatmaps of all patients, which showed that in many cases, not only did patients experience an increase in mean sensitivity, but also, as illustrated below, the area of the retina responding to light expanded, which is an important component to the patient's quality of life.

Patient 12 (Group 5): BCVA and 7/5 Responder

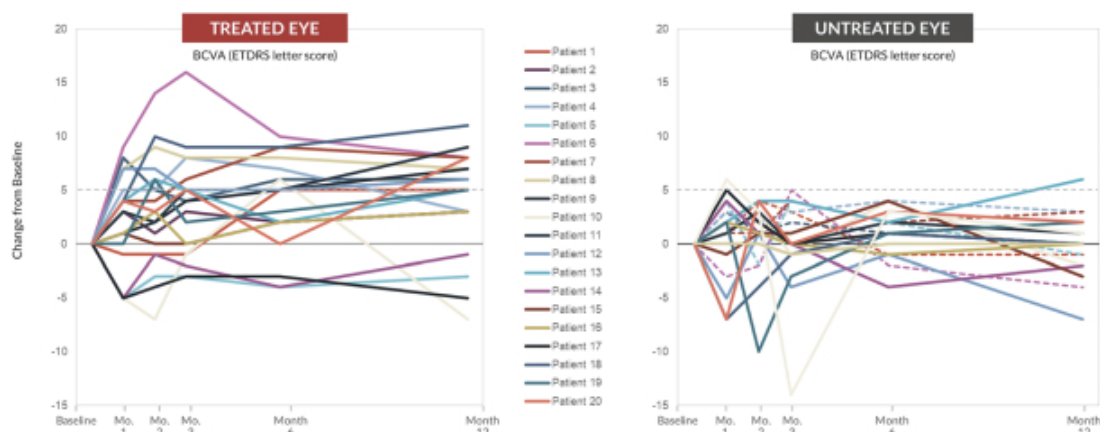


Patient 19 (Group 6): 7/5 Microperimetry Responder



In addition to improved visual sensitivity, 10 of 20 centrally treated eyes showed gains of at least five letters in best corrected visual acuity (BCVA) at Month 12, providing further supportive evidence of biologic activity. This change was statistically significant with a p value of 0.0004 for patients with at least five letter improvement in treated eyes versus fellow untreated eyes by Fisher's exact test, a statistical significance test most often used when sample sizes are small that allows the p value to be calculated exactly rather than relying on an approximation that becomes exact in the limit as the sample size grows to infinity, as with many statistical tests.

BCVA Change from Baseline All groups at Month 12



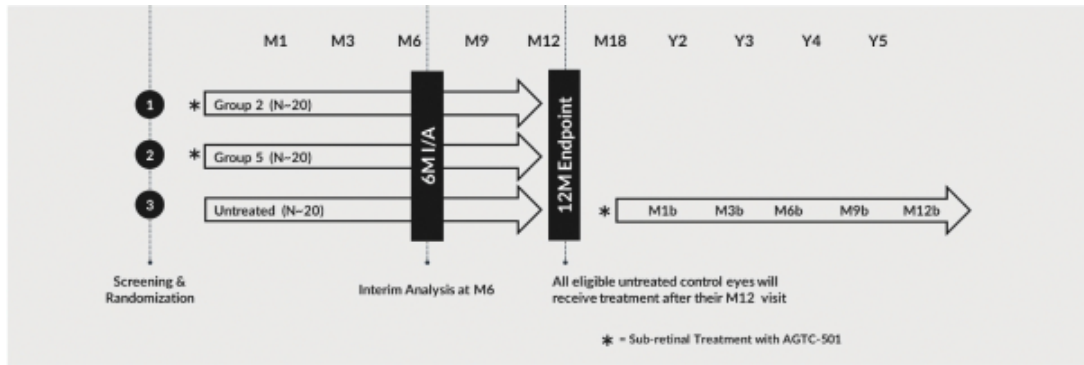
We are applying the lessons we learned in the XLRP Phase 1/2 trial to our Skyline and Vista clinical trials. For example, patients with baseline evidence of severe disease will be excluded from ongoing and future trials because they have not shown a treatment benefit in the XLRP Phase 1/2 trial. Had these patients been excluded from the 11 patients in the two highest dose groups in Phase 1/2 (Groups 5 and 6), three non-responders would have been excluded from the analysis (double asterisk in the above Table), leaving four of eight (50%) patients meeting the definition of responder.

For ophthalmology studies in general, and especially with low sample sizes, there is often a concern of possible patient bias that could influence endpoints due to the psychometric nature of the test protocols, and that to the extent possible, this should be minimized. In order to mitigate potential patient bias that could influence endpoints due to the psychometric nature of the test procedures, and incorporating feedback provided by FDA on this issue, the proposed Vista protocol randomizes approximately 60 patients to two masked active doses and an untreated control arm in the Vista trial. The dose concentrations are 1.2E+11 vg/mL (Group 2 in the XLRP Phase 1/2 trial) and 1.1E+12 vg/mL (Group 5 in the XLRP Phase 1/2 trial).

We added an important secondary endpoint to the Skyline and Vista trials, a standardized functional mobility test, which captures real-world impacts on XLRP patients by objectively assessing changes in patient mobility that are secondary to improvements in visual function resulting from therapeutic intervention. This test, analogous to the one used as the primary basis for approval of ophthalmology gene therapy product Luxturna, determines the lowest light level that patients are able to walk through a deliberately arranged course. This arrangement is changed between test points. Successful navigation of the course, as measured by factors such as speed and accuracy at diminishing light levels, will indicate a positive treatment response. Other secondary endpoints will include BCVA, full-field sensitivity threshold (FST) and changes in contrast sensitivity.

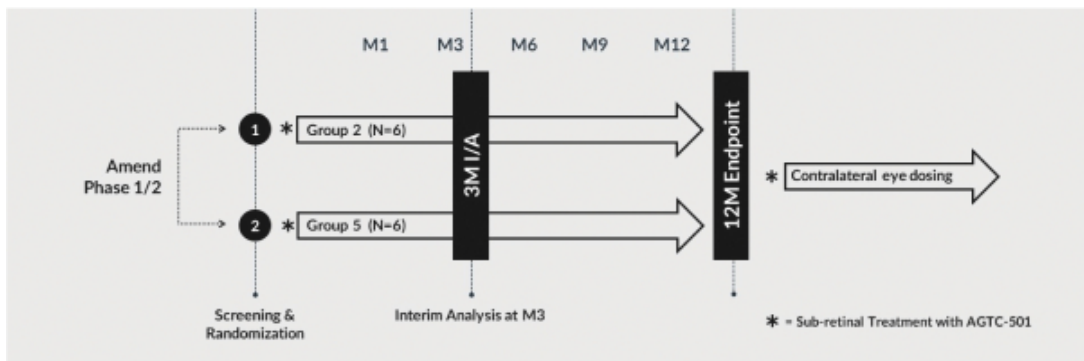
Based on the projected responder rate, using the pointwise analysis of the data from the XLRP Phase 1/2 trial, the Vista trial is intended to determine a difference between either active arm and the control arm. We expect to provide results from a 6-month interim analysis during the fourth quarter of calendar year 2022. We plan to request FDA feedback on the 6-month interim data, at which time we will also have 24-month data from the original Phase 1/2 and 12-month data from the Skyline trial. Based on this feedback, we may modify the final trial design, enrollment numbers and statistical analysis plan and any other adjustments suggested by the data in consultation with the FDA. If the totality of the data collected at 12 months shows a compelling risk-benefit balance, we believe it may support the submission of a BLA filing. Timing of the reporting of this data may be impacted by future effects of the COVID-19 pandemic on clinical trial enrollment.

Outline of the Vista Trial



While not required prior to initiating the Vista trial, at our discretion, we plan the Skyline trial to include 12 additional patients that will be masked and randomized to doses of $1.2E+11$ vg/mL (Group 2 in original trial plan) and $1.1E+12$ vg/mL (Group 5 in original trial plan). We expect to provide results from a three-month interim analysis from all 12 patients in the first half of calendar year 2022. We expect these data to provide a near-term assessment of the correlation between changes in visual sensitivity and the patients' ability to navigate the functional mobility course, the additional secondary endpoint we plan to measure in the Phase 2/3 Vista trial.

Outline of the Skyline Trial



Achromatopsia (ACHM)

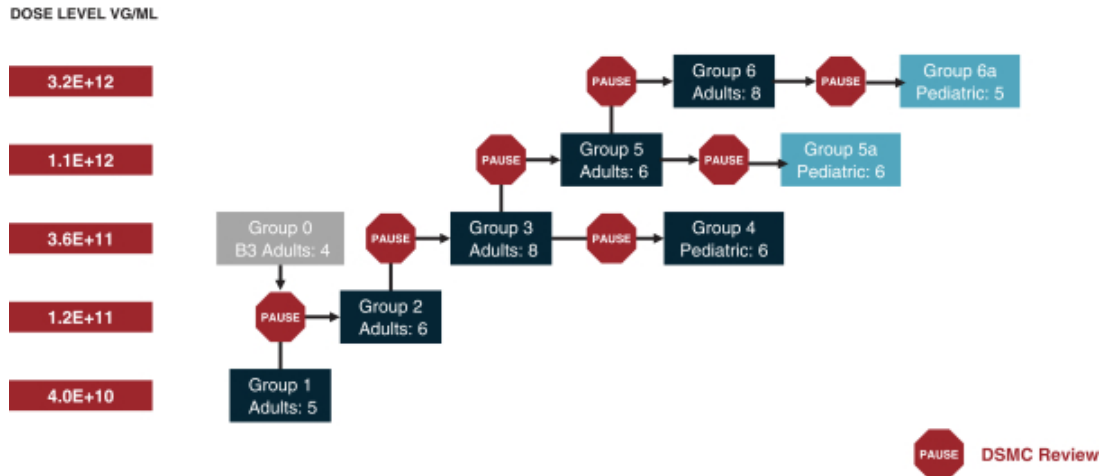
ACHM is an inherited retinal disease, meaning that children are born with the defective gene that causes poor visual function, which significantly affects daily activities. ACHM is present from birth and throughout life and is characterized by a lack of cone photoreceptor function. Cone photoreceptors 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.

Table of Contents

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.

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. A schematic of the ACHM Phase 1/2 Trial is shown below as a dose escalation, age de-escalation design for both the CNGB3 trial and the CNGA3 trial; patient numbers are combined.



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. We have completed enrollment of 26 and 20 patients in the dose escalation portions of the CNGB3 and CNGA3 trials, respectively. The primary endpoint of these clinical trials is safety, and available data thus far for all adult groups and the lowest pediatric group have shown that the ACHM CNGB3 and CNGA3 product candidates are generally safe and well tolerated. At the beginning of the trial, we experienced initial variability in surgical procedures along with ocular inflammation, which we have now resolved through our extensive surgical training procedures.

We recently enrolled six pediatric ACHMB3 patients and five pediatric ACHMA3 patients in higher dose groups 5a and 6a. Three new SAEs of significant inflammation that are considered a Suspected Unexpected Serious Adverse Reaction, or SUSAR, occurred in pediatric patients at the highest trial dose group 6a with a concentration of 3.2e12 vg/mL; two patients are in the CNGA3 trial, the other is in the CNGB3 trial. The

[Table of Contents](#)

inflammation was observed in both the anterior and posterior segments of the eye, approximately one month after treatment, leading to a subsequent procedure to remove vitreous fluid for diagnostic purposes and/or to administer treatment to the vitreous cavity. We reported the events to the FDA according to regulatory requirements. An additional CNGB3 pediatric patient at this same dose also has presented with significant inflammation during approximately the same post-operative time frame but has not required a subsequent procedure. To address the above safety events in pediatric patients, systemic and local steroid doses have been increased and patients are being monitored closely. No comparable inflammation has been seen in the six pediatric patients across both trials at dose group 5a, nor in any of the adult patients or the lowest dose group 4 pediatric patients on which we previously reported. These new data do not change our plans to continue development of the ACHM product candidates. We are currently postponing enrollment of the last pediatric patient in the ACHMA3 trial pending review of longer-term data for the high dose pediatric patients.

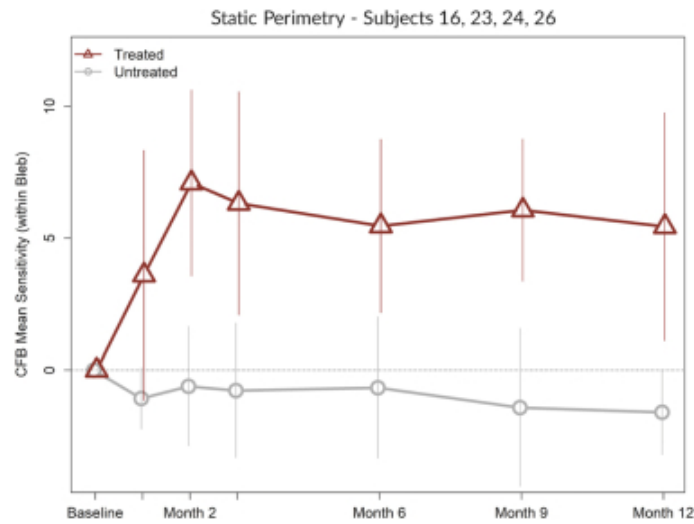
On July 22, 2021, we provided a comprehensive review of ACHM data for all adult groups and pediatric patients in dose group 4 in both the ACHMB3 and ACHMA3 trials. This data indicated biologic activity in the dose escalation portions in both the ACHMB3 and ACHMA3 trials. The response of ACHMB3 patients was more robust than the ACHMA3 patients and therefore we plan to move forward with planning for late-stage development of the ACHMB3 product candidate.

In CNGA3, improved retinal sensitivity within the bleb-treated visual field was observed in only one patient at Month 9 (Month 12 data was unreliable). This patient also showed improved light discomfort in both the treated and untreated eyes. At our virtual Research Day in July 2021, Medical College of Wisconsin study investigator Joseph Carroll, Ph.D., proposed an explanation for the more robust treatment effect in the CNGB3 trial relative to the CNGA3 trial based on the genetic differences between the two patient populations. Specifically, all enrolled CNGB3 patients have “null” gene mutations, which are predicted to make no protein; in contrast, all but two of the enrolled CNGA3 patients have missense mutations which are predicted to yield dysfunctional protein (the two exceptions had null mutations). Although yet to be confirmed experimentally, it is biologically plausible that the presence of an abnormal CNGA3 protein from may interfere with the function of the transfected wild type CNGA3 gene protein and/or the target cone photoreceptor cell. Indirect support for this rationale includes the fact that the CNGA3 patient with a robust treatment response noted above has a null mutation.

Data from the CNGB3 trial shows signs of biologic activity as evidenced by improved retinal sensitivity and light discomfort, with anecdotal patient reports supporting clinically meaningful improvement in their daily lives.

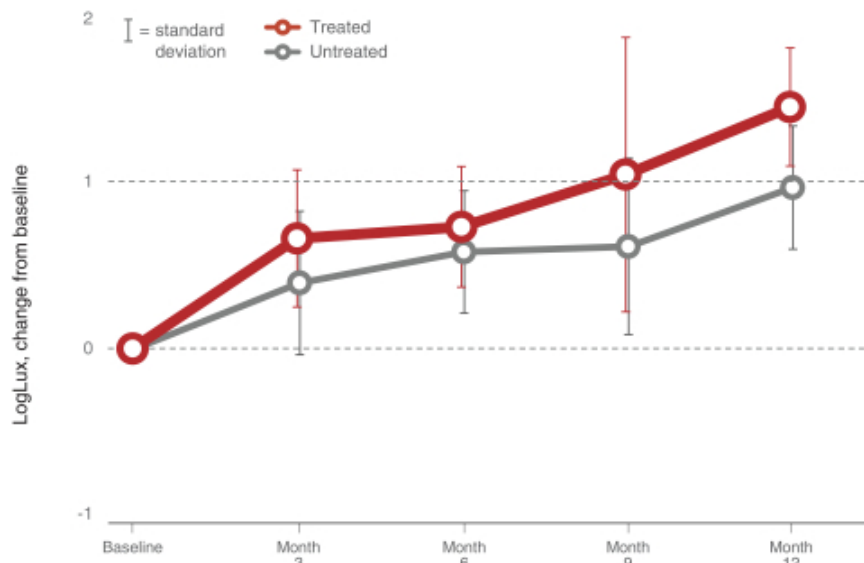
Retinal sensitivity as measured by full-field static perimetry improved in four of 11 CNGB3 patients in the high dose (Groups 5 and 6) and pediatric groups, as well as two patients in the lower dose groups. These improvements started at Month 2 and persisted through Month 12 as shown below for the higher dose groups and corresponded to the treated areas of the retina. There were no notable changes in the untreated fellow eyes.

Static Perimetry – Patients 16, 23, 24, 26



The light level at which the patients experienced discomfort, the single most important symptom to patients, also improved in six of the 11 high dose groups and pediatric CNGB3 patients, with evidence of improvement also seen in the untreated fellow eyes of these patients. A change in light discomfort is considered an improvement if it exceeds the statistical and clinical threshold of one loglux light. Three of these patients were also responders for visual sensitivity providing more evidence of overall improvements.

Light Discomfort Mean Change – Patients 16, 17, 20, 22, 23, 24



[Table of Contents](#)

Patients showing improved light discomfort in the study eye also showed some improvement in the untreated fellow eyes. At our Research Day, Dr. Carroll noted that bilateral effects to monocular stimuli are not uncommon in ophthalmology, and he described well-established neuro-anatomical and physiological explanations for this observation. For example, cortical adaptation to stimuli presented monocularly can manifest in a similar adaptation in the contralateral eye. This interocular transfer of visual effects may be attributed to binocular neurons in the brain and potentially enhanced by the post-chiasmatal decussation (crossing) of visual information, sending output from both retinas to the ipsilateral and contralateral brain centers, including higher cortical areas responsible for multisensory integration and gain control.

Given the evidence of treatment response described above for all adults and lowest dose group 4 pediatric patients as well as supportive anecdotal patient reports, we are preparing for an EOP2 submission and to request a meeting with the FDA in advance of initiating a Phase 2/3 trial. We expect this meeting to occur in the first half of calendar year 2022. We are also collecting novel measures of efficacy including color brightness (CoBri) testing and functional magnetic resonance imaging (fMRI) testing for the recently enrolled and currently enrolling pediatric patients. These additional tests may further support the patient anecdotal reports and the existing evidence of biologic activity of the CNGB3 candidate.

For CNGA3, we are focused on analysis of the data from pediatric patients in the Phase 1/2 trial. Preclinical animal data showed a treatment effect in young sheep, which might predict comparable treatment responses in younger pediatric Phase 1/2 patients despite the CNGA3 genetic considerations described above. We plan to provide an interim analysis of the pediatric patients in dose groups 5a and 6a in the fourth quarter of calendar year 2021.

Product Candidate to Treat Advanced Retinal Disease

In partnership with Bionic Sight, we provided preclinical and IND (investigational new drug) application support in Bionic Sight's development of 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 that is independent of a patient's 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 and functional.

Optogenetics is a biological technique by which cells are modified to express light-sensitive proteins. When the cells expressing these proteins are activated by light, they produce neural signals, which they can pass on to other neurons. Bionic Sight expresses the optogenetic proteins in the retina's ganglion cells, allowing them to send neural signals down the optic nerve to neurons in the visual areas of the brain.

The candidate treatment currently in clinical development by Bionic Sight is an AAV2 vector, injected intravitreally, that expresses a modified optogenetic gene, ChronosFP, in the retinal ganglion cells. The ChronosFP protein that is expressed is believed to have a more dynamic range of sensitivity and responsiveness than other optogenetic proteins being developed. In conjunction with the gene therapy treatment, Bionic Sight is developing a wearable prosthetic device that uses a novel algorithm to provide light signals to the retinal ganglion cells in a pattern similar to that produced by normal photoreceptor cells, which gives the treatment the potential to produce images the brain can recognize and may significantly enhance vision in patients receiving the optogenetic treatment. The IND for the program was successfully cleared by the FDA, and Bionic Sight initiated a Phase 1/2 clinical trial to test safety and potential efficacy of the treatment with the first patient treated in March 2020. Bionic Sight suspended enrollment by the clinical site due to the impact of COVID-19, but reinitiated clinical activities in July 2020 consistent with applicable COVID-19 guidelines. In March 2021, Bionic Sight, which has responsibility for conducting the clinical trial, reported promising results in its first two

[Table of Contents](#)

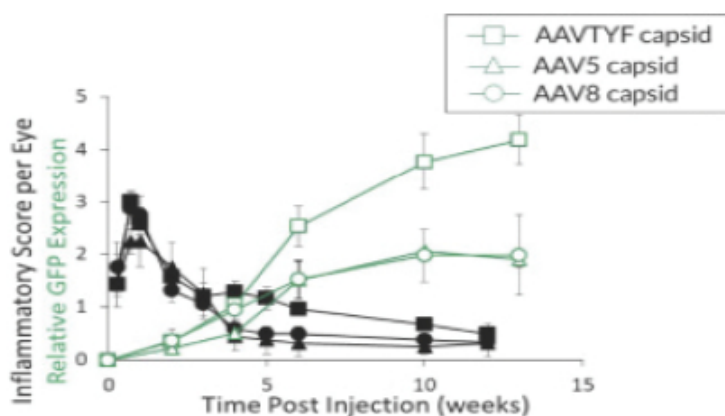
cohorts of patients. Bionic Sight reported that the treated patients, all of whom have complete or near-complete blindness, can now see light and motion, and, in two cases, can detect the direction of motion. Based on this report the product appears to be safe and well tolerated and Bionic Sight is continuing to enroll patients at the highest dose levels.

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

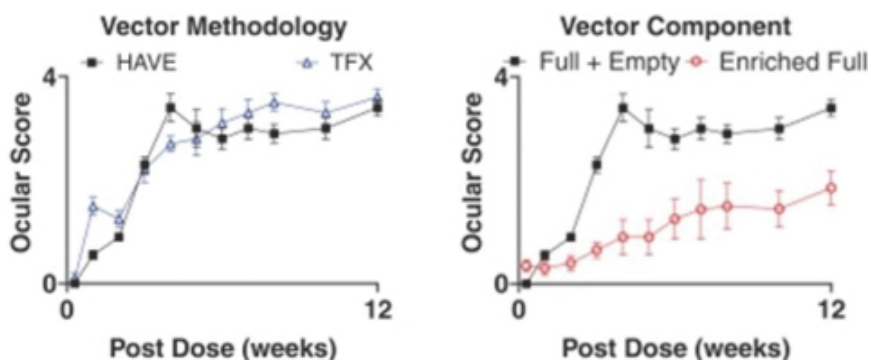
Three subretinal AAV gene therapy vectors are currently in clinical development for treatment of patients with XLRP. To compare the relative attributes of these vectors, a study was conducted which compared the photoreceptor transduction efficiency of subretinally delivered AAVTYF, the AAV capsid used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

Purpose	Parameters	Observations
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 and AAV8
Pre-existing Immunity (Low, Medium and 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



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 was accepted by Human Gene Therapy (Timmers et al., 2019).

Other opportunities in ophthalmology

We believe that our advanced gene therapy platform will enable us to develop and test new AAV vectors that carry gene sequences both for other inherited diseases in ophthalmology (it is estimated that approximately 290 genes causing inherited retinal disease have been identified), as well as larger ocular indications for which intervention at a specific target gene or pathway has been clearly identified. By leveraging the existing work on our lead programs and further deployment of technology advances, we believe 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. This efficiency is currently impacted by supply chain issues related to the COVID-19 pandemic and are affecting both material supplies and access to animal models. We have added two additional ophthalmology programs to our preclinical pipeline:

- **Dry AMD:** An estimated 15 million people in North America have AMD, of which 85-90 percent are diagnosed with the non-exudative dry form. This medical condition may result in blurred or no vision in the center of the visual field, which can make it hard to recognize faces, read, drive and perform daily activities. Progression to geographic atrophy (or wet AMD) leads to serious risk of blindness. Dysregulated complement pathway is considered an important factor in the disease etiology, and a component of the alternative complement pathway CFH, is known to have a strong genetic risk association with AMD. Individuals with mutations in CFH have an increased risk of developing AMD that is six times greater than those who do not have such mutation (Sepp et al., 2006). Preclinical data in relevant animal models support the approach of CFH gene augmentation as a potential therapeutic strategy for AMD. The full length CFH gene is too large to fit into a single AAV, and so in this case, we adopted a different approach and designed multiple engineered truncated forms, testing these in combination with different promoters to determine if they retain activity. From these studies, we identified a preferred construct that retains functionality both in vitro and in vivo. For example, we have shown that the construct targets the complement cascade in the retina of a *cfh* knockout mouse model and have performed expression studies in NHP retina. The program is positioned to proceed to IND-enabling safety and biodistribution studies. Despite the current global shortage of NHP test subjects, we have recently been able to secure enough subjects to initiate these studies in 2022.
- **Stargardt Disease:** In November 2019 we selected Stargardt disease as a new orphan ophthalmology indication to move forward towards the clinic. Stargardt disease is a macular dystrophy characterized by a blinding, progressive loss of photoreceptors due to mutations in the ABCA4 gene. However, this gene (~6.8 kilobases) exceeds the packaging capacity of AAV, and thus requires the use of a novel dual AAV vector system to deliver the two halves of the gene. Studies in a relevant *abca4* knockout mouse model have successfully shown correction of the disease phenotype (Dyka et al., 2019). We have also demonstrated reconstitution of the full length, functional protein in NHP retina after subretinal injection. The program is de-prioritized internally in light of ongoing work to move ACHMB3 forward, but we are discussing potential partnerships to build on the completed work.

Central Nervous System

An additional strategic area of focus for us 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 several unmet medical needs in severe diseases. We are actively developing two opportunities and have

established a world-class scientific advisory board to assist and guide our efforts as we advance these programs through preclinical development:

- **Frontotemporal dementia (FTD)**: FTD is a degenerative brain disorder, second only to Alzheimer's disease in terms of prevalence and incidence on the dementia spectrum, is on the rise due to the aging population and has no approved treatments. Mutations in the progranulin gene are one of the three main genetic causes of FTD, representing approximately 20% of familial FTD, and accounting for 7,500 to 15,000 cases in the US. Progranulin (PGRN) is a glycoprotein that undergoes protease enzyme-dependent cleavage into smaller subunits called granulins, and these granulins may play a key role in inflammation, wound repair, tumorigenesis and sexual differentiation. PGRN is critical in neurons for proper trafficking and function of lysosomal enzymes such as b-glucocerebrosidase and cathepsin D. PGRN haploinsufficiency (the loss of gene expression from one allele, resulting in reduced levels) is causally connected to FTD, and PGRN-deficient neurons are prone to accumulation of the protein TDP-43, which is thought to then lead to neurodegeneration. We are seeking to augment PGRN levels in order to restore its physiological balance, and this approach is supported by several studies in PGRN-deficient mouse models, where both the pathological and behavioral changes that occur as a result of PGRN loss have been rescued (Arrant et al., 2017, 2018). Following extensive preclinical analysis exploring different capsid, promoter and transgene combinations, we have devised a novel AAV construct to enhance PGRN expression in the brain following direct vector administration into the cerebrospinal fluid. We measured in dosed NHPs the cerebrospinal fluid levels of PGRN and confirmed that projected therapeutic levels are achievable within a defined dose range without affecting PGRN levels in plasma. The program is now positioned to proceed to IND-enabling safety and biodistribution studies in 2022 and subsequent IND submission. As stated for the ophthalmology programs, despite the uncertainty surrounding the availability of animal models we have been able to secure enough subjects to initiate these studies in 2022.
- **Amiotrophic lateral sclerosis (ALS)**: ALS (Lou Gehrig's disease) is an autosomal dominant, fatal, adult-onset disease with no truly effective therapy. It is the most common adult-onset motor neuron disease, with approximately ~30,000 cases in the US, and is characterized by upper and lower motor neuron degeneration. Early symptoms are of muscle weakness that progresses and then ultimately results in respiratory failure, with death usually occurring within 3 to 5 years of first symptoms. There are both sporadic (~90%) and familial (~10%) forms of the disease, with the most common genetic cause linked to the C9orf72 gene, representing 30-40% of cases. C9orf72 mutations are also present in FTD. C9orf72 gene six nucleotide repeat expansions can result in both gain-of-toxicity and loss-of-function, both of which are believed to contribute to the pathogenesis in C9orf72-related disease. Targeting of such repeat sequences with antisense oligonucleotides or artificial microRNAs, for example, has been shown to reduce the accumulation of intranuclear transcripts (Martier et al., 2019). We are working on a novel integrated therapeutic approach that we believe has the potential to fully address all of the cellular deficits associated with the mutations. Currently we are identifying the optimal microRNAs (knockdown of gain-of-toxicity) and functional C9orf72 gene product (replace) combination to develop therapeutic AAV that addresses all aspects of the disease-causing mutation.

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

[Table of Contents](#)

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 and CNS 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.

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 October 1, 2019, we entered a strategic collaboration with Otonomy, a San Diego based biopharmaceutical company focused on neurotology. We plan to work with Otonomy to develop and commercialize gene therapy products for genetic forms of hearing loss with an initial focus on GJB2, which is the most common cause of congenital hearing loss. The collaboration leverages our experience and technology in the development and design of optimized AAV gene therapy products with Otonomy's expertise in preclinical and clinical development for neurotology products.

Under the terms of the collaboration agreement, we and Otonomy share the expenses and any revenue or other proceeds equally for jointly developed products. Thus far, the focus of our efforts has been to design and test the optimal product construct, including the identification of a novel capsid with tropism for the target tissues. Additionally, at the May 2021 ASGCT meeting, the companies presented proof-of-concept results in two independent preclinical models showing an improvement in hearing across multiple frequencies and normalization of cochlear morphology. These results supported selection of the product candidate for further development and the companies are focused on the activities required to advance the selected candidate into clinical trials. A Pre-IND meeting was held with the FDA that provided guidance regarding nonclinical study design, manufacturing requirements and clinical trial considerations. Based on this feedback, IND-enabling activities are underway with an IND filing anticipated in first half of calendar year 2023.

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 our deep experience in gene therapy and ophthalmology and Bionic Sight's innovative neuro-prosthetic device and algorithm for retinal coding.

Under the terms of the agreement, we provided cash investment and in-kind support in the form of ongoing research and development efforts focused activities required to file an IND for the selected product candidate and to achieve successful clearance by a relevant Institutional Review Board (IRB). Based on a pre-determined formula in the collaboration agreement to value our contributions, our aggregate equity ownership in Bionic Sight currently is 15.5%.

Bionic Sight is responsible for conducting the Phase 1/2 clinical trial, which enrolled its first patient in March 2020, and we have no further obligations under the agreement. Upon completion of the trial or the achievement of certain pre-agreed definitions of potential efficacy, we have an exclusive option to negotiate to license or partner the program. If we and Bionic Sight are not able to reach agreement after a defined timeframe, Bionic Sight may negotiate with third parties but only on terms that are no more favorable to the third party than last offered by us without our consent.

[Table of Contents](#)

In April 2021, we announced a licensing agreement with TeamedOn International, Inc., a biotechnology company dedicated to advancing gene therapies for rare diseases, including ophthalmic indications, to advance gene therapy to treat XLRS, an inherited disease that causes loss of vision due to degeneration of the retina in males. Under the terms of the agreement, we will provide TeamedOn with the clinical trial material, preclinical and clinical data generated for the development of our investigational intravitreal gene therapy candidate, rAAV2tYF-CB-hRS1. We previously demonstrated a reasonable safety profile for our XLRS program but discontinued development in 2018 because defined efficacy endpoints were not met using intravitreal injection. The goal of the licensing agreement to evaluate whether a sub-retinal approach to administering the therapy will have an increased likelihood for producing detectable biological activity in patients with XLRS. TeamedOn has prepared to reinstate clinical development of the program and we will be eligible to receive milestones and royalties based on clinical progress.

In April 2021, we announced a licensing agreement to provide its proprietary cone specific promoter technology to SparingVision SAS, a genomic medicine company developing vision saving treatments for ocular diseases. Our proprietary PR1.7 cone specific promoter helps drive increased gene expression in cone photoreceptors only, thereby allowing enhanced targeting of gene therapies for indications in which the gene defect is cone specific and limiting expression of the gene in other cells that could be undesirable. Under the terms of the agreement, SparingVision SAS receives nonexclusive rights to our PR1.7 promoter for use in the development of two non-competing products with an opportunity to obtain rights to use the promoter for one additional product in the future. We received an upfront fee and are eligible to receive milestone payments for successful clinical development and royalties on future sales on a per product basis (if any products are approved).

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.

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 six 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, 2021, we have received payments in the aggregate amount of \$3.4 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

[Table of Contents](#)

Foundation Fighting Blindness (FFB-US), Fighting Blindness Canada (FFB-Canada) and other organizations that are well known for their advocacy of patients' interests in obtaining diagnosis, developing treatments and providing for reimbursement. Many actively support research into treatment, and we have been awarded three research grants totaling \$1.6 million from the FFB-US. 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, Italian Achromatopsia Association (IAA), and Alliance for Regenerative Medicine.

In order to gain further patient specific insights to support our later stage ophthalmology clinical development, we have formed a Patient Advisory Council comprised of individuals with inherited retinal diseases (IRDs) and members from the global community of organizations that represent them. AGTC's Patient Advisory Council will initially focus on providing input on XLRP clinical trial patient experiences, processes, recruitment, and enrollment. In addition, the council will serve as consultants on ongoing and future clinical trial activities, including protocol design, patient registries, development of patient outreach and education materials, and will liaise with AGTC's Scientific Advisory Board and the broader healthcare providing community. 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 other disease areas, such as CNS and otology, that we have an interest in. 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 intellectual property 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 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.

[Table of Contents](#)

As of July 31, 2021, our patent portfolio included approximately 110 patents and patent applications that we own and approximately 50 patents and patent applications that we have licensed. More specifically, we own 7 U.S. patents, 15 pending U.S. applications, 61 foreign patents and 25 foreign patent applications. We have licensed six U.S. patents, one pending U.S. application, 42 foreign patents and one pending foreign patent application. Of the patents and patent applications that we own or license, 38 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.

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 on 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 2022 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 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.

[Table of Contents](#)

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.

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, XLRs 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, XLRs and XLRP but could be important for treating a wide variety of diseases as the engineered 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.

Table of Contents

On April 20, 2020, we amended the capsid license to add further rights to these licenses in exchange for a non-exclusive grant-back of the intellectual property for use by UF investigators to enable research on four gene targets that are not of strategic interest to us. In exchange, we will receive pre-defined portion of any proceeds received any UFRF if they enter into a license agreement for these gene targets with a third party. Further, UFRF agrees that it will notify us of potential license opportunities any of the four gene targets, so long as not otherwise restricted by confidentiality agreements with third parties.

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, relates to the use of engineered AAV capsids in the field of otology. Under the terms of the agreement, we undertook the evaluation of multiple promising capsid candidates for potential application in otology. In December 2019, we entered into a non-exclusive license agreement for three capsids that showed the most potential to support therapeutic development. Under the terms of the license agreement, we made a cash up-front payments to UFRF and will be 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 \$0.25 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 low four figures under these licenses until such time as royalties on commercial sales exceeds these amounts.

Competition

Specific Competition for Our Lead Programs

For XLRP, 4D Molecular Therapeutics, MeiraGTx and Biogen are developing AAV-based gene therapies and MeiraGTx also has competing programs in ACHM-B3 and ACHM-A3. We believe that these companies and others could be planning to initiate clinical trials in the future that have the potential to be competitive with our programs. We further believe that 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.

General Competition in the Gene Therapy Space

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.

[Table of Contents](#)

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., Akous, Allergan plc, Apic Bio, Inc., Axovant-now Sio Gene Therapies, Biogen Inc., bluebird bio, Inc., Decibel Therapeutics, Editas Medicine, Inc., 4D Molecular Therapeutics, GenSight Biologics S.A., Gyroscope Therapeutics Limited, Hemera Biosciences, Limelight Bio, Inc., MeiraGTx Limited (partnered with Janssen Pharmaceuticals), IVERIC bio, Oxford Biomedica plc, Passage Bio, Prevail Therapeutics, 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.

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, recordkeeping, 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. 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, and our communication is specifically with the Office of Tissues and Advanced Therapeutics within CBER. CBER works closely with the National Institutes of Health, or NIH, both of which may engage in a public discussion of scientific, safety, ethical 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 NIH Recombinant DNA Advisory Committee, or the RAC, has long played an active role in advising the NIH director on gene therapy and required initial registration of gene therapy protocols in addition to FDA IND requirements; however, in August 2018 the NIH revised the role of the RAC and amended its gene therapy research guidelines to delete the NIH protocol registration submission and reporting requirements, which were duplicative of the existing FDA regulatory requirements. The FDA has also 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. The FDA's guidance for Human Gene Therapy for Retinal Disorders, which was finalized in January 2020, provides recommendations for product development, preclinical testing and clinical trial design for these products. The FDA also issued draft guidance in January 2021 for sponsors developing human gene therapy for neurodegenerative diseases.

Due to the COVID-19 pandemic, the FDA issued guidance in January 2021 to sponsors of gene therapy products (licensed and investigational) which provides risk-based recommendations to minimize potential transmission of the novel coronavirus during manufacturing. This guidance will remain in effect for as long as the Department of Health and Human Services keeps the COVID-19 Public Health Emergency in effect.

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.

[Table of Contents](#)

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 four additional gene therapy product approvals, including Luxturna (voretigene neparvovec-rzyl) in December 2017. The Luxturna approval is of relevance to us 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. In 2021, the FDA approved Abecma (idecabtagene vicleucel) a cell-based gene therapy for the treatment of multiple myeloma in March and BREYANZI (lisocabtagene maraleucel) for the treatment of patients with relapsed or refractory large B-cell lymphoma in February.

The FDA's acknowledged recognition of the promise of gene therapy and their expectation that the field will continue to expand has led it to take additional steps to support the advancement of gene therapy products. In January 2020, the FDA finalized six gene therapy guidance documents, which address manufacturing and clinical development. One guidance document provides the FDA's recommendations for gene therapy product development and clinical trial design specifically for retinal disorders. Our review of the FDA's recommendations found that 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, ten gene therapy products have been approved. In 2012, the EMA approved a gene therapy product called Glybera, which was the first gene therapy product approved by regulatory authorities anywhere in the Western world. The marketing authorization for Glybera has since expired following the marketing authorization holder's decision not to apply for renewal. Most recently, Libmeldy became the tenth 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;
- 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;

Table of Contents

- 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 ensure 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 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. Under the FD&C Act, the FDA has the authority to prohibit a sponsor from conducting a clinical trial, referred to as a clinical hold, if the investigational product poses an unreasonable risk to the safety of trial subjects, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved, or for any other reason the FDA has established by regulation, which are numerous and include, for example, deficiencies in study design or insufficient information to assess the risks to the subjects of a proposed study. If the FDA places the clinical trial on clinical hold within the 30-day time period after submission of an IND, the IND sponsor must address the FDA's concerns and the FDA must lift the clinical hold before the clinical trial can begin. With gene therapy protocols, the FDA may seek advice from the FDA's Cellular, Tissue, and Gene Therapies Advisory Committee at any time on data, including preclinical data, related to the safety, effectiveness, and appropriate use of gene transfer therapies. This Advisory Committee consists of members selected by the FDA Commissioner considered to be authorities knowledgeable in the fields of gene therapies and related specialties. If the FDA recommends public review of the protocol or seeks comments from the Cellular, Tissue, and Gene Therapies Advisory Committee, initiation of the clinical trial could be delayed. The FDA may also impose a clinical hold at any time during the conduct of a clinical trial due to, for example, new safety concerns, another drug under investigation or approved for the same indication and available to the same patient population has demonstrated a better potential benefit/risk balance, or one or more adequate and well-controlled studies strongly suggest the lack of effectiveness. A trial on clinical hold may be initiated or continued when the FDA lifts the hold in writing and then only under terms specified 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

[Table of Contents](#)

the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including rules that ensure 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 IND. Clinical trials must be conducted and monitored in accordance with the GCP standards, human subject protection requirements, and the 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 before licensure, which may include annual examinations and/or annual queries, either in person or by questionnaire, of trial subjects. After licensure, the FDA may recommend the establishment of a patient registry specifically to collect adverse event data from gene therapy patients.

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.

Human gene therapy products are a new category of therapeutics. Although the FDA has approved five 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 in January 2020 finalized a guidance for gene therapy products for rare diseases in which the FDA encourages sponsors to communicate with the FDA in the early stages of development as well as throughout the development and clinical study process. This guidance provides the FDA's recommendations for manufacturing, preclinical and clinical trial design issues for all phases of the clinical development program.

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 GMP 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.

In January 2021, the FDA issued final guidance with recommendations regarding the design of long-term follow-up studies for the collection of data on delayed adverse events following the administration of an investigational gene therapy products. The FDA expects these long-term studies to extend beyond the scheduled observations and active follow-up period of a clinical trial and be in place post-licensure. This guidance finalized the draft guidance of the same title issued in July 2018 and supersedes the FDA guidance titled "Gene Therapy Clinical Trials – Observing Subjects for Delayed Adverse Events" dated November 2006. The final guidance is also intended to supplement the guidance titled "Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus during Product Manufacture and Patient Follow-Up," which was issued in January 2020.

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 laboratory, animal and human studies, 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 submitted to the FDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's

[Table of Contents](#)

fee schedule, effective October 1, 2021 and through September 30, 2022, the user fee for an application requiring clinical data, such as a BLA, will be \$3,117,218. PDUFA also imposes an annual prescription drug program fee (\$369,413 effective on October 1, 2021) 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. Importantly for us, 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 GMP regulations to ensure 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, such as the Cellular, Tissue, and Gene Therapy 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 ensure 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 ensure 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 GMP 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. If information from such an inspection, or from any other source, raises a significant question about the integrity of the clinical data, the FDA may suspend review of the BLA under its Application Integrity Policy, or AIP. After AIP has been invoked, the FDA will not resume substantive review of any pending application unless and until the data have been validated. To ensure data integrity and GMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, recordkeeping, 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

[Table of Contents](#)

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. If the FDA issues a complete response letter at the end of the initial review cycle and the sponsor resubmits its BLA addressing all deficiencies, a new two or six-month review cycle will begin, depending on the extent of the deficiencies to be addressed.

Orphan-drug designation

Under the Orphan Drug Act, the FDA may grant orphan-drug 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 200,000 or more individuals in the United States if there is no 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-drug designation must be requested before submitting a New Drug Application, or NDA, or BLA. After the FDA grants orphan-drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan-drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. Orphan-drug designation may also be rescinded if the product candidate no longer meets the criteria for designation.

If a product candidate that has orphan-drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, 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. In January 2020, the FDA issued a draft guidance in which the FDA proposed its interpretation of the "sameness" criterion for determining whether a gene therapy product will be eligible for orphan drug market exclusivity. The FDA proposed to consider two gene therapy products for the same indication to be different, thus each eligible for market exclusivity, if they have different transgenes and different vectors, different transgenes regardless of whether they have the same vectors, or different vectors from a different viral class. The public docket to submit comments on the draft guidance closed on July 28, 2020. There is no required timeframe within which the FDA must complete its review of comments and decide whether to revise the guidance, finalize it as proposed, or withdraw it.

The FDA may approve a second drug or biological product that is the same as the reference 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 determined 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 and 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 shown to have 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.

In addition to the Fast Track program, the FDA provides other expedited programs for qualifying product candidates, 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. A drug or biological product will qualify for accelerated approval if the product treats a serious or life-threatening illness and, based on adequate and well-controlled clinical trials, is shown generally to provide a meaningful therapeutic benefit over existing treatments, and demonstrates an effect on a surrogate endpoint, or an intermediate clinical endpoint (i.e., an endpoint that can be measured earlier than irreversible morbidity or mortality) that is reasonably likely to predict a clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA may require that a sponsor of a drug or biological product candidate 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, the 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.

[Table of Contents](#)

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 GMP 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 GMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products include reporting of GMP 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 may also 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.

FDA regulations prohibit the promotion of an investigational product for an unapproved use, which may include certain company-sponsored scientific and educational activities if the content of those activities is not independent of a company's influence or control. The FDA distinguishes impermissible promotion of an investigational product from the permissible exchange of scientific and medical information among healthcare professionals, which may include company-sponsored scientific and educational activities if the content of those activities is free of company influence or control. The FDA has issued Warning Letters and untitled letters to sponsors and clinical investigators who have claimed, directly or indirectly, that an investigational product is safe and effective for its intended use.

FDA regulations also impose requirements and limitations on advertising and promotional activities specifically for approved biological products. While a BLA is still under review, the BLA applicant must submit to the FDA copies of all promotional materials intended for use within 120 days following BLA approval, after which time the applicant must submit promotional materials at least 30 days prior to the intended time of use, unless otherwise directed by the FDA. For all drug and biological products, the FD&C Act prohibits false or misleading labeling, which includes statements in promotional materials about the product's safety, effectiveness, and indications for use. The FDA's regulations require advertising and promotional materials and activities to provide, among other things, adequate safety and risk information and fair balance, and prohibit the promotion of products for uses or in-patient populations that are not described in the product's approved labeling (known as "off-label use"). In addition, the FDA has published guidelines, which include limitations on direct-to-consumer advertising and promotional activities via the Internet and social media. The failure to comply with the applicable regulatory requirements may result in Warning Letters to come into compliance and the FDA further requesting the cessation or revision of marketing materials and activities or the dissemination of corrective marketing materials. The FDA has the authority to seek an injunction to stop the dissemination of violative marketing materials and activities if adequate corrective actions are not taken voluntarily.

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 GMPs

and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain GMP compliance. 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.

The FDA has the authority to take a variety of actions to address violations, including invoking the AIP and suspending the review of a pending application; refusing to approve or withdrawing approval of a marketing application; placing a study on clinical hold; issuing warning or untitled letters; ordering a biological product recall; seizing product in distribution; seeking an injunction to stop manufacture and distribution of a product; seeking restitution, disgorgement of profits, and fines; and debaring a company and its executives individually from participation in any capacity in the drug approval process. The U.S. Department of Justice has the authority to criminally prosecute companies and company executives for violations of the FD&C Act and the PHS Act.

United States patent term restoration and marketing exclusivity

Depending on 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's 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, or BPCI Act, 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 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.

The BPCI Act provides a reference biological product 12 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

[Table of Contents](#)

(PRICED) Act (H.R. 5573) was introduced, which would have reduced exclusivity for reference biological drugs from 12 to seven years. The PRICED Act was reintroduced on June 20, 2019 (H.R. 3379) and, if passed into law, would reduce exclusivity for reference biological products from 12 to five years. The Emergency Access to Insulin Act of 2019 (H.R. 4010 introduced July 25, 2019 and S. 2004 introduced June 27, 2019), in addition to a number of provisions designed to decrease cost and increase access to insulin, included provisions that would shorten the new biological product exclusivity from 12 years to seven years.

The BPCI Act also provides that the first biological 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 healthcare programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services, and increasing oversight and transparency on how products are priced and reimbursed. 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 \$44.4 million and \$35.8 million for the years ended June 30, 2021 and 2020, respectively.

Employees

As of June 30, 2021, we had 83 full-time employees, 48 of whom have Ph.D., M.D. or other post-graduate degrees. Of these full-time employees, 63 were engaged in research and development activities and 20 were engaged in finance, human resources, facilities and general management.

During the years ended June 30, 2021 and 2020, all of our personnel were co-employees of AGTC and a professional human resource service organization, Insperty PEO Services, L.P., or Insperty. Insperty is a co-employer of our personnel and is responsible for administering all payroll functions, including tax withholdings, and providing health insurance and other benefits to those individuals. We reimburse Insperty for its costs and pay Insperty an administrative fee for its services. We are responsible for, and control, all aspects of the hiring, retention, compensation, management and supervision of our personnel. We consider the terms of our contract with Insperty to be reasonable and customary and believe that this arrangement provides substantial benefit to us in the form of lower costs for employee benefits and a reduced administrative burden on us.

We believe that our future success will depend, in part, on our continued ability to attract, hire and retain qualified personnel. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation and cash-based performance bonus awards, to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

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 materials with, or furnish them to, the Securities and Exchange Commission. 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, 2021, these trademarks have been registered in the United States, the 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 ™ 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 those 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

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading “Risk Factors” and should be carefully considered, together with other information in this Form 10-K and our other filings with the Securities and Exchange Commission, before making an investment decision regarding our common stock.

- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- 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.
- 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.
- 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.
- We may be unable to obtain orphan-drug designation or exclusivity for some of our product candidates.
- 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.
- The COVID-19 pandemic could materially and adversely affect our ability to conduct clinical trials and engage with our third-party vendors and thereby have a material adverse effect on our financial results.
- 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 and our contract manufacturers are subject to significant regulatory oversight with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and may have limited capacity.
- Collaborations with third parties may be important to our business. If these collaborations are not successful, our business could be adversely affected.
- 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 insurance coverage and reimbursement status of newly-approved products are uncertain.
- 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.
- 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.
- Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.
- 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.

[Table of Contents](#)

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

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 Securities and Exchange Commission, or 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 revenue from product sales. We have incurred losses from operations in each year since inception, except for fiscal year 2017, wherein we reported net income of \$0.4 million due, in part, to profits from a collaboration agreement that was terminated in March 2019. For the fiscal years ended June 30, 2021 and 2020, we reported net losses of \$57.8 million and \$45.9 million, respectively. As of June 30, 2021, we had an accumulated deficit of \$239.3 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 debt financing, research grants from third parties or milestone payments. 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 revenue 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;

[Table of Contents](#)

- 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;
- execute our plan to open and operate a leased build-to-suit manufacturing and quality control facility;
- 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.

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 and Otonomy, Inc., to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We do not anticipate generating revenue 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 revenue 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, or successfully executing our plan to open and operate a leased build-to-suit manufacturing and quality control facility;

Table of Contents

- 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 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 revenue from the sale of any approved products, we may not become profitable and may 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.

We are party to a loan and security agreement that contains operating and financial covenants that may restrict our business and financing activities and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

In June 2020, we entered into a Loan and Security Agreement, which, as amended, we refer to as the Loan Agreement, with the several banks and other financial institutions or entities that are from time to time parties to the Loan Agreement, referred to herein as the Lenders, and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and Lenders, providing for a term loan to us with an aggregate principal amount of up to \$25.0 million. This term loan originally consisted of a term loan advance in an aggregate principal amount of \$10.0 million on June 30, 2020 and a right to request that the Lenders make, in the Lenders' sole discretion, additional term loan advances to us in an aggregate principal amount of up to \$15.0 million.

Effective May 13, 2021, we entered into an amendment to the Loan Agreement, which we refer to as the Amendment, whereby, among other things: (i) a second term loan advance of \$10.0 million was authorized by the lenders and advanced to us on such date; (ii) the period that we will make interest-only payments on outstanding borrowings was extended to March 31, 2022; and (iii) the maturity date of the facility was extended from December 1, 2023 to April 1, 2024. Subject to certain conditions provided in the Amendment, the interest-only period and the maturity date can be further extended. Subject to the Lenders' investment committee's sole discretion, we have the right to request that the Lenders make additional term loan advances in an aggregate principal amount of up to \$5.0 million.

[Table of Contents](#)

The Loan Agreement contains customary representations, warranties and both affirmative and negative covenants applicable to us. The negative covenants include, among other things, agreements by us limiting additional indebtedness, liens (including a negative pledge on intellectual property and other assets), guaranties, mergers and consolidations, substantial asset sales, investments and loans, certain corporate changes, transactions with affiliates, and fundamental changes.

The covenants, restrictions and obligations in our Loan Agreement, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants. A breach of any of these covenants could result in a default under the Loan Agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable.

If we are unable to generate sufficient cash to repay our debt obligations when they become due and payable, either when they mature, or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our business operations and financial condition.

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 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, 2021 and 2020, our cash and cash equivalents and investments amounted to \$107.1 million and \$80.5 million, respectively. Our research and development expenses were \$44.4 million and \$35.8 million for the fiscal years ended June 30, 2021 and 2020, respectively. We believe that our available cash and cash equivalents and investments at June 30, 2021 will be sufficient to allow us to generate data from our ongoing and planned clinical programs and fund currently planned research and discovery programs into calendar year 2023. In order to complete the process of obtaining regulatory approval for our lead product candidates and to build the sales, marketing, manufacturing 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 shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of additional 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 additional restrictive covenants, such as limitations on our ability to incur

[Table of Contents](#)

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.

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 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 the FDA will require to establish substantial evidence of safety and effectiveness 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 countries and regulatory authorities, 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;
- 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;

[Table of Contents](#)

- the patients recruited for a particular clinical program may not be sufficiently broad or representative to establish the safety of the product candidate in the full population of patients with the condition for which we seek approval;
- the clinical trial 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 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, clinical development guidelines and recommendations, 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 revenue. 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' marketing, promotion, distribution or manufacturing processes;
- 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;
- imposition of restrictions on operations, including costly new manufacturing requirements;

[Table of Contents](#)

- suspension of substantive review of pending applications, such as BLAs or INDs, pending data validation; 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 revenue 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, five gene therapy products have been approved in the United States and ten 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.

The regulatory framework for evaluating and approving gene and cell therapy products has changed frequently and may continue to change in the future. For example, the FDA established the Office of Tissues and Advanced Therapies within 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. Before a clinical trial can begin at a study site, that institution's IRB and its 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 their standards for the quantity and quality of data needed to support approval of any of our product candidates.

These regulatory review committees and advisory groups and any 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 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.

Interim data and ad hoc analyses are preliminary in nature. 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 early 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 or interim data for our lead product candidates will result in success in our clinical trials of those product candidates. For example, we have reported interim results, from our XLRP Phase 1/2 expansion, or Skyline, trial, at 12 months for eight patients who were included in our responder analysis. Four of these eight patients (50%) were considered responders, all four of whom met the strict criteria of at least a 7 decibel (dB) improvement in at least 5 loci. One additional patient did not meet these criteria but had a statistically significant improvement in retinal sensitivity in the treated eye compared with the untreated eye at 12 months. We have also reported 24-month data for our Skyline trial for three of the seven Group 4 patients, including two who were responders at Month 12 (one by the 7dB change in at least 5 loci response criteria and the other based on improved retinal sensitivity in the treated eye compared with the untreated eye). These two patients were still responders at Month 24 according to the same criteria and the third patient who has reached Month 24 was not a responder at Month 12 or Month 24. There is no assurance that the data obtained at the completion of the Skyline trial or from our XLRP Phase 2/3, or Vista, trial will indicate a clinically meaningful benefit or support the submission of a BLA.

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 a high-dose AAV therapy have led to several well-publicized adverse events, including reported deaths related to sepsis. 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. We previously experienced delays in enrollment of our pediatric patients in the dose escalation portions of our CNGB3 and CNGA3 trials for ACHM in connection with the COVID-19 pandemic and we previously encountered slower-than-expected enrollment as a result of patients not meeting one or more study eligibility criteria. Additionally, the latest surge in cases due to a COVID-19 variant has created new challenges for us to schedule patients for screening at some sites due to capacity and bandwidth limitations, which has impacted enrollment in our XLRP Phase 1/2 trial.

[Table of Contents](#)

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.

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 the 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.

[Table of Contents](#)

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;
- 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 or as a result of an unexpected, serious adverse event;
- 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 practice, or GCP requirements and guidelines or similar regulatory requirements and 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 the FDA's current GMP requirements or similar regulatory requirements and 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.

For example, in connection with the clinical development of our XLRP product candidate, we received comprehensive written feedback regarding the design and execution of our proposed registration trial and future

[Table of Contents](#)

regulatory submissions. Based on this feedback, we have revised our development plan to include the Skyline trial in parallel with the Vista trial, which is designed to evaluate sustained efficacy across multiple measures of potential benefit in patients with XLRP. While we continue to move forward as planned with manufacturing, clinical site preparation and other activities to complete the studies as quickly as possible, such expansion will result in additional costs and may delay the completion of the clinical development of our XLRP product candidate.

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, information from an inspection or other source that raises significant concerns about the integrity of the clinical trial data, 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 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 revenue 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 revenue 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 trials 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.

[Table of Contents](#)

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 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 trials, including in the XLRP and ACHM trials. In August 2021, for example, three new SAEs of significant inflammation that are considered a suspected unexpected serious adverse reaction occurred in pediatric patients at the highest trial dose concentration in our ACHM trial (two CNGA3 patient and one CNGB3 patient). 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 revenue 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 healthcare 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-drug designation or exclusivity for some of our product candidates. If our competitors are able to obtain approval and orphan-drug 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 equal to or 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 five 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, 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 CNGA3 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 before approval if the 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 the same indication during the exclusivity period, except in limited circumstances. The FDA has not defined the meaning of "same drug" specifically for gene therapy products in a regulation. In January 2020, the FDA issued draft guidance in which the FDA proposed its interpretation of the "sameness" criterion for determining whether a gene therapy product would be eligible for orphan-drug exclusivity. The FDA proposed to consider two gene therapy products for the same indication to be different, thus each eligible for market exclusivity, if they have different transgenes and different vectors, different transgenes regardless of whether they have the same vectors, or different vectors from a different viral class. The public docket to submit comments on the draft guidance closed on July 28, 2020. There is no required timeframe within which the FDA must complete its review of comments. The FDA could decide to revise the draft sameness guidance, finalize it as proposed, or withdraw it. It is possible that the FDA could conclude that no two gene therapy products could ever be considered the same, thus precluding any gene therapy product from obtaining orphan drug exclusivity. The applicable orphan exclusivity 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 the regulatory body that it can provide sufficient quantity of the product to meet the needs of patients with the rare disease or condition, or if a gene therapy product considered to be the same as our product candidate is superior in certain respects.

[Table of Contents](#)

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 that is considered the “same 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.

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, recordkeeping, 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 and claims must be consistent with approved labeling and be in compliance with FDA regulations as well as other potentially applicable federal and state laws. In addition, biological product advertising and promotional materials intended to be used during the first 120 days after approval must be submitted to the FDA during the BLA review period. After approval, advertising and promotional materials must be submitted to the FDA 30 days prior to their intended use.

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.

Table of Contents

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 revenue.

In addition, the FDA's policies may change and additional government laws may be enacted and implementing regulations promulgated, which 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.

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

[Table of Contents](#)

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.

The COVID-19 pandemic could materially and adversely affect our ability to conduct clinical trials and engage with our third-party vendors and thereby have a material adverse effect on our financial results.

The FDA has indicated that the staff of the Center for Biologics Evaluation and Research continue to operate according to historical timelines despite the allocation of substantial resources to address the COVID-19 pandemic. The FDA has noted, however, that its current levels of performance may be impacted by the workload created by COVID-19 activities. It is possible that the FDA could prioritize and shift more resources to COVID-19 activities in the future, which could delay future meetings or preclude in-person meetings with the FDA regarding next-phase clinical study design for our product candidates, including XLRP, and thus could delay their development programs. Any decision by the FDA to delay or refuse meeting with us or to limit communications with us in light of COVID-19 could have a material adverse effect on our scheduled clinical trials, which could increase our operating expenses and have a material adverse effect on our financial results.

We have experienced delays in enrollment of our pediatric patients in the dose escalation portions of our CNGB3 and CNGA3 trials for ACHM in connection with the COVID-19 pandemic. Additionally, the latest surge in cases due to a COVID-19 variant has created new challenges for us to schedule patients for screening at some sites due to capacity and bandwidth limitations, which has impacted enrollment in our XLRP Phase 1/2 trial. We could also experience delays in critical follow-up visits required under clinical trial protocols, which could increase the cost of those trials and also impact their expected timelines. Our ability to fully interpret the trial outcomes and the ability of certain lab-based employees to perform their jobs due to stay-at-home orders or other restrictions related to COVID-19 could also result in delays and increase our operating expenses. We have engaged a mobile vision center as an alternative method of data acquisition in an effort to maintain existing timelines for our programs. However, this method of data acquisition and/or other methods to respond to the impact of COVID-19 has, and may continue to, increase our operating costs.

Furthermore, third-party vendors, such as raw material suppliers and contracted manufacturing, testing or research organizations, could also be impacted by COVID-19, which could result in unavoidable delays and/or increases in our operating costs. In particular, we obtain certain raw materials in the synthesis of our drug candidates and NHPs for toxicology testing in countries affected by the COVID-19 pandemic. If we are unable to obtain these raw materials or NHPs in sufficient quantity and in a timely manner, the development, testing and clinical trials of our drug candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

The extent to which the COVID-19 pandemic may impact our clinical trials and our dealings with vendors will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19, and the effectiveness of actions to prevent transmission, contain the virus, and treat those who have contracted COVID-19.

Risks related to our reliance on third parties and our plans to develop manufacturing capacity

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.

During May 2021, we entered into a lease for a build-to-suit 21,250 square foot cGMP manufacturing and quality control facility adjacent to our existing Florida facility to prepare for late-stage development of our XLRP and ACHM programs. The build-out of the new manufacturing and quality control facility is in its very early stages and we do not expect that this facility will be completed until the second half of calendar year 2022. Moreover, 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 currently rely and, until such manufacturing and quality control facility is built, validated and operational, we 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 the third parties' activities. Additionally, we may experience delays in the build-out of our proposed manufacturing and quality control facility, which will require completing the construction, development and startup of our new facilities, substantial additional expenditures, time, and various regulatory approvals and permits, all of which may be impacted by the COVID-19 pandemic. In addition, we will need to hire and train a significant number of employees and managerial personnel to staff expanded manufacturing and supply chain operations. Due to these risks and uncertainties, we may fail to complete the build-out at all, incur significant costs and be required to continue to rely solely on third party manufacturers.

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. Our 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 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.

[Table of Contents](#)

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 recordkeeping) 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 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.

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.

Separately, even if we complete and commence operations of our leased build-to-suit manufacturing and quality control facility, we do not have experience in manufacturing product candidates or manufacturing products on a commercial scale. We may encounter difficulties in the manufacture of our product candidates due to our limited manufacturing experience. These difficulties could delay the build-out and equipping of a commercial manufacturing facility and regulatory approval of the manufacture of our product candidates, if approved, using the facility, increase our costs or cause production delays or result in us not manufacturing sufficient product to meet our expected commercial requirements, any of which could damage our reputation and hurt our profitability. If we are unable to successfully increase our manufacturing capacity to commercial scale, either through our leased build-to-suit manufacturing and quality control facility or through alternative manufacturers, our business may be materially adversely affected.

Additionally, if our supply or the supply of materials and products 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

[Table of Contents](#)

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 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 revenue 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

[Table of Contents](#)

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 revenue 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.

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;
- 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;

[Table of Contents](#)

- if we fail to obtain orphan drug 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, 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.

We may in the future determine to collaborate with other pharmaceutical and biotechnology companies for development and potential commercialization of product candidates. 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. For example, in December 2019, as a result of certain milestone triggers outlined in our strategic research and development collaboration agreement with Bionic Sight, we became obligated to purchase additional equity in Bionic Sight for \$4.0 million and receive such equity interest based on certain pre-determined valuation criteria. We completed this purchase in March 2020.

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

[Table of Contents](#)

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 revenue 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 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 revenue.

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 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 XLRP and ACHM. However, for XLRP, 4D Molecular Therapeutics, MeiraGTx and Biogen are developing AAV-based gene therapies and MeiraGTx also has competing programs in ACHM-B3 and ACHM-A3. We believe that 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 preclinical stages.

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, we expect to experience particularly intense competition from larger and better funded pharmaceutical

[Table of Contents](#)

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-drug 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 are 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 frequently, coverage determinations for new products are made by the individual Medicare Administrative Contractors, or 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 that 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 regulations 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 revenue 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 five gene therapy products approved to date in the United States and only ten 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 a high-dose AAV therapy have led to several well-publicized adverse events, including reported deaths related to sepsis. 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 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 healthcare 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. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or the TCJA, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseparable feature of the ACA and, therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. An appeal was taken to the U.S. Supreme Court, which heard oral arguments in the case on November 10, 2020. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions. There may be other efforts to challenge, repeal or replace the ACA. If successful, it may potentially impact our business in the future.

Further changes to and under the ACA remain possible, although President Biden's administration has signaled that it plans to build on the ACA and expand the number of people who are eligible for subsidies under it. Specifically, President Biden indicated that he intends to use executive orders to undo changes to the ACA made by the Trump administration and would advocate for legislation to build on the ACA. It is unknown what form any such changes or any law proposed to replace the ACA would take, and how or whether it may affect our business in the future. We expect that changes to the ACA, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug and biologic prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

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 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 healthcare payors, we will not be able to generate significant revenue 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;

Table of Contents

- 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;
- 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 revenue, 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

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

[Table of Contents](#)

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 and restricted stock units that vest over time. The value to employees of stock options and restricted stock units 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.

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, healthcare clearinghouses and healthcare 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 healthcare programs and commercial insurers;
- 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 healthcare 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 healthcare programs, such as Medicare and Medicaid,

[Table of Contents](#)

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, 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 that 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. Additionally, 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.

We rely on our relationship with a professional human resource service organization for our human relations function and as a co-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 human resource service organization, Insperty. Under the terms of our arrangement, Insperty 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 to those individuals. We reimburse Insperty for those costs, and pay Insperty an administrative fee for its services. If Insperty 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 Insperty 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 revenue 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.

Our ability to use our net operating losses 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 that 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, net operating losses arising in tax years beginning after December 31, 2017, and before January 1, 2021, generally may be carried back to each of the five tax years preceding the loss and then carried forward indefinitely. To the extent that such losses are carried forward to tax years beginning after December 31, 2020, a taxpayer's ability to utilize such carryforwards is limited to 80% of taxable income. In addition, net operating loss carryforwards arising in tax years beginning after December 31, 2020 can be carried forward indefinitely and can be utilized to the extent of 80% of a taxpayer's taxable income in the relevant carryforward tax year; however, carryback of such losses is generally prohibited. Net operating loss carryforwards generated in tax years beginning before January 1, 2018 will not be subject to the taxable income limitation and will continue to have a two-year carryback period and 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 and financial results.

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

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including, but not limited to, intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information.

Table of Contents

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 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. Despite the implementation of security measures, given the size and complexity of our internal information technology systems and those of our current and any future third-party vendors, collaborators and other contractors and consultants, and the increasing amount of confidential information that they maintain, such information technology systems are vulnerable to damage or interruption from computer viruses, computer hackers, malicious code, employee theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies.

If we fail to prevent the theft of valuable information such as financial data, sensitive information about 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, we could incur liability and it would damage our reputation, which could adversely impact the confidence of our partners, investors and employees. Additionally, such an event could cause interruptions in our operations or result in a disruption of our development programs and our business. 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, which could result in a material adverse effect on our results of operations and financial condition. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counterparties and data subjects could be material. In addition, our remediation efforts may not be successful. Moreover, if the information technology systems of our third-party vendors, collaborators and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of that nature from occurring.

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

[Table of Contents](#)

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, if 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 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, including claims related to our XLRP product candidate, 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

[Table of Contents](#)

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 compositions, 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 or product candidates infringes upon these patents.

For example, we are aware of a third-party U.S. patent that may be construed to cover our gene therapy compositions for treating XLRP. In Europe, the third party limited the claims in its pending patent application to require a nucleotide sequence not present in our gene therapy compositions for treating XLRP. We are also aware of other corresponding international applications owned by such third party. If such third party asserts this U.S. patent or other patents that may issue from corresponding international patent applications against us and our XLRP product candidate, we believe that we would have defenses against any such assertion, however, there can be no assurance that any such defenses will be successful. If such patents, or any other 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, and are not held to be invalid or unenforceable, the holders of any such patents may be able to block our ability to commercialize such product candidate, including our XLRP 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, and are not held to be invalid or unenforceable, 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. 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, including our XLRP product candidate. 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. If a license is available from the applicable third party, we may have to pay royalties, upfront fees and other amounts, and/or grant cross-licenses under our intellectual property rights. Further, we may be required to redesign our infringing products so they do not infringe the applicable third-party patents 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

[Table of Contents](#)

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, and Johns Hopkins University, 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 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 that 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;

[Table of Contents](#)

- 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 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.

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, which could have a material adverse effect on our business.

Changes in U.S. 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 and legal complexity. 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 has 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

[Table of Contents](#)

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 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, 2021, 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.

[Table of Contents](#)

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;
- 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;

Table of Contents

- 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 rate, fuel price and international currency fluctuations, global health pandemics, such as COVID-19, 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 that investors perceive to be similar to us, the opportunities in the digital simulation market or the stock market in general could each depress our stock price regardless of our business, prospects, financial conditions or results of operations.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans or the exercise of outstanding warrants to acquire shares of our common stock, 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, including sales made at-the-market under our existing sales agreement with Cantor Fitzgerald & Co., at prices and in a manner that 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.

Pursuant to our equity incentive plans, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. No awards have been issued to date under our 2013 Employee Stock Purchase Plan and, as such, all of the 128,571 shares previously authorized under that plan remain available for issuance. As of June 30, 2021, 1,233,889 shares were available for issuance under our 2013 Equity and Incentive Plan. As of June 30, 2021, we have granted options to purchase 4,286,361 shares of our common stock and 628,000 restricted stock units to acquire shares of our common stock. Additionally, on February 1, 2021, in connection with an underwritten public offering of common stock, we issued accompanying warrants to purchase 8,370,786 shares of our common stock, with an exercise price of \$6.00 per share (subject to certain adjustments). Such warrants are immediately exercisable and expire on February 1, 2026. Any exercise of our outstanding options or warrants, or vesting of our restricted stock units, or any further issuance of options, warrants or restricted stock units may result in material dilution to our existing stockholders.

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.

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.

General Risk Factors

Our ability to raise capital may be materially adversely impacted by the COVID-19 pandemic.

We have funded our operations and capital spending, in part, through proceeds from the sale of our capital stock, debt financings and collaboration agreements. 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. Any sustained disruption in the capital markets from the COVID-19 pandemic could negatively impact our ability to raise capital from the offering of equity or debt securities. In addition, the safety measures that have been implemented, and may continue to be implemented, by national, state and local governments, including quarantines, border closures, travel restrictions, shelter-in-place orders and shutdowns, are disrupting normal business operations both in and outside of affected areas and have had significant negative impacts on businesses and financial markets worldwide that could negatively impact our ability to secure funding through collaborations, strategic alliances and licensing arrangements.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to report our financial results timely and accurately, which could adversely affect investor confidence in our 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, or SOX, requires that companies evaluate and report on their systems of internal control 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 SOX Section 404, 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, each of 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 (to include a new leased build-to-suit manufacturing and quality control facility), 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, in the meantime, we may have incurred substantial expenses and devoted significant 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 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 that 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.

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.

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 waste products. 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 waste products. 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 could also incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses that 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 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 may also result in substantial fines, penalties or other sanctions.

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 all available funds and future earnings, if any, to fund our future growth and do not expect to declare or pay any

[Table of Contents](#)

dividend on shares of our common stock in the foreseeable future. Moreover, our ability to declare or pay any cash dividends on our common stock is restricted by the agreement governing our outstanding debt. 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.

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. 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.

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 divert management's attention and resources, which could harm our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and are not required to provide this information.

ITEM 2. PROPERTIES

Alachua, Florida

Our corporate headquarters is located in Alachua, Florida where we lease approximately 21,500 square feet of office and laboratory space under a lease arrangement that expires in December 2027. We have options to extend the term of the Alachua lease for three additional five-year periods.

In May 2021, we signed a 20-year lease for a build-to-suit 21,250 square foot cGMP manufacturing and quality control facility adjacent to our existing Florida facility to prepare for late-stage development of our XLRP and ACHM programs. We anticipate that the build-out of the new manufacturing and quality control facility will be completed during the second half of calendar year 2022. Additional information regarding our new cGMP manufacturing and quality control facility can be found in Note 3 to our financial statements in this Annual Report on Form 10-K.

Cambridge, Massachusetts

We lease approximately 8,000 square feet of office and laboratory space in Cambridge, Massachusetts under a lease arrangement that expires in February 2025. We have an option to extend the Cambridge 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. However, due to the nature of our business, we may be subject to lawsuits or other claims arising at any particular time in the ordinary course of our business, and we expect that this situation will continue to be the case in the future.

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 16, 2021, a total of 42,859,675 shares of our common stock were outstanding and we had 30 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.

Moreover, as discussed in Note 8 to our financial statements in this Annual Report on Form 10-K, our ability to declare or pay any cash dividends on our common stock is restricted by the agreement governing our outstanding debt.

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."

ITEM 6. SELECTED FINANCIAL DATA

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

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 people suffering from rare and debilitating diseases. Our initial focus is in the field of ophthalmology, where we have active clinical programs in X-linked retinitis pigmentosa ("XLRP"), achromatopsia ("ACHM") and optogenetics, as well as a preclinical program in age-related macular degeneration ("AMD"). In addition to ophthalmology, we have initiated one preclinical program in otology and two preclinical programs targeting central nervous system disorders ("CNS"), including frontotemporal dementia ("FTD") and amyotrophic lateral sclerosis ("ALS"). Our optogenetics program is being developed in collaboration with Bionic Sight, LLC ("Bionic Sight") and our otology program is being developed in collaboration with Otonomy, Inc. ("Otonomy"). With a number of important clinical milestones on the horizon, we believe that we are well

[Table of Contents](#)

positioned to advance multiple programs toward pivotal studies. In addition to our product pipeline, we have also developed broad technological and manufacturing capabilities utilizing both our internal scientific resources and collaborations with others, such as our efforts with the University of Florida, which provides us with expertise in vector design and access to novel capsids.

Since our inception, we have devoted substantially all of our resources to development efforts relating to our proof-of-concept programs in ophthalmology, otology, CNS, and alpha-1 antitrypsin deficiency, an inherited orphan lung disease, including manufacturing 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 offerings of our common stock and warrants to purchase our common stock, private placements of our preferred stock, collateralized borrowing 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 and the Alpha-1 Foundation.

We have incurred losses from operations in each year since inception, except for fiscal year 2017, wherein we reported net income of \$0.4 million due, in part, to profits from a collaboration agreement that was ultimately terminated in March 2019. For the years ended June 30, 2021 and 2020, we reported net losses of \$57.8 million and \$45.9 million, respectively. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and general and administrative and other expenses 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:

- continue to conduct preclinical studies and clinical trials for our XLRP and ACHM product candidates and preclinical studies for our other ophthalmology, otology and CNS 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 AMD and other retinal diseases; and
 - other inherited diseases, such as otology and CNS indications;
- manufacture clinical trial materials and develop larger-scale manufacturing capabilities, including the lease of a new build-to-suit manufacturing and quality control facility;
- seek regulatory approval for our product candidates;
- further develop our gene therapy platform;
- add personnel to support our scientific, collaboration, product development and commercialization efforts; and
- continue to operate as a public company.

As of June 30, 2021, we had cash and cash equivalents and liquid investments totaling \$107.1 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 available cash and cash equivalents and investments will be sufficient to allow us to generate data from our ongoing and planned clinical programs and fund currently planned research and discovery programs into calendar year 2023. In order to complete the XLRP Phase 2/3 (“Vista”) trial, move our ACHMB3 product candidate forward, obtain regulatory approval for our lead product candidates and 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, acquisitions or other business development activities, 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 and continue our research and development efforts.

Recent Developments

XLRP

In November 2020, we announced a modification to the primary endpoint for our Vista and Phase 1/2 Expansion (“Skyline”) trials based on comments received from the FDA. The design of our Vista trial is expected to include approximately 60 patients randomized across three arms: a low-dose group (the 1.2E+11 vg/mL Group 2 dose from the ongoing Phase 1/2 trial), a high-dose group (the 1.1E+12 vg/mL Group 5 dose from the ongoing Phase 1/2 trial) and an untreated control group. The primary endpoint will be visual sensitivity defined as having at least a 7 decibel improvement in visual sensitivity in at least 5 pre-specified loci at Month 12. Together with a third-party vendor, we have developed a machine learning algorithm that, on a patient-by-patient basis, predicts the loci most likely to improve through evaluation of baseline visual sensitivity. The algorithm was developed using the microperimetry data available to date from the Phase 1/2 dose escalation study. Secondary endpoints include mean change in visual sensitivity, improvements in visual acuity and improvements in performance on a visual navigation course. We also plan to include a masked interim analysis at Month 6, with that data expected to be released in the fourth quarter of calendar year 2022, which may provide us with the opportunity to adjust the trial, if necessary, to optimize outcomes.

In November 2020, we also provided additional data from our XLRP Phase 1/2 trial that indicated 2 of 8 evaluable centrally dosed patients in Groups 2 and 4 were responders at Month 12. A third patient, who was a responder at Month 6, fell just below the responder criterion. All eight evaluable patients also showed stable or improving visual acuity. In addition, we provided six-month data for the 11 centrally dosed patients in Groups 5 and 6 and reported that 5 of 11 patients were responders at Month 6. Nine of these patients also had stable or improving visual acuity. If we apply the planned Vista trial inclusion criteria, 3 of the 11 patients in Groups 5 and 6 would be removed from the analysis, and 5 of 8 patients, or 62%, would be considered responders. We do not have a control arm in the Phase 1/2 trial, which will be part of our Vista trial and necessary to evaluate efficacy.

In May 2021, we provided 12-month data from our XLRP Phase 1/2 trial from seven patients in Group 5 and four patients in Group 6. One patient in Group 5 and two patients in Group 6 would not meet the inclusion criteria for the Skyline and Vista trials, resulting in a total of eight patients who were included in the responder analysis. Four of these eight patients (50%) were considered responders, all four of whom met the strict criteria of at least a 7 decibel improvement in at least 5 loci. One additional patient did not meet these criteria but had a statistically significant improvement in retinal sensitivity in the treated eye compared with the untreated eye at 12 months.

Consistent with previously reported 6-month data from Groups 2, 4, 5 and 6, assessment of Best Corrected Visual Acuity (“BCVA”) in these groups at 12 months continues to provide supportive evidence of improved visual acuity in these patients; the difference between treated and untreated eyes is statistically significant. We believe that these data, together with the favorable safety profile, have the potential to differentiate our XLRP candidate from competitors.

Data from three of the seven Group 4 patients were available for analysis at Month 24, including two who were responders at Month 12 (one by the 7 decibel change in at least 5 loci response criteria and the other based on

Table of Contents

improved retinal sensitivity in the treated eye compared with the untreated eye). These two patients are still responders at Month 24 according to the same criteria; the third patient who has reached Month 24 was not a responder at Month 12 or Month 24. To the best of our knowledge, this is the first XLRP gene therapy clinical trial to demonstrate continued durability of response at this time point.

Data from all 28 patients across six dose groups in the Phase 1/2 trial continue to demonstrate a favorable safety profile with no dose-limiting inflammatory responses observed. This safety profile, which has shown no clinically significant inflammation not manageable with steroids, continues to be observed out to 24 months.

We believe that we have a best-in-class XLRP product candidate that may provide significant benefits to patients with XLRP. We expect to:

- present 12-month trial results from the ongoing Phase 1/2 clinical trial at the American Academy of Ophthalmology Annual Meeting in November 2021;
- provide Skyline trial results from the 3-month masked interim analysis in the first half of calendar year 2022;
- provide Skyline trial results from the 12-month data in the fourth quarter of calendar year 2022; and
- provide Vista trial results from the 6-month masked interim analysis in the fourth quarter of calendar year 2022.

As part of the Skyline trial, we intend to dose a total of 12 additional patients across two dose groups. The Skyline trial is intended to evaluate the correlation of a new mobility navigation course developed for use with retinitis pigmentosa patients, with the primary endpoint of visual sensitivity at pre-specified loci, providing such data within the earliest timeframe. This trial will have the same overall design as the Vista trial.

ACHM

In January 2021, we reported results based on a patient-by-patient analysis of data from both ACHMB3 and ACHMA3 trials. For ACHMB3, this consisted of 12-month data from 15 patients, 9-month data from five patients, 6-month data from three patients and 3-month data from three patients for a total of 26 patients across all dose groups. Seven of the 16 patients in the three highest dose groups in the ACHMB3 trial showed improvements in visual sensitivity in the treated area, as measured by static perimetry. No consistent results were seen in the other dose groups. In a subset of these patients with evaluable multi-focal electroretinograms (“ERGs”), improvements in electrical signaling were measurable in the same treated area.

For ACHMA3, data analysis consisted of 12-month data from 10 patients, 9-month data from four patients, 6-month data from one patient and 2- or 3-month data from three patients for a total of 18 patients across five dose groups. One additional patient did not have evaluable data. In the 16 patients in the four highest dose groups, three patients showed improvements in visual sensitivity in the treated area, as measured by static perimetry. No consistent results were seen in other dose groups. None of these three patients with improvements in visual sensitivity had evaluable ERGs.

In June 2021, we announced 12-month data from our on-going Phase 1/2 ACHM clinical trials showing biological activity in patients with mutations in the ACHMB3 gene. In July 2021, we hosted a virtual Research Day that provided an expanded analysis of the 12-month data from our ongoing Phase 1/2 clinical trials in ACHM, including a discussion on light sensitivity and ACHM genetics. These data indicated biologic activity in the dose escalation portions in both the ACHMB3 and ACHMA3 trials. The response was more robust in the ACHMB3 patients than the ACHMA3 patients and, therefore, we plan to move forward with planning for late-stage development of the ACHMB3 product candidate.

Retinal sensitivity, as measured by full-field perimetry, improved in four of 11 ACHMB3 patients in the high dose adult and pediatric groups, as well as two patients in the low dose adult groups. There were no notable

Table of Contents

changes in the untreated fellow eyes. The light level in which the patients experienced discomfort, the single most important symptom to patients, also improved in six of the 11 patients with improvement also seen in the fellow eye of those six patients. At our virtual Research Day, Medical College of Wisconsin study investigator Joseph Carroll, Ph.D., noted that bilateral effects to monocular stimuli are not uncommon in ophthalmology, and he described well-established neuro-anatomical and physiological explanations for this observation. Three of these patients were also responders for visual sensitivity providing more evidence of overall improvement in visual function.

Given the evidence of treatment response described above for all adults and the lowest dose group 4 pediatric patients, as well as supportive anecdotal patient reports, we are preparing for an End of Phase 2 (EOP2) submission for our ACHMB3 program and to request a meeting with the FDA in advance of initiating a Phase 2/3 trial. We expect this meeting to occur in the first half of calendar year 2022. We are also collecting novel measures of efficacy including color brightness (CoBri) testing and functional magnetic resonance imaging (fMRI) testing for the recently enrolled and currently enrolling pediatric patients. These additional tests may further support the patient anecdotal reports and the existing evidence of biologic activity of the CNGB3 candidate.

For CNGA3, we are focused on analysis of the data from pediatric patients in the Phase 1/2 trial. Preclinical animal data showed a treatment effect in young sheep, which might predict comparable treatment responses in younger pediatric Phase 1/2 patients despite the CNGA3 genetic considerations described above.

We recently enrolled six pediatric ACHMB3 patients and five pediatric ACHMA3 patients in higher dose groups 5a and 6a. Three new serious adverse events (SAEs) of significant inflammation that are considered a Suspected Unexpected Serious Adverse Reaction, or SUSAR, occurred in pediatric patients at the highest trial dose concentration (3.2e12 vg/mL); two patients are in the CNGA3 trial, the other is in the CNGB3 trial. An additional CNGB3 pediatric patient at this dose also has presented with significant inflammation during approximately the same post-operative time frame but has not required a subsequent procedure. To address the above safety events in pediatric patients, systemic and local steroid doses have been increased and patients are being monitored closely. No comparable inflammation has been seen in the six pediatric patients across both trials at dose group 5a, nor in any of the adult patients or lowest group 4 pediatric patients on which we previously reported. These new data do not change our plans to continue development of the ACHM product candidates and, as a result, we plan to release 3-month data for high dose pediatric patients, both ACHMB3 and ACHMA3, in the fourth quarter of calendar year 2021. We are currently postponing enrollment of the last pediatric patient in the ACHMA3 trial pending review of longer-term data for the high dose pediatric patients.

Build-To-Suit Manufacturing and Quality Control Facility in Alachua, Florida

In May 2021, we signed a 20-year lease for a build-to-suit 21,250 square foot current Good Manufacturing Practices (“cGMP”) manufacturing and quality control facility adjacent to our existing Florida facility to prepare for late-stage development of our XLRP and ACHM programs. Leasing this cGMP facility is part of our strategy to enable more rapid filing of a Biologics Licensing Application and commercial launch of our XLRP candidate upon potential FDA approval. The cGMP facility is also expected to support more rapid advancement of our product pipeline while providing supply chain redundancy and reducing manufacturing risk. We anticipate that the build-out of the new manufacturing and quality control facility will be completed during the second half of calendar year 2022.

Additional information regarding our new cGMP manufacturing and quality control facility can be found in Note 3 to our financial statements in this Annual Report on Form 10-K.

Underwritten Public Offering

On February 1, 2021, we closed an underwritten public offering of 16,741,573 shares of our common stock, together with accompanying warrants to purchase 8,370,786 shares of our common stock. The combined offering

[Table of Contents](#)

price of each share of common stock and accompanying warrant was \$4.45, generating gross proceeds of \$74.5 million, before deducting underwriting discounts, commissions and other offering expenses payable by us, which totaled \$5.2 million. The warrants have an exercise price of \$6.00 per share (subject to certain adjustments), are immediately exercisable and expire on February 1, 2026.

We intend to use the net proceeds from the offering, together with other available funds, to fund our ongoing Skyline and Vista trials and our ongoing Phase 1/2 clinical trials in our ACHMB3 and ACHMA3 programs, and for working capital and other general corporate purposes.

At-The-Market Offering Program

On April 2, 2021, we entered into a Controlled Equity OfferingSM Sales Agreement with Cantor Fitzgerald & Co. as sales agent to sell shares of our common stock, from time to time, through an “at-the-market offering” program having an aggregate offering price of up to \$50.0 million. However, we have not sold any shares under this agreement and are not obligated to do so in the future.

Long-Term Debt Agreement

Effective May 13, 2021, our long-term loan agreement was amended (the “Amendment”) whereby, among other things: (i) a term loan advance of \$10.0 million was authorized by the lenders and advanced to us on such date; (ii) the period that we will make interest-only payments on outstanding borrowings was extended to March 31, 2022; and (iii) the maturity date of the facility was extended from December 1, 2023 to April 1, 2024. Subject to certain conditions provided in the Amendment, the interest-only period and the maturity date can be further extended. Subject to the lenders’ investment committee’s sole discretion, we have the right to request that the lenders make additional term loan advances in an aggregate principal amount of up to \$5.0 million. However, there can be no assurances that any term loan advances will be funded by the lenders in the future.

Additional information regarding our long-term loan agreement and the Amendment can be found in Note 8 to our financial statements in this Annual Report on Form 10-K.

Strategic Collaborations

Bionic Sight

During February 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. The collaboration agreement grants to us, 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.

In March 2021, Bionic Sight, which has responsibility for conducting the clinical trial, reported promising results in its first two cohorts of patients. Bionic Sight reported that these patients, all of whom have complete or near-complete blindness, can now see light and motion, and, in two cases, can detect the direction of motion. The product appears to be safe and well tolerated and Bionic Sight is continuing to enroll patients at higher doses.

Otonomy

During October 2019, we entered into a strategic collaboration agreement with Otonomy to co-develop and co-commercialize an adeno-associated virus-based gene therapy to restore hearing in patients with sensorineural

[Table of Contents](#)

hearing loss caused by a mutation in the gap junction protein beta 2 gene (“GJB2”) – the most common cause of congenital hearing loss. Mutations in GJB2 account for approximately 30% of all genetic hearing loss cases. Patients with this mutation can have severe-to-profound deafness in both ears that is identified in screening tests routinely performed in newborns. Under the collaboration agreement, the parties began equally sharing the program costs and proceeds in January 2020 and can include additional genetic hearing loss targets in the future. We and Otonomy announced promising preclinical data at the American Society of Gene and Cell Therapy meeting in May 2021, demonstrating the rescue of hearing loss and cochlear morphology in two independent mouse models. Collectively, we are conducting IND (investigational new drug)-enabling activities based on pre-IND meeting feedback from the FDA, with an IND filing anticipated in the first half of calendar year 2023.

Additional information regarding the Bionic Sight and Otonomy collaborative agreements can be found in Note 9 to our financial statements in this Annual Report on Form 10-K.

Financial Operations Review

Revenue

We generate revenue primarily through: (i) collaboration agreements; (ii) sponsored research arrangements with nonprofit organizations for the development and commercialization of product candidates; (iii) federal research and development grant programs; and (iv) licensing arrangements. In the future, we may generate revenue from product sales (if any products are approved), license fees, milestone payments, development services, research and development grants, or 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 that any are approved and 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 and our results of operations, financial position and cash flows would be materially adversely affected.

Research and development expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates and 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 toward 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 revenue from the commercialization and

[Table of Contents](#)

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 clinical trials, as well as any additional clinical trials that we are required to, or decide to, initiate 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, if any, 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 through, among other things, our lease of a new cGMP build-to-suit manufacturing and quality control facility;
- 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 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, which could be adversely impacted by the COVID-19 pandemic, we could be required to expend significant additional financial resources and time on the completion of clinical development.

From our inception and through June 30, 2021, we have incurred approximately \$282.6 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, explore potential applications of our gene therapy platform in other indications and execute our plan to open and operate a leased cGMP manufacturing and quality control facility.

General and administrative and other expenses

General and administrative and other expenses primarily consist 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, facility-related costs not otherwise included in research and development expenses, 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 and other expenses will continue to increase in the future as we hire additional employees to support our research and development efforts, collaboration arrangements, and the potential commercialization of our product candidates. Additionally, if and when we believe that regulatory approval of our 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. Our general and administrative expenses are also expected to increase as we execute our plan to open and operate a leased cGMP manufacturing and quality control facility.

[Table of Contents](#)

Investment income, net

Investment income, net consists of interest earned on cash and cash equivalents and held-to-maturity investments in debt securities. During the year ended June 30, 2021, investment income, net declined by \$1.1 million when compared to the prior year. Such reduction in investment income, net was primarily due to lower interest rates in the marketplace.

Interest expense

Interest expense during the year ended June 30, 2021 was primarily attributable to the loan agreement that we entered into on June 30, 2020 and amended in May 2021. Additional information regarding our long-term loan agreement can be found in Note 8 to our financial statements in this Annual Report on Form 10-K.

Provision for (benefit from) income taxes

Income tax benefit for the year ended June 30, 2021 was \$2.1 million compared to income tax expense of \$83,000 for the year ended June 30, 2020. The income tax benefit during the year ended June 30, 2021 was primarily due to the reversal of our uncertain tax position liabilities, including the related interest and penalties. During the year ended June 30, 2020, income tax expense was primarily due to estimated interest and penalties on our then-existing uncertain tax positions. Additional information regarding our income taxes can be found in Note 11 to our financial statements in this Annual Report on Form 10-K.

Critical Accounting Policies and Estimates

Management's Discussion and Analysis of Financial Condition and Results of Operations included in this Annual Report on Form 10-K is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of those financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, judgments and methodologies, including those related to accrued expenses and share-based compensation. We base our estimates on historical experience, current conditions, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from our estimates under different assumptions or conditions. Moreover, we may need to change the assumptions underlying our estimates due to risks and uncertainties related to the COVID-19 pandemic or otherwise and those changes could have a material adverse effect on our statements of operations, financial condition and cash flows. While our significant accounting policies are described in Note 2 to our financial statements in this Annual Report on Form 10-K, we believe that the following accounting policies are most critical to the preparation of our financial statements.

Revenue recognition

We recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that 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 Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, we perform 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 any constraints 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 if it is probable that we will collect consideration that we are entitled to in exchange for the goods or services we transfer to the customer.

[Table of Contents](#)

Performance obligations are promises to transfer distinct goods or services to a 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. When 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 a customer to develop the intellectual property on its 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 and variable consideration. At the inception of an arrangement that includes variable consideration and at the end of each reporting period, we evaluate the amount of potential customer payments and the likelihood that such payments will be received. We utilize either the most likely amount method or the 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 to determine whether a significant financing component exists and conclude that a significant financing component does not exist in an arrangement if the: (a) 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 often include development and regulatory milestone payments. At contract inception, we evaluate whether any such 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 reevaluate the probability of achievement of such development milestones and any related constraint and, if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue 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 sale occurs 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 stand-alone selling price of the underlying performance obligation or, in the case of certain variable consideration, to one or more performance obligations. We use assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in a 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 related performance obligation. Certain variable consideration is allocated specifically to one or more performance obligation in a contract when the terms of the variable consideration relate to the satisfaction of a performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts we would expect to receive for each performance obligation.

For performance obligations consisting of licenses and other promises, we use 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 upfront fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. If the license to our intellectual

[Table of Contents](#)

property is determined to be distinct from the other performance obligations identified in the arrangement, we will recognize revenue from upfront 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 our 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 we perform our obligations under those arrangements. Amounts are recorded as accounts receivable when the right to consideration is unconditional.

Research and development expenses

Research and development expenses 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 preclinical expenses; and payments for sponsored research, scientific and regulatory consulting fees and testing.

As part of the process of preparing our financial statements, estimates of accrued expenses are necessary. The estimation process involves reviewing quotations and contracts, identifying services that have been performed on our behalf, and determining the level of services performed and associated costs incurred for services for which we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice monthly in arrears for services performed or when contractual milestones are met. We estimate our accrued expenses at the end of each reporting period based on the facts and circumstances known at that time. The significant estimates in our accrued research and development expenses primarily relate to expenses incurred with respect to academic research centers, contract research organizations and other vendors in connection with research and development activities for which we have not yet been invoiced.

There are instances where our service providers require advance payments at the inception of a contract and other circumstances where our payments to a vendor will exceed the level of services provided, in both cases resulting in a prepayment of research and development expenses. 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 Standards Codification Topic 718, *Compensation—Stock Compensation*, and generally recognize share-based compensation expense on a straight-line basis over the period that an employee is required to provide service in exchange for the award. In certain instances, we use a graded vesting schedule to recognize compensation expense. We also award stock options and restricted stock units to nonemployees in exchange for consulting services. The determination of share-based compensation costs for nonemployees is generally consistent with that of employee awards, with expense recognized as services are provided to us over the related service period.

For purposes of calculating share-based compensation expense, we estimate the fair value of stock options using a Black-Scholes option-pricing model. The determination of the fair value of a share-based compensation award utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including the expected volatility of our stock, the expected life of the stock option, the risk-free interest rate and expected dividends. Additionally, we use a Monte Carlo simulation model to determine the fair value of restricted stock units with market-based vesting conditions for purposes of calculating share-based compensation expense. The Monte Carlo simulation model incorporates the probability of satisfying a market condition and uses transaction details such as our stock price, contractual terms, maturity and risk-free interest rates, as well as volatility. The fair value of restricted stock units with no performance or market vesting conditions is based on the market value of our common stock on the date of grant.

[Table of Contents](#)

If factors change and we employ different assumptions, share-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 share-based compensation expense and the actual factors that become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining share-based compensation costs for future awards. These changes, if any, may materially impact our results of operations in the period that such changes are made.

Income taxes

We use the asset and liability method to account 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 projected 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. Interest and penalties related to uncertain tax positions are reflected in the provision for (benefit from) income taxes.

Recent Accounting Pronouncements

See Note 2 to our financial statements in this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our business.

Results of Operations

Comparison of the years ended June 30, 2021 and 2020

Revenue

During the years ended June 30, 2021 and 2020, we recognized total revenue of \$0.5 million and \$2.5 million, respectively.

Effective April 13, 2021, we entered into a license agreement with a third party whereby we provided nonexclusive rights to our proprietary cone-specific promoter technology for use in the development of two non-competing products. In connection with this agreement, we recognized \$0.5 million of license fee revenue during the year ended June 30, 2021.

During December 2019, Bionic Sight met a milestone related to clearance of filing of an Investigational New Drug application under its collaboration agreement with us and, as a result, we recognized \$2.2 million of non-cash collaboration revenue during the year ended June 30, 2020 in connection with in-kind contributions made since inception of the Bionic Sight collaboration agreement. During the year ended June 30, 2020, we also recorded \$0.2 million and \$0.1 million of grant revenue and other milestone revenue, respectively.

Additional information regarding the abovementioned license agreement and the Bionic Sight collaborative agreement can be found in Note 9 to our financial statements in this Annual Report on Form 10-K.

[Table of Contents](#)

Research and development expenses

The table below summarizes our research and development expenses by product candidate or program for the years indicated.

<u>In thousands</u>	<u>Year Ended June 30,</u>		<u>Increase</u>	<u>% Increase</u>
	<u>2021</u>	<u>2020</u>	<u>(Decrease)</u>	<u>(Decrease)</u>
External research and development expenses:				
XLRP	\$15,250	\$ 6,492	\$ 8,758	>100%
ACHM	4,720	5,956	(1,236)	(21)%
XLRS	314	706	(392)	(56)%
Research and discovery programs	2,799	1,781	1,018	57%
Total external research and development expenses	23,083	14,935	8,148	55%
Internal research and development expenses:				
Employee-related costs	12,663	12,466	197	2%
Share-based compensation	1,110	1,451	(341)	(24)%
Other	7,544	6,926	618	9%
Total internal research and development expenses	21,317	20,843	474	2%
Total research and development expenses	<u>\$44,400</u>	<u>\$35,778</u>	<u>\$ 8,622</u>	24%

External research and development expenses consist of collaboration, licensing, manufacturing, testing and other miscellaneous costs that are directly attributable to our most advanced product candidates and discovery programs. We do not allocate employee-related costs, including share-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 the years ended June 30, 2021 and 2020 were \$44.4 million and \$35.8 million, respectively, an increase of \$8.6 million, or 24%. Such increase was primarily attributable to:

- \$8.8 million of increased external spending for our XLRP trials due to our planned manufacturing, clinical site preparation and other activities related to our Skyline and Vista trials;
- \$1.0 million of increased external spending for our research and discovery programs, which was primarily due to planned material production costs in connection with our CNS preclinical program targeting FTD; and
- \$0.6 million of increased other internal research and development expenses for temporary staffing and consultants while we recruit new employees, partially offset by a reduction in laboratory supply costs due to the timing of our needs.

Such increases were partially offset by: (i) a \$1.2 million decrease in external spending for our ACHM trials; (ii) a \$0.4 million decrease in expenses in connection with the wind-down of our X-linked retinoschisis, or XLRS, program; and (iii) a \$0.3 million decrease in our share-based compensation expense. The decrease in ACHM expenses was primarily due to reduced patient enrollment, patient visits and new site activations during the year ended June 30, 2021 when compared to the prior year, all of which reduce our overall clinical programs costs, partially offset by incremental expenses for our mobile vision center. The decline in share-based compensation expense was due to, among other things, the cost attributable to a performance-based stock option award that achieved a milestone during the year ended June 30, 2020 with no corresponding current year activity.

[Table of Contents](#)

General and administrative and other expenses

The table below summarizes our general and administrative and other expenses for the years indicated.

<u>In thousands</u>	<u>Year Ended June 30,</u>		<u>Increase</u>	<u>% Increase</u>
	<u>2021</u>	<u>2020</u>	<u>(Decrease)</u>	<u>(Decrease)</u>
Employee-related costs	\$ 5,312	\$ 5,746	\$ (434)	(8)%
Share-based compensation	1,568	1,547	21	1%
Legal and professional fees	1,636	468	1,168	>100%
Other	6,035	5,856	179	3%
Total general and administrative and other expenses	<u>\$14,551</u>	<u>\$13,617</u>	<u>\$ 934</u>	<u>7%</u>

General and administrative and other expenses for the years ended June 30, 2021 and 2020 were \$14.6 million and \$13.6 million, respectively, an increase of \$0.9 million, or 7%. Such increase was primarily due to higher (i) legal fees resulting from increased reliance on external legal counsel and (ii) recurring operating and business development costs pertaining to normal operations. Such increases were partially offset by a reduction in employee-related costs of \$0.4 million that resulted from a lower corporate headcount during the year ended June 30, 2021 when compared to the prior year.

Liquidity and Capital Resources

We have incurred cumulative losses and negative cash flows from operations since our inception and, as of June 30, 2021, we had an accumulated deficit of \$239.3 million. It will be several years, if ever, before we have a product candidate ready for commercialization. We expect that our research and development expenses and general and administrative and other 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.

Most recently, we received: (i) \$34.8 million of proceeds from the issuance of our common stock, net of issuance costs, in February 2020; (ii) \$9.9 million of loan proceeds, net of debt discounts, during each of June 2020 and May 2021; and (iii) net proceeds of \$69.3 million in February 2021 from the underwritten public offering that is described above under "Recent Developments." Among other things, the May 2021 net cash proceeds are expected to partially fund certain equipment and shared building fit out costs, as well as new employee hires, in connection with our lease and operation of a new cGMP build-to-suit manufacturing and quality control facility in Alachua, Florida. Importantly, through a tenant improvement allowance and tiered rental rates, we have structured our third-party leasing costs for such facility in a way that will not significantly impact our cash runway until the fiscal year ending June 30, 2024. Additional information regarding the new manufacturing and quality control facility and our long-term loan agreement can be found in Notes 3 and 8, respectively, to our financial statements in this Annual Report on Form 10-K.

We are closely monitoring ongoing developments in connection with the COVID-19 pandemic, which may negatively impact our projected cash position and access to capital. We will continue to assess our cash position and, if circumstances warrant, make appropriate adjustments to our operating plan.

Cash in excess of immediate requirements is invested in accordance with our investment policy, which primarily seeks to maintain adequate liquidity and preserve capital by generally limiting investments to certificates of deposit and investment-grade debt securities that mature within twelve months. As of June 30, 2021, our cash and cash equivalents were held in bank accounts and money market funds, while our investments consisted of a U.S. Treasury security that matured in July 2021, consistent with our investment policy.

[Table of Contents](#)

Cash flows

The table below sets forth the primary sources and uses of cash for the years indicated.

<u>In thousands</u>	<u>Year Ended June 30,</u>		<u>Increase</u>	<u>% Increase</u>
	<u>2021</u>	<u>2020</u>	<u>(Decrease)</u>	<u>(Decrease)</u>
Cash provided by (used in):				
Operating activities	\$ (51,173)	\$ (41,620)	\$ (9,553)	(23)%
Investing activities	38,147	8,399	29,748	>100%
Financing activities	79,615	44,981	34,634	77%
Net increase in cash and cash equivalents	<u>\$ 66,589</u>	<u>\$ 11,760</u>	<u>\$ 54,829</u>	>100%

Operating activities. For both the years ended June 30, 2021 and 2020, cash used in operating activities was primarily the result of research and development expenses and general and administrative and other expenses incurred in conducting normal business operations. Specifically, the cash used in operating activities of \$51.2 million during the year ended June 30, 2021 was due to a net loss of \$57.8 million, partially offset by non-cash items in our statement of operations of \$2.8 million and favorable changes in our operating assets and liabilities of \$3.9 million. The cash used in operating activities of \$41.6 million during the year ended June 30, 2020 was due to a net loss of \$45.9 million, partially offset by non-cash items in our statement of operations of \$2.2 million and favorable changes in our operating assets and liabilities of \$2.1 million.

Investing activities. Cash provided by investing activities of \$38.1 million during the year ended June 30, 2021 consisted primarily of cash proceeds of \$61.0 million from maturities of investments, net of investment purchases of \$21.0 million, partially offset by purchases of property and equipment of \$1.5 million and intellectual property costs of \$0.4 million. Cash provided by investing activities of \$8.4 million during the year ended June 30, 2020 consisted primarily of cash proceeds of \$72.5 million from maturities of investments, net of investment purchases of \$58.9 million, partially offset by an equity investment in Bionic Sight of \$4.0 million, purchases of property and equipment of \$0.9 million and intellectual property costs of \$0.3 million.

Financing activities. Cash provided by financing activities of \$79.6 million during the year ended June 30, 2021 included: (i) proceeds of \$69.3 million from the issuance of common stock and accompanying warrants, net of issuance costs; (ii) net cash received of \$9.9 million from a second term loan advance under our collateralized debt arrangement; and (iii) proceeds from exercises of common stock options of \$0.8 million. These items were partially offset by (i) payments for deferred financing fees and taxes related to equity awards and (ii) principal payments on a finance lease. Cash provided by financing activities of \$45.0 million during the year ended June 30, 2020 primarily consisted of: (i) proceeds of \$34.8 million from the issuance of common stock, net of issuance costs; (ii) net cash received of \$9.9 million from our collateralized debt arrangement that closed on June 30, 2020; and (iii) proceeds from exercises of common stock options of \$0.4 million. These items were partially offset by principal payments on a finance lease.

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 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 available cash and cash equivalents and investments, which totaled \$107.1 million on June 30, 2021, will be sufficient to allow us to generate data from our ongoing and planned clinical programs and

[Table of Contents](#)

fund currently planned research and discovery programs into calendar year 2023. However, we will require substantial additional funding to: (i) finish our Vista trial; (ii) move our ACHMB3 product candidate forward; (iii) complete the process necessary to seek regulatory approval for our lead product candidates; (iv) build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidates, if approved; and (v) execute our plan to open and operate a leased cGMP manufacturing and quality control facility.

Contractual obligations and commitments

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

Off-balance sheet arrangements

During the years presented in this Annual Report on Form 10-K and as of June 30, 2021, we did not 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

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

APPLIED GENETIC TECHNOLOGIES CORPORATION
INDEX TO FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	109
Financial Statements	
Balance Sheets as of June 30, 2021 and 2020	111
Statements of Operations for the years ended June 30, 2021 and 2020	112
Statements of Stockholders' Equity for the years ended June 30, 2021 and 2020	113
Statements of Cash Flows for the years ended June 30, 2021 and 2020	114
Notes to Financial Statements	115

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, 2021 and 2020, the related statements of operations, stockholders' equity and cash flows for each of the two years in the period ended June 30, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at June 30, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended June 30, 2021, in conformity with U.S. generally accepted accounting principles.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosure to which it relates.

Accrued Research and Development Expenses

<i>Description of the Matter</i>	<p>As of June 30, 2021, the Company had \$9.8 million of accrued research and development expenses in accrued and other liabilities on its balance sheet. As described in Note 2 to the financial statements, this accrual includes costs incurred for services related to the Company's obligations under its contracts with vendors in connection with research and development efforts. Because the financial terms and billing frequency of these contracts vary, the Company may make vendor payments that differ from the periods during which materials are consumed or services are provided. The Company develops estimates of costs incurred based on reviewing quotations and contracts, identifying services that have been performed on the Company's behalf and estimating the level of services performed and the associated costs incurred for services for which the Company has not yet been invoiced or otherwise notified of the actual cost.</p> <p>Auditing the Company's accrued research and development expenses was complex because the financial terms and billing frequency of vendor contracts may differ from when the services are actually provided and the estimate can incorporate significant assumptions such as progress towards the achievement of project milestones.</p>
<i>How We Addressed the Matter in Our Audit</i>	<p>To evaluate the accrued research and development expenses, our audit procedures included, among others, inspecting the Company's contracts with its research and development vendors and evaluating the underlying data used in the estimates of the services provided. We also corroborated the progress of research and development activities through inquiry with the Company's contract monitors and with information obtained directly from third-party vendors, as well as tested invoices received from vendors throughout the Company's fiscal year and subsequent to the balance sheet date.</p>

/s/ Ernst & Young LLP

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

Tampa, Florida
September 23, 2021

APPLIED GENETIC TECHNOLOGIES CORPORATION
BALANCE SHEETS

In thousands, except per share data	June 30,	
	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 105,052	\$ 38,463
Investments	2,000	41,995
Prepaid and other current assets	2,655	2,506
Total current assets	109,707	82,964
Property and equipment, net	4,658	4,311
Intangible assets, net	1,287	1,098
Investment in Bionic Sight, LLC	8,000	8,096
Right-of-use assets—operating leases	3,167	3,422
Right-of-use asset—financing lease	34	80
Other assets	113	348
Total assets	<u>\$ 126,966</u>	<u>\$ 100,319</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,879	\$ 1,355
Accrued and other liabilities	14,500	10,502
Lease liabilities—operating	1,116	1,058
Lease liability—finance	38	48
Current portion of long-term debt	2,181	—
Total current liabilities	19,714	12,963
Lease liabilities—operating, net of current portion	3,418	4,070
Lease liability—finance, net of current portion	—	38
Long-term debt, net of debt discounts and deferred financing fees	17,727	9,677
Other liabilities	299	2,555
Total liabilities	<u>41,158</u>	<u>29,303</u>
Stockholders' equity:		
Preferred stock, par value \$0.001 per share, 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value \$0.001 per share, 150,000 shares authorized; 42,835 and 25,813 shares issued; 42,794 and 25,793 shares outstanding at June 30, 2021 and 2020, respectively	43	25
Additional paid-in capital	325,245	252,519
Treasury stock at cost; 41 and 20 shares at June 30, 2021 and 2020, respectively	(211)	(88)
Accumulated deficit	(239,269)	(181,440)
Total stockholders' equity	85,808	71,016
Total liabilities and stockholders' equity	<u>\$ 126,966</u>	<u>\$ 100,319</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	Year Ended June 30,	
	2021	2020
Revenue:		
Collaboration and milestone revenue	\$ —	\$ 2,297
License fee revenue	500	—
Grant revenue	—	156
Total revenue	500	2,453
Operating expenses:		
Research and development	44,400	35,778
General and administrative and other	14,551	13,617
Total operating expenses	58,951	49,395
Loss from operations	(58,451)	(46,942)
Other income (expense), net:		
Investment income, net	116	1,185
Interest expense	(1,506)	(11)
Other income	—	6
Total other income (expense), net	(1,390)	1,180
Loss before provision for (benefit from) income taxes	(59,841)	(45,762)
Provision for (benefit from) income taxes	(2,108)	83
Loss before equity in net losses of an affiliate	(57,733)	(45,845)
Equity in net losses of an affiliate	(96)	(47)
Net loss	\$(57,829)	\$(45,892)
Weighted average shares outstanding:		
Basic	32,756	21,102
Diluted	32,756	21,102
Net loss per common share:		
Basic	\$ (1.77)	\$ (2.17)
Diluted	\$ (1.77)	\$ (2.17)

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

APPLIED GENETIC TECHNOLOGIES CORPORATION
STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED JUNE 30, 2021 AND 2020

<u>In thousands</u>	<u>Common Stock</u>		<u>Treasury Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Totals</u>
	<u>Outstanding Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balances at June 30, 2019	18,207	\$ 18	19	\$ (85)	\$214,324	\$ (135,548)	\$ 78,709
Issuance of common stock, net of issuance costs	7,475	7	—	—	34,804	—	34,811
Share-based compensation expense	—	—	—	—	2,998	—	2,998
Shares issued under employee plans and related share repurchases	111	—	1	(3)	393	—	390
Net loss	—	—	—	—	—	(45,892)	(45,892)
Balances at June 30, 2020	25,793	25	20	(88)	252,519	(181,440)	71,016
Issuance of common stock and accompanying warrants, net of issuance costs	16,742	17	—	—	69,244	—	69,261
Share-based compensation expense	—	—	—	—	2,678	—	2,678
Shares issued under employee plans and related share repurchases	259	1	21	(123)	804	—	682
Net loss	—	—	—	—	—	(57,829)	(57,829)
Balances at June 30, 2021	<u>42,794</u>	<u>\$ 43</u>	<u>41</u>	<u>\$ (211)</u>	<u>\$325,245</u>	<u>\$ (239,269)</u>	<u>\$ 85,808</u>

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

APPLIED GENETIC TECHNOLOGIES CORPORATION
STATEMENTS OF CASH FLOWS

<u>In thousands</u>	<u>Year Ended June 30</u>	
	<u>2021</u>	<u>2020</u>
Operating activities:		
Net loss	\$ (57,829)	\$ (45,892)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	2,678	2,998
Depreciation and amortization	1,460	1,335
Investment discount accretion, net	(13)	(299)
Amortization of debt discounts and deferred financing fees	381	—
Reduction in the carrying amount of operating lease right-of-use assets	366	303
Collaboration revenue from Bionic Sight, LLC	—	(2,197)
Income tax benefit from the reversal of uncertain tax position liabilities	(2,171)	—
Equity in net losses of an affiliate	96	47
Changes in operating assets and liabilities:		
Grants receivable	—	13
Prepaid and other assets	311	(28)
Deferred revenue	—	149
Accounts payable	497	83
Operating lease liabilities	(705)	(714)
Accrued and other liabilities	3,756	2,582
Cash used in operating activities	<u>(51,173)</u>	<u>(41,620)</u>
Investing activities:		
Purchases of property and equipment	(1,457)	(943)
Purchases of and capitalized costs related to intangible assets	(404)	(254)
Investment in Bionic Sight, LLC	—	(4,000)
Maturities of investments	61,000	72,500
Purchases of investments	(20,992)	(58,904)
Cash provided by investing activities	<u>38,147</u>	<u>8,399</u>
Financing activities:		
Proceeds from the issuance of common stock and accompanying warrants, net of issuance costs	69,261	34,811
Proceeds from exercises of common stock options	804	393
Proceeds from long-term debt borrowing, net of debt discounts	9,850	9,855
Payments for deferred financing fees	(129)	(30)
Taxes paid related to equity awards	(123)	(3)
Principal payments on finance lease	(48)	(45)
Cash provided by financing activities	<u>79,615</u>	<u>44,981</u>
Net increase in cash and cash equivalents	66,589	11,760
Cash and cash equivalents, beginning of the year	38,463	26,703
Cash and cash equivalents, end of the year	<u>\$105,052</u>	<u>\$ 38,463</u>
Supplemental information:		
Cash paid (refunds received) during the year for income taxes, net	\$ (396)	\$ (396)
Cash paid during the year for interest	1,346	9
Deferred financing fees included in accrued and other liabilities	—	149
Costs for purchases of property and equipment included in accrued and other liabilities	448	326
Costs for intangible assets included in accounts payable/accrued and other liabilities	27	60

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 people suffering from rare and debilitating ophthalmic, otologic and central nervous system diseases.

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, licensing of its intellectual property, sponsored research 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 the ability to transition to large-scale production of products.

As of June 30, 2021, the Company had (i) an accumulated deficit of \$239.3 million and (ii) cash and cash equivalents and liquid investments of \$107.1 million. Management believes that there is sufficient funding available to allow the Company to generate data from its ongoing and planned clinical programs and fund currently planned research and discovery programs. While the Company expects to generate some revenue from partnering, sponsored research, grants and licensing of its intellectual property, management believes that the Company will incur losses for the foreseeable future. The Company has funded its operations to date primarily through public offerings of its common stock and warrants to purchase its common stock, private placements of its preferred stock, collateralized borrowing and collaborations.

2. Summary of Significant Accounting Policies

Basis of presentation

The accompanying financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”). The Company’s fiscal year ends on June 30.

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 when making decisions regarding resource allocation and assessing performance. To date, management has viewed the Company’s operations and managed its business as one segment.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP and guidelines from the Securities and Exchange Commission (the “SEC”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during reporting periods. Actual results could differ from those estimates.

[Table of Contents](#)

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 have historically consisted 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 at each balance sheet date. Debt securities are classified as held-to-maturity when management 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, net. Interest income from debt securities classified as held-to-maturity is also included in investment income, net.

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 its amortized cost. Once a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded to investment income, net and a new cost basis in the investment is established.

Concentrations of Credit Risk

As of June 30, 2021, the Company's cash and cash equivalents were held on deposit with a financial institution that is federally insured. However, a large portion of those cash and cash equivalents exceed 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 management 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 one-year period from their purchase date, which is consistent 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 the related liability is 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 unique drug.

Fair value of financial instruments

The Company is required to disclose information regarding all assets and liabilities reported at fair value that enables an assessment of the inputs used when determining the reported fair values. The Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 820, *Fair Value Measurements and Disclosures*, establishes a hierarchy of inputs used when available. Observable inputs are inputs that market participants would use when pricing an asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use when pricing an asset or liability and are developed based on

[Table of Contents](#)

the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used when determining the reported fair value of financial instruments and is not a measure of an investment's 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 unobservable.

To the extent that a 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 when determining fair value is greatest for financial 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, which consists of laboratory equipment, furniture and fixtures, computer equipment and leasehold improvements, is recorded at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful life of the underlying asset, which is generally three to ten years. Leasehold improvements are amortized over the shorter of the estimated useful life of the underlying asset or the related lease term, including any renewal periods that are deemed to be reasonably assured. As of June 30, 2021, the weighted average useful life of the Company's property and equipment was 6.6 years. Repair and maintenance costs that do not improve service potential or extend an asset's economic life are recorded as an expense when incurred.

Leases

The Company follows the provisions of ASC Topic 842, *Leases* ("Topic 842"), for all contracts and agreements that are within its scope. Under Topic 842, leases are accounted for using a right-of-use model whereby a lessee must record a right-of-use asset and a related lease liability on its balance sheet for most of its leases. Under Topic 842, leases are classified as either operating or finance arrangements, with such classification affecting the pattern of expense recognition in an entity's income statement. For operating leases, Topic 842 requires recognition of a single lease cost in an entity's statement of operations, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. Finance lease accounting is not material to the Company.

The Company does not record a right-of-use asset or lease liability for leases with an expected duration of 12 months or less at inception; however, such leases are not material to the Company. For leases with terms greater than 12 months, the Company records a right-of-use asset and lease liability at the present value of the future lease payments. Right-of-use assets may also include initial direct costs incurred by the Company and lease payments made to a lessor on or before the related lease commencement date, less any lease incentives received directly from the lessor. When it is reasonably certain that the Company will exercise a renewal option or termination provision for one of its leases, the present value of the lease payments for the affected lease is adjusted accordingly. Variable lease payments that are not dependent on an index or a rate are excluded from the determination of the Company's right-of-use assets and lease liabilities, and such payments are recognized as expense in the period that the related obligation is incurred. As the Company's leases do not provide readily determinable implicit interest rates, an incremental borrowing rate commensurate with a lease's term is used to discount future lease payments. The Company's operating leases include rent escalation clauses that are factored

[Table of Contents](#)

into the determination of future lease payments when appropriate. The Company does not separate lease and nonlease components of its contracts when applying the provisions of Topic 842.

The Company's leases are further discussed at Note 3 in these Notes to Financial Statements.

Intangible assets

Intangible assets primarily consist of 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 existing and/or 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. The Company writes off costs associated with patents that are no longer being actively pursued or provide no future benefit.

Amortization expense for intangible assets is computed using the straight-line method over the estimated useful life of the underlying asset, which is generally eight to twenty years (a weighted average useful life of 13.2 years as of June 30, 2021). 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 expensed.

Impairment of long-lived assets

The Company reviews its long-lived asset groups for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or an asset group may not be recoverable. Such evaluation could be triggered by a number of factors, including current and projected operating results/cash flows and changes in management's strategic direction, as well as external economic and market factors. The Company evaluates the recoverability of assets and asset groups by determining whether their carrying values can be recovered through undiscounted future cash flows. If events or circumstances indicate that the carrying values might not be recoverable based on undiscounted future cash flows, an impairment charge may be recognized. Management considers various factors when calculating an impairment charge, including trends and prospects, as well as the effects of obsolescence, demand, competition and other macroeconomic information. The Company did not record any impairment charges for long-lived assets during the years ended June 30, 2021 and 2020.

Financing fees

Financing fees consist of costs, including those for legal services, that are necessary to secure commitments under debt financing arrangements. Those costs are deferred and recognized as interest expense over the period of the related financing arrangement using the effective interest method. If a financing arrangement is terminated or otherwise satisfied, any remaining deferred financing fees are immediately recognized as interest expense. The Company's financial statements present deferred financing fees as a direct reduction of the carrying amount of the corresponding liability.

Revenue recognition

The Company follows the provisions of ASC Topic 606, *Revenue from Contracts with Customers* ("Topic 606"), for all customer contracts and agreements that are within its scope.

The Company may enter into collaboration agreements, which are within the scope of Topic 606, where it licenses rights to its technology and certain of its product candidates and performs research and development services for third parties. The terms of these arrangements may include payment of one or more of the following: upfront fees; reimbursement of research and development costs; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

[Table of Contents](#)

Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that 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 any constraints 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 if it is probable that it will collect consideration that the Company 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 a 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. When 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 a customer to develop the intellectual property on its 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 and variable consideration. At the inception of an arrangement that includes variable consideration and at the end of each reporting period, the Company evaluates the amount of potential customer payments and the likelihood that such payments will be received. The Company utilizes either the most likely amount method or the 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 to determine whether a significant financing component exists and conclude that a significant financing component does not exist in an arrangement if the: (a) 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 often include development and regulatory milestone payments. At contract inception, the Company evaluates whether any such milestones are considered probable of being reached and estimates 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 reevaluates 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 revenue 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 sale occurs 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 stand-alone selling price of the underlying performance obligation or, in the case of certain variable consideration, to one or more performance obligations. The Company uses assumptions that require judgment to determine the stand-alone selling price for

[Table of Contents](#)

each performance obligation identified in a 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 related performance obligation. Certain variable consideration is allocated specifically to one or more performance obligation in a contract when the terms of the variable consideration relate to the satisfaction of a 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 uses 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 upfront fees. The Company evaluates the measure of progress 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 upfront 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 those arrangements. Amounts are recorded as accounts receivable when the right to consideration is unconditional.

Collaboration arrangements

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC Topic 808, *Collaborative Arrangements* ("Topic 808"), and 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 a collaboration arrangement with special consideration given to changes in the responsibilities of the parties in the arrangement. For collaboration arrangements within the scope of Topic 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of Topic 808 and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of Topic 606. For elements of collaboration arrangements that are accounted for pursuant to Topic 808, a recognition method is determined and applied consistently, generally by analogy to Topic 606.

As discussed below under the heading "New accounting pronouncements—Adopted during the year ended June 30, 2021," the Company adopted Accounting Standards Update No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, on July 1, 2020; however, the new standard did not have a significant impact on the Company's financial statements.

The Company's collaboration arrangements are further discussed at Note 9 in these Notes to Financial Statements.

Income taxes

The Company uses the asset and liability method to account 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 projected to be recovered or settled.

[Table of Contents](#)

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. Interest and penalties related to uncertain tax positions are reflected in the provision for (benefit from) income taxes.

The Company's income taxes are further discussed at Note 11 in these Notes to Financial Statements.

Research and development expenses

Research and development expenses 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 preclinical expenses; and payments for sponsored research, scientific and regulatory consulting fees and testing.

As part of the process of preparing the Company's financial statements, estimates of accrued expenses are necessary. The estimation process involves reviewing quotations and contracts, identifying services that have been performed on the Company's behalf, and determining the level of services performed and associated costs incurred for services for which the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice monthly in arrears for services performed or when contractual milestones are met. Management estimates the Company's accrued expenses at the end of each reporting period based on the facts and circumstances known at that time. The significant estimates in the Company's accrued research and development expenses primarily relate to expenses incurred with respect to academic research centers, contract research organizations and other vendors in connection with research and development activities for which the Company has not yet been invoiced.

There are instances where the Company's service providers require advance payments at the inception of a contract and other circumstances where the Company's payments to a vendor will exceed the level of services provided, in both cases resulting in a prepayment of research and development expenses. 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 \$0.9 million and \$1.0 million at June 30, 2021 and 2020, respectively, and are included in prepaid and other current assets on the Company's balance sheets.

Share-based compensation

The Company accounts for share-based awards issued to employees in accordance with ASC Topic 718, *Compensation—Stock Compensation*, and generally recognizes share-based compensation expense on a straight-line basis over the period that an employee is required to provide service in exchange for the award. In certain instances, the Company uses a graded vesting schedule to recognize compensation expense. The Company also awards stock options and restricted stock units to nonemployees in exchange for consulting services. The determination of share-based compensation costs for nonemployees is generally consistent with that of employee awards, with expense recognized as services are provided to the Company over the related service period.

For purposes of calculating share-based compensation expense, the Company estimates the fair value of stock options using a Black-Scholes option-pricing model. The determination of the fair value of a share-based compensation award utilizing the Black-Scholes model is affected by the Company's stock price and a number of assumptions, including the expected volatility of the Company's stock, the expected life of the stock option, the risk-free interest rate and expected dividends. Additionally, the Company uses a Monte Carlo simulation model

Table of Contents

to determine the fair value of restricted stock units with market-based vesting conditions for purposes of calculating share-based compensation expense. The Monte Carlo simulation model incorporates the probability of satisfying a market condition and uses transaction details such as the Company's stock price, contractual terms, maturity and risk-free interest rates, as well as volatility. The fair value of restricted stock units with no performance or market vesting conditions is based on the market value of the Company's common stock on the date of grant.

If factors change and the Company employs different assumptions, share-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 share-based compensation expense and the actual factors that become known over time, specifically with respect to anticipated forfeitures, the Company may change the input factors used in determining share-based compensation costs for future awards. These changes, if any, may materially impact the Company's results of operations in the period that such changes are made.

Net income or loss per share

Basic net income or loss per share is calculated by dividing net income or loss by the weighted average shares outstanding during the period, without consideration of common stock equivalents. Diluted net income or loss per share is calculated by adjusting the weighted average shares outstanding for the dilutive effects of common stock equivalents outstanding during the period, determined using the treasury stock method. For purposes of diluted net income or loss per share calculations, warrants to purchase the Company's common stock, stock options, restricted stock awards, restricted stock units and performance service awards are considered to be common stock equivalents if they are dilutive. The dilutive impact of common stock equivalents for the years ended June 30, 2021 and 2020 was approximately 0.4 million and 0.2 million shares, respectively. However, the dilutive impact of common stock equivalents was excluded from the calculations of diluted net loss per share for each of the years ended June 30, 2021 and 2020 because their effects were anti-dilutive.

The abovementioned dilutive impact of common stock equivalents for the year ended June 30, 2021 excluded certain warrants to purchase the Company's common stock, which are described at Note 14 in these Notes to Financial Statements, because the exercise price of such warrants was greater than the average market price of the Company's common stock for the related period.

Comprehensive loss

Comprehensive income or loss consists of net income or loss and changes in equity during a period from transactions and other equity and circumstances generated from non-owner sources. For the years ended June 30, 2021 and 2020, the Company's net loss is the same as its comprehensive loss.

New accounting pronouncements

Adopted during the year ended June 30, 2021

Fair Value Measurement

In August 2018, the FASB issued Accounting Standards Update ("ASU") No. 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 the FASB's disclosure framework project. Under the new standard, the amount and reason for a transfer between Level 1 and Level 2 of the fair value hierarchy are no longer required to be disclosed, but public companies are required to disclose a range and weighted average of significant unobservable inputs for Level 3 fair value measurements. The Company adopted the new standard on July 1, 2020; however, it did not have a significant impact on the Company's financial statements.

[Table of Contents](#)

Collaborative Arrangements

In November 2018, the FASB issued ASU No. 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 Topic 606 when the counterparty is a customer. The new standard also 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 Topic 808 to refer to the unit-of-account guidance in Topic 606 and requires it to be used only when assessing whether a transaction is in the scope of Topic 606. The Company adopted the new standard on July 1, 2020; however, it did not have a significant impact on the Company's financial statements.

Adopted effective July 1, 2021

Financial Instruments—Credit Losses

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The new standard requires that financial assets measured at amortized cost 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 those financial assets. The Company early adopted the new standard on July 1, 2021; however, it did not have a significant impact on the Company's financial statements.

Income Taxes

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The new standard includes several provisions that simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and increasing consistency and clarity for the users of financial statements. The Company adopted the new standard on July 1, 2021; however, it did not have a significant impact on the Company's financial statements.

Investments – Equity Securities, Investments – Equity Method and Joint Ventures, and Derivatives and Hedging

In January 2020, the FASB issued ASU No. 2020-01, *Investments – Equity Securities (Topic 321), Investments – Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)—Clarifying the Interactions between Topic 321, Topic 323, and Topic 815*. The new standard addresses interactions between the guidance to account for certain equity securities under ASC Topic 321, the guidance to account for investments under the equity method of accounting in ASC Topic 323 and the guidance in ASC Topic 815, which could change how an entity accounts for an equity security under the measurement alternative or a forward contract or purchased option to purchase securities that, upon settlement of the forward contract or exercise of the purchased option, would be accounted for under the equity method of accounting or the fair value option in accordance with ASC Topic 825, *Financial Instruments*. These amendments improve current U.S. GAAP by reducing diversity in practice and increasing comparability of the accounting for any such interactions. The Company adopted the new standard on July 1, 2021; however, it did not have a significant impact on the Company's financial statements.

3. Leases

The Company leases certain laboratory and office space under operating leases, which are described below. Additionally, as discussed below under the heading "Build-To-Suit Manufacturing and Quality Control Facility in Alachua, Florida," the Company entered into a long-term lease arrangement in May 2021 for a building that is currently under construction.

[Table of Contents](#)

Alachua, Florida

The Company's headquarters is located in Alachua, Florida where it leases approximately 21,500 square feet of office and laboratory space under a lease arrangement that expires in December 2027. The Company has options to extend the term of the Alachua lease for three additional five-year periods.

Cambridge, Massachusetts

The Company leases approximately 8,000 square feet of office and laboratory space in Cambridge, Massachusetts under a lease arrangement that expires in February 2025. The Company has an option to extend the Cambridge lease for one additional three-year term. The Cambridge facility primarily focuses on business development, pharmacology and basic research and development.

The Company also leases certain office equipment under a finance lease.

Historical lease costs and other

The table below summarizes lease costs and other information pertaining to the Company's operating and finance leases for the years indicated.

In thousands	Year Ended June 30,	
	2021	2020
Lease cost:		
Finance lease cost		
Amortization of right-of-use asset	\$ 46	\$ 46
Interest on lease liability	5	8
Operating lease cost	779	770
Short-term lease cost	32	—
Variable lease cost	409	379
Total lease cost	\$ 1,271	\$ 1,203
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used for finance lease	\$ 5	\$ 8
Operating cash flows used for operating leases	\$ 1,160	\$ 1,091
Financing cash flows used for finance lease	\$ 48	\$ 45
Right-of-use asset obtained in exchange for new operating lease liabilities (non-cash)	\$ 111	\$ —
Other information (as of the end of the year):		
Weighted average remaining lease term—operating leases (in years)	5.1	6.1
Weighted average remaining lease term—finance lease (in years)	0.8	1.8
Weighted average discount rate—operating leases	8.6%	8.5%
Weighted average discount rate—finance lease	6.9%	6.9%

Amortization of the right-of-use asset—finance lease is included in general and administrative and other in the Company's Statements of Operations. Operating lease cost and variable lease cost are included as rent expense in general and administrative and other, and research and development in the Company's Statements of Operations. Variable lease cost primarily includes the Company's allocated share of the expenses incurred by its landlords to operate and manage the office and laboratory space that the Company leases. Short-term lease cost, which pertains to a facility used for clinical trial protocols that the Company began leasing in January 2021, is classified as a research and development expense.

[Table of Contents](#)

Future lease commitments

As of June 30, 2021, future minimum commitments for the Company's operating and finance leases for the years ending June 30 are summarized below.

<u>In thousands</u>	
Operating lease liabilities:	
2022	\$ 1,171
2023	1,190
2024	1,203
2025	888
2026	480
Thereafter	679
Total future minimum payments for operating leases	5,611
Imputed interest	(1,077)
Operating lease liabilities per the balance sheet	<u>\$ 4,534</u>
Finance lease liability:	
2022	39
Total future minimum payments for finance lease	39
Imputed interest	(1)
Total finance lease liability per the balance sheet	<u>\$ 38</u>

In addition to the amounts included in the table above, the Company entered into a long-term real property lease that has not yet commenced and, therefore, is not recorded on the Company's balance sheets. This lease, which is discussed below under the heading "Build-To-Suit Manufacturing and Quality Control Facility in Alachua, Florida," requires non-cancelable undiscounted future base rent payments aggregating \$26.8 million over twenty years (assuming that the Company does not elect the early termination option).

Build-To-Suit Manufacturing and Quality Control Facility in Alachua, Florida

On May 13, 2021, the Company entered into a non-cancelable long-term lease for a to-be-constructed build-to-suit single story facility of approximately 21,250 square feet in Alachua, Florida (the "Premises") for office, research and development, laboratory, light pharmaceutical and medical systems manufacturing and fabrication and distribution use. The new facility will be adjacent to the Company's corporate headquarters. The landlord will be responsible for all permitting, site and infrastructure preparation work, and construction of the shell and core of the building and the quality control laboratory portion of the building. The Company will be responsible for completion of the remaining tenant fit out work. The landlord will be responsible for the cost of the base building work and will contribute approximately \$6.0 million towards the tenant fit out work, with the Company responsible for all costs in excess of such amount.

The lease will commence upon substantial completion of the Premises, including the tenant fit out work, estimated to be completed in the second half of calendar year 2022 (the "Commencement Date"), and the rent commencement date will occur simultaneous with the Commencement Date. The initial lease term is 20 years from the Commencement Date (the "Term"). Under the lease, the Company will pay annual base rent during the Term (beginning on the Commencement Date) as set forth below.

<u>Lease Months</u>	
1-12	\$ —
13-18	\$ 637,500
19-30	\$ 1,253,750

Base rent shall increase 1.5% each lease year (12-month period) thereafter commencing in month 31 for the remainder of the Term.

[Table of Contents](#)

During the Term, the Company will also pay its share of operating expenses, taxes and any other expenses payable under the lease. The lease includes three extension options of five years each at an annual base rent rate of the greater of a 1.5% increase from the previous year or pursuant to the increase in the Consumer Price Index for the applicable prior year.

In addition, the lease provides the Company with a one-time option to terminate the lease after year 16.5 by providing notice of such termination prior to the end of the 15th lease year and paying a termination fee of \$3.3 million. The Company has the further option to expand the facility to double the initial square footage during the first five years of the Term.

The lease also includes customary representations, warranties and covenants on behalf of the parties and provides for certain customary mutual indemnities. No security deposit is required upon lease execution, provided that the landlord reserves the right to institute a security deposit if the Company defaults in its lease obligations.

4. Investments

Cash in excess of immediate requirements is invested in accordance with the Company's investment policy, which primarily seeks to maintain adequate liquidity and preserve capital. At both June 30, 2021 and 2020, the Company's investments consisted entirely of held-to-maturity debt securities that were due in one year or less from the respective balance sheet dates.

The Company's debt securities that were classified as held-to-maturity are summarized below.

<u>In thousands</u>	<u>June 30,</u>	
	<u>2021</u>	<u>2020</u>
U.S. Treasury securities:		
Amortized cost	\$2,000	\$41,995
Gross unrealized gains	—	54
Gross unrealized losses	—	(3)
Fair value of investments	<u>\$2,000</u>	<u>\$42,046</u>

At the end of each reporting period, the Company evaluates its securities for impairment, if and when, the fair value of an investment is less than its amortized cost. In the event that the fair value of an investment is less than its amortized cost, the Company will evaluate the underlying credit quality and credit ratings of the issuer. Specifically, management believes that the unrealized losses at June 30, 2020 that are disclosed in the above table were primarily due to interest rate changes rather than unfavorable changes in the credit ratings associated with those securities. The Company does not intend to sell any of its investments before recovering its amortized cost, which may be at maturity.

5. Fair Value of Financial Instruments and Investments

Certain assets and liabilities are measured at fair value in the Company's financial statements or have fair values disclosed in these Notes to Financial Statements. Such assets and liabilities are classified into one of the three levels of a fair value 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. The methods and assumptions described below were used to estimate fair values and determine the fair value hierarchy classification of each class of financial instrument held by the Company.

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

[Table of Contents](#)

Debt securities—held-to-maturity. The Company's investments in debt securities classified as held-to-maturity consist of U.S. Treasury securities that are valued using quoted market prices. Valuation adjustments are not applied.

The fair value hierarchy table below provides information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis or disclosed at fair value in these Notes to Financial Statements.

<u>In thousands</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total Fair Value</u>
June 30, 2021				
Cash and cash equivalents	\$105,052	\$ —	\$ —	\$105,052
Held-to-maturity investment (U.S. Treasury security)	2,000	—	—	2,000
Total assets	<u>\$107,052</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$107,052</u>
June 30, 2020				
Cash and cash equivalents	\$ 38,463	\$ —	\$ —	\$ 38,463
Held-to-maturity investments (U.S. Treasury securities)	42,046	—	—	42,046
Total assets	<u>\$ 80,509</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 80,509</u>

The Company's financial instruments also include its variable-rate borrowing under a debt agreement that is described at Note 8 in these Notes to Financial Statements. Management believes that the carrying amount of such debt (i.e., \$19.9 million and \$9.7 million at June 30, 2021 and 2020, respectively) reasonably approximates its fair value on those dates because the rate of interest on such borrowing reflects current market rates of interest for similar instruments with comparable maturities and risk profiles. This assessment primarily uses Level 2 inputs under the fair value hierarchy.

6. Property and Equipment, Net

The table below summarizes the Company's property and equipment, net as of the dates indicated.

<u>In thousands</u>	<u>June 30,</u>	
	<u>2021</u>	<u>2020</u>
Laboratory equipment	\$ 5,822	\$ 4,251
Leasehold improvements	3,881	3,881
Office equipment	845	837
Property and equipment, gross	10,548	8,969
Accumulated depreciation and amortization	(5,890)	(4,658)
Property and equipment, net	<u>\$ 4,658</u>	<u>\$ 4,311</u>

All of the Company's property and equipment is located in the United States. The Company recognized depreciation and amortization expense of \$1.3 million and \$1.2 million during the years ended June 30, 2021 and 2020, respectively, including \$0.5 million of amortization expense for leasehold improvements during each year.

[Table of Contents](#)

7. Intangible Assets, Net

The tables below summarize the Company's intangible assets, net as of the dates indicated.

<u>In thousands</u>	<u>June 30, 2021</u>		
	<u>Cost</u>	<u>Accumulated Amortization</u>	<u>Intangible Assets, net</u>
Patents	\$3,001	\$ (1,809)	\$ 1,192
Licenses	289	(229)	60
Other	66	(31)	35
Totals	<u>\$3,356</u>	<u>\$ (2,069)</u>	<u>\$ 1,287</u>

<u>In thousands</u>	<u>June 30, 2020</u>		
	<u>Cost</u>	<u>Accumulated Amortization</u>	<u>Intangible Assets, net</u>
Patents	\$2,637	\$ (1,649)	\$ 988
Licenses	289	(214)	75
Other	59	(24)	35
Totals	<u>\$2,985</u>	<u>\$ (1,887)</u>	<u>\$ 1,098</u>

The Company recognized amortization expense related to intangible assets of \$182,000 and \$170,000 during the years ended June 30, 2021 and 2020, respectively.

Estimated amortization expense for the years ending June 30 for the next five years and thereafter is summarized in the table below.

<u>In thousands</u>	
2022	\$ 190
2023	104
2024	70
2025	60
2026	60
Thereafter	780
	<u>\$1,264</u>

8. Debt

On June 30, 2020, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with several banks and other financial institutions or entities from time to time parties to the Loan Agreement (collectively, referred to as the "Lenders") and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and the Lenders (in such capacity, the "Agent").

The Loan Agreement provides for a term loan in an aggregate principal amount of up to \$25.0 million to be delivered in multiple tranches (the "Term Loan"). The first tranche consisted of an initial term loan advance of \$10.0 million on June 30, 2020 (the "Closing Date"). Thereafter, subject to the Lenders' investment committee's sole discretion, the Company had the right to request that the Lenders make additional term loan advances in an aggregate principal amount of up to \$15.0 million prior to January 1, 2022.

Effective May 13, 2021, the Loan Agreement was amended (the "Amendment") whereby, among other things, (i) a second term loan advance of \$10.0 million was authorized by the Lenders and advanced to the Company on such date and (ii) the period of time to request additional discretionary term loan advances of up to \$5.0 million

[Table of Contents](#)

was changed to be prior to April 1, 2022 or, if certain conditions are satisfied, then prior to January 1, 2023. However, there can be no assurances that any additional term loan advances will be funded by the Lenders in the future.

In connection with entering into the Loan Agreement, the Company paid an aggregate of \$165,000 to the Lenders for an initial facility charge, due diligence fees and reimbursement of legal expenses. Such amount was recorded as either a debt discount or a deferred financing fee, both of which reduce the carrying value of the outstanding Term Loan. Additionally, the Company paid \$150,000 of fees to the Lenders to effectuate the Amendment and such amount was recognized as a debt discount.

As a result of the Amendment, the Term Loan now matures on April 1, 2024; provided that, in the event that the Company meets certain conditions, including achievement of performance milestones, then the Term Loan matures on July 1, 2024. The date on which the Term Loan matures (i.e., either April 1, 2024 or July 1, 2024) is referred to as the “Term Loan Maturity Date.”

The Term Loan bears interest at a rate equal to the greater of either: (i) the sum of (x) the prime rate as reported in *The Wall Street Journal* minus 3.25% and (y) 9.75%; or (ii) 9.75%. As a result of the Amendment, borrowings under the Loan Agreement are being repaid in monthly interest-only payments from the Closing Date through March 31, 2022, with the possibility to extend the interest-only period to December 31, 2022 upon the Company’s achievement of certain performance milestones. After the interest-only period ends, borrowings under the Loan Agreement will be repaid in equal monthly installments of principal and interest until the Term Loan Maturity Date.

The Company may, at its option, prepay all, but not less than all, of the outstanding Term Loan balance plus all accrued and unpaid interest thereon, together with a prepayment charge equal to: (i) 2.0% of the amount so prepaid if such prepayment occurs after 12 months but prior to 24 months from the Closing Date; (ii) 1.0% of the amount so prepaid if such prepayment occurs after 24 months but prior to 36 months from the Closing Date; and (iii) zero percent of the amount so prepaid if such prepayment occurs three years or more after the Closing Date.

On the earliest to occur of the (i) Term Loan Maturity Date, (ii) date that the Company prepays the outstanding secured payment obligations in full or (iii) date that the secured payment obligations become due and payable, the Company will pay (in addition to any prepayment charge) an end of term charge of 6.95% of the aggregate term loan advances. End of term charges are recorded as discounts to the carrying value of the outstanding Term Loan each time a term loan advance is received.

The Term Loan is secured by substantially all of the Company’s assets, other than its intellectual property. However, the Company has agreed to not pledge or secure its intellectual property to others. In connection with granting security interests in its cash and cash equivalents and investments, the Company was required to enter into certain account control agreements with the Agent regarding future control of the underlying bank and securities accounts. Pursuant to the terms of the account control agreements, the Company’s control of those accounts will not be affected unless the Agent elects to obtain unilateral control by declaring that an event of default under the Loan Agreement has occurred and is continuing.

During the term of the Loan Agreement, the Lenders or their assignee or nominee have the right to participate in any equity offerings by the Company that are broadly marketed to multiple investors, in an amount up to \$2.0 million, on the same terms, conditions and pricing afforded to other investors participating in any such offering.

The Loan Agreement contains customary representations, warranties and both affirmative and negative covenants. The Loan Agreement requires that after July 1, 2021 and upon term loan advances exceeding \$10.0 million, the Company will maintain minimum unrestricted cash of at least \$5.0 million, plus the amount of the Company’s accounts payable not paid after the 120th day following a vendor’s invoice date, until the

[Table of Contents](#)

Company has a market capitalization equal to or greater than \$300.0 million. The negative covenants in the Loan Agreement include, among other things, agreements by the Company limiting additional indebtedness, liens (including a negative pledge on intellectual property and other assets), guaranties, mergers and consolidations, substantial asset sales, investments and loans, certain corporate changes, transactions with affiliates, and fundamental changes. Additionally, the Company may not declare or pay any cash dividends during the term of the Loan Agreement. The Company was in full compliance with all covenants of the Loan Agreement as of June 30, 2021.

The Loan Agreement provides for events of default customary for term loans of this type, including, but not limited to, non-payment of interest or principal when due, breaches or defaults in the performance of covenants, insolvency, bankruptcy and the occurrence of an event that could have a material adverse effect on the Company. Upon the occurrence of an event of default that has not otherwise been remedied by the Company, the Agent may: (i) accelerate payment of all or any part of the secured obligations, impose a prepayment charge and terminate the Lenders' commitments under the Loan Agreement; (ii) sign and file in the Company's name any notices, assignment or agreements necessary to perfect payment; or (iii) notify any of the Company's debtors to make payment directly to such agent.

As of June 30, 2021 and 2020, the carrying value of the Term Loan on the Company's balance sheets was \$19.9 million and \$9.7 million, respectively, which consisted of the outstanding principal of such loan and the end of term charge accrual, less unamortized debt discounts and deferred financing fees of \$1.5 million and \$1.0 million, respectively, that are being amortized to interest expense over the duration of the Loan Agreement using an effective interest method. As of both June 30, 2021 and 2020, the variable contractual interest rate on the Term Loan was 9.75% per annum. As a result of the Amendment, beginning on May 13, 2021, the effective interest rate on the Term Loan is now 13.26%. Prior to the consummation of the Amendment, the effective rate on the Term Loan was 13.53%.

Future minimum principal payments of the outstanding Term Loan balance, excluding the end of term charges, are as follows: \$2.2 million in the year ending June 30, 2022; \$9.3 million in the year ending June 30, 2023; and \$8.5 million in the year ending June 30, 2024.

9. Collaboration Agreements, Revenue and Contract Liabilities

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. 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.

Under the agreement, AGTC made an initial \$2.0 million payment to Bionic Sight for an equity interest in that company. This initial investment represented an equity interest of approximately 5% in Bionic Sight. In addition to the initial investment, AGTC contributed ongoing research and development support costs through additional payments and other in-kind contributions (the "AGTC Ongoing R&D Support"). The AGTC Ongoing R&D Support payments and in-kind contributions were made over time and continued until December 2019, the month that Bionic Sight received both Investigational New Drug ("IND") clearance from the United States Food and Drug Administration (the "FDA") and receipt of written approval from an internal review board to conduct clinical trials at one clinical site for that product candidate (the "IND Trigger"). Prior to the achievement of the

IND Trigger, the Company had incurred approximately \$2.2 million of research and development support costs and in-kind contributions, which were reported as research and development expenses in the Company's financial statements.

Upon achievement of the IND Trigger, AGTC was (i) entitled to receive additional equity in Bionic Sight, based on a valuation that was in place at the beginning of the agreement, for the AGTC Ongoing R&D Support payments and in-kind contributions, and (ii) obligated to purchase additional equity in Bionic Sight for \$4.0 million based on certain pre-determined valuation criteria. The Company made the \$4.0 million payment to Bionic Sight in January 2020 and received the incremental shares during March 2020 upon the execution of a subscription agreement between the parties. The Company's equity interest in Bionic Sight increased to approximately 15.5% upon the issuance of the additional shares. AGTC is not obligated to purchase additional equity in Bionic Sight or make any additional in-kind contributions under the agreement.

The Company concluded that the AGTC Ongoing R&D Support was within the scope of Topic 606 because the services rendered represented a distinct service delivered to a counterparty that meets the definition of a customer. The Company further concluded that those services represented one combined performance obligation. Because the consideration that the Company was entitled to was contingent upon achievement of the IND Trigger, that consideration was determined to be variable and the amount was fully constrained until achievement of the IND Trigger. As a result of achieving the IND Trigger, the Company recognized \$2.2 million of collaboration revenue during the year ended June 30, 2020. With regard to the obligation to purchase additional equity in Bionic Sight, the Company concluded at contract inception that such option represented 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 the inception of the Bionic Sight agreement and determined the value to be *de minimis*. As the forward contract did not have a readily determinable fair value, the Company elected to use a measurement alternative for all subsequent measurements of the financial instrument. Under such measurement alternative, the forward contract was remeasured at fair value when observable transactions involving the underlying equity securities or impairment of those securities occurred. As noted above, the Company made a supplemental investment of \$4.0 million in Bionic Sight and the underlying equity interests were delivered in March 2020, resulting in the settlement of the forward contract at that time. From the inception of the Bionic Sight arrangement and through the settlement date in March 2020, no observable transactions or impairment involving the underlying equity securities had occurred.

The Company recorded its initial investment in Bionic Sight using the equity method of accounting for investments. Upon receipt of additional shares in March 2020, the Company concluded that equity method accounting was still appropriate. Because the conversion price used to calculate the number of additional shares that the Company was to receive was based on contractually fixed valuation amounts, the Company assessed whether there was a difference between the cost of the investment and the underlying equity in the net assets of Bionic Sight. The Company concluded that any such difference was not material to the Company's financial statements and, therefore, recorded its additional investment in Bionic Sight at \$6.2 million during March 2020.

Otonomy, Inc.

During October 2019, the Company entered into a strategic collaboration agreement with Otonomy, Inc. ("Otonomy") to co-develop and co-commercialize an adeno-associated virus-based gene therapy to restore hearing in patients with sensorineural hearing loss caused by a mutation in the gap junction protein beta 2 gene ("GJB2") – the most common cause of congenital hearing loss. Mutations in GJB2 account for approximately 30% of all genetic hearing loss cases. Patients with this mutation can have severe-to-profound deafness in both ears that is identified in screening tests routinely performed on newborns. Under the collaboration agreement, the parties began equally sharing the program costs and proceeds in January 2020 and can include additional genetic hearing loss targets in the future.

The Company concluded that the Otonomy collaboration agreement is within the scope of Topic 808, which defines collaborative arrangements and addresses the presentation of transactions between the parties in an

[Table of Contents](#)

entity's statement of operations and the related disclosures. However, Topic 808 does not provide guidance on the recognition of consideration exchanged or accounting for the obligations that may arise between the parties. The Company concluded that ASC Topic 730, *Research and Development*, should be applied by analogy to payments between the parties during the development activities. As such, payments made to or received from Otonomy for development activities are recorded as research and development expenses. For the years ended June 30, 2021 and 2020, settlement activity between the parties under the Otonomy agreement had an immaterial effect on the Company's research and development expenses.

SparingVision SAS

Effective April 13, 2021, the Company entered into an agreement that licenses certain of its proprietary technology to SparingVision SAS, a genomic medicine company developing vision-saving treatments for ocular diseases. Under the terms of the agreement, SparingVision SAS received nonexclusive rights to the Company's proprietary cone-specific promoter technology for use in the development of two non-competing products with an opportunity to obtain rights to use the promoter for one additional product in the future. The Company received an upfront license fee payment and will be eligible to receive milestone payments for successful clinical development and royalties on future sales on a per product basis (if any products are approved). The Company recognized the upfront payment of \$500,000 as license fee revenue in accordance with the provisions of Topic 606. Milestone and royalty revenue is contingent on future events and, therefore, will be fully constrained until such events occur, if ever.

Contract Liabilities

As of June 30, 2021 and 2020, accrued and other liabilities on the Company's balance sheets included \$374,000 and \$149,000, respectively, of deferred revenue. The account balance at June 30, 2021 included \$225,000 that was billed to a customer but remained uncollected as of such date. Management is unable to estimate when the Company will satisfy the performance obligations pertaining to its deferred revenue at June 30, 2021.

10. Share-Based Compensation Plans

The Company uses stock options, performance service awards, restricted stock awards and restricted stock units to provide long-term incentives to its employees, nonemployee 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, as such, all of the 128,571 shares previously authorized under that plan remain available for issuance. As of June 30, 2021, the total number of shares available for issuance under the 2013 Equity and Incentive Plan was 1,233,889. See Note 14 in these Notes to Financial Statements for an increase in the shares available for issuance under such plan subsequent to June 30, 2021. Currently, the Company issues new shares of common stock upon the exercise, release or settlement of share-based compensation awards.

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 a restricted stock unit award; (ii) the date on which a 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 on the date of grant; (iv) the vesting term; and (v) the duration of an option (which, in the case of incentive stock options, may not exceed ten years). Employee stock options typically vest over a three- or four-year period.

[Table of Contents](#)

Stock Options

Information about the Company's stock options that do not have performance conditions is provided below.

	Year Ended June 30,			
	2021		2020	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
(In thousands, except per share amounts)				
Outstanding at the beginning of the year	3,846	\$ 7.82	3,585	\$ 9.19
Granted	1,456	5.15	1,219	3.28
Exercised	(204)	3.94	(100)	3.94
Forfeited	(794)	4.44	(474)	3.82
Expired	(118)	8.99	(384)	12.06
Outstanding at the end of the year	4,186	\$ 7.69	3,846	\$ 7.82
Exercisable at the end of the year	2,866		2,418	
Weighted average fair value of options granted during the year	\$ 3.67		\$ 2.10	

The intrinsic value of stock options exercised during each of the years ended June 30, 2021 and 2020 was \$0.3 million. The total fair value of stock options that vested during the years ended June 30, 2021 and 2020 was \$2.3 million and \$2.8 million, respectively.

The table below summarizes information about stock options (i) vested and expected to vest and (ii) exercisable as of June 30, 2021.

	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Contractual Life (in years)
(In thousands, except per share amounts)				
Vested and expected to vest	4,012	\$ 7.81	\$ 979	5.60
Exercisable	2,866	9.09	776	4.38

The aggregate intrinsic values presented in the above table were calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock on June 30, 2021 for the options that were in the money.

In addition to the stock option activity described above, the Company also granted 100,000 performance-based stock options to a senior officer during the year ended June 30, 2020 with an exercise price of \$3.91. That award: (i) was issued under the 2013 Equity and Incentive Plan; (ii) has a term of ten years; and (iii) includes six separate tranches with performance criteria that will each vest 25% upon their achievement, with the remaining 75% of the tranche vesting on a monthly basis over a period of three years subsequent to achieving the underlying performance objective (assuming continued service by the awardee). Each tranche represents one-sixth of the total award. If any of the performance criteria are not satisfied, that corresponding tranche will be forfeited. As of June 30, 2021, one of the six performance criteria has been met and one criterion will likely never be met. The Company used a Black-Scholes stock option pricing model to estimate the grant date fair value of each option to be \$2.58; however, determining the appropriate periodic share-based compensation expense for this award requires management to estimate the likelihood of the achievement of the performance targets.

Subsequent to June 30, 2021, the Company granted approximately 1.5 million new service-only stock options to its employees, with each such option having an exercise price equal to the closing price of the Company's common stock on the date of grant.

[Table of Contents](#)

Restricted Stock Awards and Restricted Stock Units

The Company granted 2,000 restricted stock awards to a senior officer during the year ended June 30, 2020. Those awards were fully vested on the date of grant. The weighted average market price of such restricted stock awards on the date of grant was \$3.75.

During August 2019, 175,500 restricted stock units, which included a market-based vesting condition related to the trading price of the Company's common stock, were granted to certain employees under the 2013 Equity and Incentive Plan with a weighted average grant date fair value of \$2.56. The market condition embedded in the award was met during the year ended June 30, 2020. On August 15, 2021 and 2020, 54,500 and 76,500 restricted stock units vested and the underlying shares were issued to the grantees. A total of 44,500 restricted stock units were forfeited through August 15, 2021 and, subsequent to that date, no restricted stock units with market-based vesting conditions remain outstanding. The fair value of each restricted stock unit awarded was estimated on the grant date using a Monte Carlo simulation pricing model, which incorporated the probability of satisfying the related market-based vesting condition.

During May and June 2021, the Company granted 577,500 restricted stock units to certain employees under the 2013 Equity and Incentive Plan with a weighted average grant date fair value of \$4.16. Those awards generally vest in equal amounts on each of the first and second anniversaries of the date of grant, assuming continuing service by the grantee. As of June 30, 2021, 4,000 restricted stock units have been forfeited. The fair value of each restricted stock unit awarded was determined based on the market value of the Company's common stock on the date of grant and the related expense is being recognized using a graded vesting schedule that is aligned with the grantees' vesting dates.

General

Share-based compensation expense pertaining to stock options awarded to employees, nonemployee directors and consultants totaled \$2.5 million for each of the years ended June 30, 2021 and 2020. Share-based compensation expense pertaining to restricted stock awards and restricted stock units awarded to employees and consultants totaled \$0.2 million and \$0.5 million for the years ended June 30, 2021 and 2020, respectively.

The table below presents the allocation of total share-based expense for the years indicated.

<u>In thousands</u>	<u>Year Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>
Research and development	\$ 1,110	\$ 1,451
General and administrative and other	1,568	1,547
Totals	<u>\$ 2,678</u>	<u>\$ 2,998</u>

The fair value of each stock option granted is estimated on the date of grant using a Black-Scholes stock option pricing model. Below are the assumptions that were used when estimating fair value for the years indicated.

<u>Assumption</u>	<u>Year Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>
Dividend yield	0.00%	0.00%
Expected term	6.00 to 6.25 years	6.00 to 6.25 years
Risk-free interest rate	0.30% to 1.08%	0.42% to 1.90%
Expected volatility	82.60%	71.20%

The dividend yield assumes that the Company will not declare dividends over the lives of the options. Since adopting ASC Topic 718, *Compensation—Stock Compensation*, the Company has been unable to use historical employee exercise and option expiration data to estimate the expected term for the Black-Scholes grant-date

[Table of Contents](#)

valuation. Therefore, the Company has utilized the “simplified” method, as prescribed by SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to estimate, on a formula basis, the expected term of the Company’s stock options that are 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 with a maturity similar to the expected life of the award. Expected volatility is based on the historical volatility of the Company’s stock price. 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 Company’s Statements of Operations does not reflect tax-related effects due to the Company’s historical and anticipated operating losses and offsetting changes in its valuation allowance that fully reserve against any deferred tax assets.

Unrecognized share-based compensation cost related to non-vested employee stock options that do not have performance conditions totaled \$3.9 million as of June 30, 2021. Such compensation cost is expected to be expensed over a weighted average period of approximately 2.9 years. As of June 30, 2021, unrecognized share-based compensation cost for the Company’s service-only restricted stock units was \$2.2 million and such costs will be expensed over approximately 1.9 years. As of June 30, 2021, the total unrecognized share-based compensation cost pertaining to the Company’s performance-based stock options and market-based restricted stock units was immaterial.

11. Income Taxes

The table below summarizes the Company’s provision for (benefit from) income taxes for the years indicated. The income tax benefit during the year ended June 30, 2021 was primarily due to the reversal of uncertain tax position liabilities, including the related interest and penalties. During the year ended June 30, 2020, income tax expense was primarily due to estimated interest and penalties on then-existing uncertain tax positions. The Company’s uncertain tax positions and related liabilities are discussed below.

<u>In thousands</u>	<u>Year Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>
Current tax expense (benefit):		
Federal	\$ —	\$ —
State	(2,108)	83
Total current tax expense (benefit)	(2,108)	83
Deferred tax expense (benefit):		
Federal	—	—
State	—	—
Total deferred tax expense (benefit)	—	—
Provision for (benefit from) income taxes	<u>\$ (2,108)</u>	<u>\$ 83</u>

[Table of Contents](#)

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

In thousands	June 30,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 44,141	\$ 30,077
Tax credit carryforwards	35,563	29,557
Share-based compensation	3,470	2,284
Lease liabilities—operating	1,133	1,314
Accruals and other	720	1,360
Depreciation and amortization	—	317
Gross deferred tax assets	85,027	64,909
Deferred tax asset valuation allowance	(83,980)	(64,032)
Total deferred tax assets, net of valuation allowance	1,047	877
Deferred tax liabilities:		
Right-of-use assets—operating leases	(791)	(877)
Depreciation and amortization	(256)	—
Total deferred tax liabilities	(1,047)	(877)
Net deferred tax asset (liability)	\$ —	\$ —

As of June 30, 2021, the Company had federal and state net operating losses of approximately \$24.8 million and \$8.1 million (tax effected), respectively, that may be applied against future taxable income and expire in various years ranging from 2022 to 2040 and federal net operating losses of \$155.1 million that do not expire. As of June 30, 2021, the Company also had federal and state research and development tax credits of approximately \$34.0 million and \$2.0 million, respectively, which may provide future tax benefits, and expire in various years ranging from 2027 to 2040.

The Company evaluated the positive and negative evidence bearing on the realizability of its deferred tax assets. Based on its history of operating losses, the Company concluded that, as of both June 30, 2021 and 2020, it was more likely than not that the benefits of its deferred tax assets would 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 and tax credit carryforwards, computed based on statutory federal and state rates, were completely offset by valuation allowances on those dates. The Company's valuation allowances increased by \$19.9 million and \$14.3 million during the years ended June 30, 2021 and 2020, respectively, primarily due to net increases in federal net operating losses.

[Table of Contents](#)

The items comprising the differences between the U.S. federal statutory income tax rate and the Company's effective tax rate on the loss before provision for (benefit from) income taxes for the years indicated are summarized in the table below.

	Year Ended June 30,	
	2021	2020
Federal income tax benefit at statutory rate	21%	21%
State income taxes, net of federal benefit	3	4
Permanent differences-incentive share-based compensation	—	(1)
Research and development tax credits	8	8
Reversal of the liability for uncertain tax positions	4	—
Other	1	—
Change in valuation allowance	(33)	(32)
Effective income tax rate	4%	0%

Under the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), the Company's net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interests of significant stockholders over a three-year period in excess of 50%, as defined in Sections 382 and 383 of the Code, respectively, as well as similar state provisions. This circumstance could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of any annual limitation would be 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 its common stock, which have resulted in a change in control as defined by Sections 382 and 383 of the Code. Subsequent ownership changes may further affect such limitation in future years. A full valuation allowance has been provided against the Company's net operating loss and tax credit carryforwards and, if an adjustment were to be required, such an adjustment would reduce both the gross deferred tax asset established for the net operating loss and tax credit carryforwards and the valuation allowance.

Through the year ended June 30, 2021, the Company generated research and development tax credits but has not conducted a study to document the qualified activities. Such a study may result in an adjustment to the Company's research and development tax credit carryforwards; however, until a study is completed and an adjustment, if any, is known, no amounts are being presented as an uncertain tax position as of June 30, 2021 or 2020. A full valuation allowance has been provided against the Company's research and development tax credit carryforwards and, if an adjustment were to be required, such an adjustment would reduce both the gross deferred tax asset established for the research and development tax credit carryforwards and the valuation allowance.

At both June 30, 2021 and 2020, the Company recorded deferred tax assets for certain awards under its share-based compensation plans that are expected to generate tax deductions in the future. Such deductions will be impacted by, among other things, the market price of the Company's common stock, expiration dates of the underlying awards and discretionary actions taken by the awardees. As such, it is currently unknown if the Company will realize some or all of the benefits pertaining to the affected deferred tax assets. A full valuation allowance has been provided against the share-based compensation plan deferred tax assets and, if an adjustment were to be required, such an adjustment would reduce both the gross deferred tax asset established therefor and the valuation allowance.

The Company files income tax returns in the United States and in various individual states. The Company's federal and state returns are generally subject to tax examination for the tax years ended June 30, 2018 through June 30, 2021. To the extent that the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state authorities if such attributes are utilized by the Company in a future period.

[Table of Contents](#)

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. The table below is a reconciliation of the beginning and ending amounts of the Company's gross unrecognized tax benefits for certain state tax matters, excluding interest and penalties, during the years indicated.

<u>In thousands</u>	<u>Year Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>
Balance at the beginning of the year	\$ 1,611	\$1,611
Reduction for expiration of statutes of limitations	(1,611)	—
Balance at the end of the year	<u>\$ —</u>	<u>\$1,611</u>

In addition to the amounts included in the above table, aggregate interest and penalties on uncertain tax positions of \$507,000 were recorded by the Company on June 30, 2020, including \$83,000 that was recognized as income tax expense during the year then ended. The Company continued to accrue interest and penalties on its uncertain tax positions through March 31, 2021; however, in April 2021, the recording of interest and penalties was discontinued because the statutes of limitations pertaining to the matters that gave rise to the Company's uncertain tax positions expired with no payments being required by the Company and no action taken by any tax authority. In addition, the entire then-existing uncertain tax position liability, including accrued interest and penalties, was reversed, resulting in an income tax benefit of \$2.2 million during the year ended June 30, 2021.

As of June 30, 2020, the Company's liability for uncertain tax positions was included in other long-term liabilities on its balance sheet.

12. Accrued and Other Liabilities

Accrued expenses and other liabilities by functional category are summarized in the table below as of the dates indicated.

<u>In thousands</u>	<u>June 30,</u>	
	<u>2021</u>	<u>2020</u>
Research and development and related items	\$ 11,045	\$ 6,715
Compensation	2,890	3,298
General and administrative and other	565	489
Total accrued and other liabilities	<u>\$ 14,500</u>	<u>\$ 10,502</u>

As of June 30, 2021, federal payroll taxes totaling \$0.4 million have been deferred by the Company pursuant to the Coronavirus Aid, Relief, and Economic Security Act and such amount is projected to be paid in equal installments on each of December 31, 2021 and 2022. This liability is included in accrued and other liabilities and other long-term liabilities on the Company's balance sheets. At June 30, 2020, the corresponding liability was \$177,000 and was included in other long-term liabilities.

13. Defined Contribution Plan

The Company sponsors an employee 401(k) salary deferral plan (the "401(k) Plan") that covers substantially all of its employees and is administered through a 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 eligible salary. The Company's matching contribution expense totaled \$381,000 and \$324,000 during the years ended June 30, 2021 and 2020, respectively.

14. Stockholders' Equity and Related Matters

February 2021 Public Offering of AGTC Equity Securities

On February 1, 2021, the Company closed an underwritten public offering of 16,741,573 shares of its common stock, together with accompanying warrants to purchase 8,370,786 shares of its common stock. The combined offering price of each share of common stock and accompanying warrant was \$4.45, generating gross proceeds of \$74.5 million, before deducting underwriting discounts, commissions and other offering expenses payable by the Company, which totaled \$5.2 million.

The warrants have an exercise price of \$6.00 per share (subject to certain adjustments), are immediately exercisable and expire on February 1, 2026. The warrants are legally detachable from the common stock that was issued on February 1, 2021 and are separately exercisable by the warrant holders. While the warrants are outstanding (but unexercised), the warrant holders will participate in any dividend or other distribution of the Company's assets to its common stockholders by way of return of capital or otherwise.

The warrants have been evaluated to determine the appropriate accounting and classification pursuant to ASC Topic 480, *Distinguishing Liabilities from Equity*, and ASC Topic 815, *Derivatives and Hedging*. Generally, freestanding warrants should be classified as (i) liabilities if the warrant terms allow settlement of the warrant exercise in cash and (ii) equity if the warrant terms only allow settlement in shares of common stock. Based on the terms of the Company's warrants, management concluded that they should be classified as equity with no subsequent remeasurement as long as the underlying warrant agreements are not modified or amended.

February 2020 Public Offering of AGTC Common Stock

On February 11, 2020, the Company closed an underwritten public offering of 6.5 million shares of its common stock at \$5.00 per share, generating gross proceeds of \$32.5 million, before deducting underwriting discounts, commissions and other offering expenses payable by the Company. Additionally, the underwriters exercised their option to purchase an additional 975,000 shares of common stock to cover over-allotments. Such transaction closed on February 13, 2020 and generated additional gross proceeds of \$4.9 million.

At-The-Market Offering Program

On April 2, 2021, the Company entered into a Controlled Equity OfferingSM Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") as sales agent to sell shares of the Company's common stock, from time to time, through an "at-the-market offering" program having an aggregate offering price of up to \$50.0 million. However, the Company has not sold any shares under the Sales Agreement and is not obligated to do so in the future. Cantor will be entitled to aggregate compensation equal to 3.0% of the gross sales price of the shares sold through it pursuant to the Sales Agreement.

Shares Reserved for Future Issuance

As of June 30, 2021, there were 150 million shares of \$0.001 par value common stock and five million shares of \$0.001 par value preferred stock that were authorized to be issued. As of that date, a total of 42,835,170 and 42,794,166 shares of common stock were issued and outstanding, respectively, while none of the preferred shares were issued and outstanding.

[Table of Contents](#)

The table below summarizes the shares of common stock that were reserved for future issuance as of June 30, 2021.

Stock options issued and outstanding, including those with performance milestones	4,286,361
Restricted stock units	628,000
Authorized for future grant under the 2013 Employee Stock Purchase Plan	128,571
Authorized for future grant under the 2013 Equity and Incentive Plan	1,233,889
Warrants	8,370,786
Total shares of common stock reserved for future issuance	<u>14,647,607</u>

The number of shares of common stock available for issuance under the 2013 Equity and Incentive Plan is subject to an automatic annual increase on each July 1 equal to (i) 4% of the number of shares of common stock issued and outstanding on the immediately preceding June 30 or (ii) such lesser number of shares of common stock as determined by the Company's Compensation Committee.

Based on the Company's issued and outstanding common shares on June 30, 2021, the number of shares of common stock reserved and available for issuance under the 2013 Equity and Incentive Plan increased by 1,711,766 shares on July 1, 2021.

15. Commitments and Contingencies

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 other agreements entered into in the ordinary course of business, including those related to licensed technology. At June 30, 2021, the Company had four license agreements with the University of Florida Research Foundation, wherein the Company is responsible for all costs related to the preparation, filing, issuance, prosecution and maintenance of the underlying patents covered in the license agreements. Additionally, the Company is required to pay minimum annual royalty and license maintenance for those licenses until such time when the license is terminated by either expiration of the underlying patents or voluntary termination by either party per the agreement.

The 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 because 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, as such, they may not be achieved. The Company may terminate its license agreements with zero to ninety days written notice depending on 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 connection with any U.S. patent or copyright or other intellectual property infringement claim by any third party.

with respect to the Company's products. The terms of these indemnification agreements are 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.

COVID-19 Pandemic

On January 30, 2020, the World Health Organization (the "WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China ("COVID-19") and the risks to the international community as the virus spread globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic based on the rapid increase in exposure globally. National, state and local governments in affected regions have implemented, and are likely to continue to implement, safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter in place orders and shutdowns, business closures, cancellations of public gatherings and other measures. Organizations and individuals are taking additional steps to avoid or reduce infection, including limiting travel and staying home from work.

The worldwide spread of COVID-19 led to a global slowdown of economic activity and decreased demand for a broad variety of goods and services, while also disrupting sales channels and marketing activities and precipitating many corporate bankruptcy filings. As a result of the COVID-19 outbreak, the Company has experienced delays in enrollment of pediatric patients in the dose escalation portions of certain of its clinical trials for achromatopsia. Additionally, the latest surge in cases due to a COVID-19 variant has created new challenges for the Company to schedule patients for screening at some sites due to capacity and bandwidth limitations, which has impacted enrollment in at least one of the Company's clinical trials. The Company could also experience delays resulting from critical follow-up visits required under clinical trial protocols, which could increase the cost of those trials and also impact their expected timelines. Management's ability to fully interpret the trial outcomes and the ability of certain lab-based employees to perform their jobs due to stay-at-home orders or other restrictions related to COVID-19 could also result in delays and increase the Company's operating expenses. Furthermore, third-party vendors, such as raw material suppliers and contracted manufacturing, testing or research organizations, could also be impacted by COVID-19, which could result in unavoidable delays and/or increases in the Company's operating costs.

Notwithstanding the rapid development and rollout of certain vaccines, it is unknown: (i) how long the COVID-19 outbreak will continue before the virus, including newly identified strains and variants, is adequately contained; (ii) the severity of the virus; and (iii) the effectiveness of actions to prevent transmission and treat those who have contracted COVID-19. The extent to which the COVID-19 outbreak may impact the Company's financial condition, results of operations or cash flows is uncertain; however, as of the date of these financial statements, management is not aware of any specific event or circumstance that would require the Company to update its estimates or judgments, or adjust the carrying values of its assets or liabilities. Because future events are subject to change, management's best estimates and judgments may require future modification. Therefore, actual results could differ materially from current estimates. Management is closely monitoring the evolving impact of the pandemic on all aspects of the Company's business and periodically evaluates its estimates, which are adjusted prospectively based on such evaluations.

General

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.

16. Quarterly Financial Information (Unaudited)

The tables below summarize certain quarterly information of the Company for the years ended June 30, 2021 and 2020.

<u>In thousands, except per share data</u>	<u>Fiscal Year 2021 by Quarter</u>			
	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>
Revenue	\$ —	\$ —	\$ —	\$ 500
Loss from operations	(15,062)	(15,115)	(14,488)	(13,786)
Net loss	(15,380)	(15,462)	(14,851)	(12,136)
Net loss per common share, basic	\$ (0.60)	\$ (0.60)	\$ (0.40)	\$ (0.28)
Net loss per common share, diluted	(0.60)	(0.60)	(0.40)	(0.28)

<u>In thousands, except per share data</u>	<u>Fiscal Year 2020 by Quarter</u>			
	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>
Revenue	\$ —	\$ 2,453	\$ —	\$ —
Loss from operations	(11,990)	(8,930)	(11,442)	(14,580)
Net loss	(11,577)	(8,623)	(11,189)	(14,503)
Net loss per common share, basic	\$ (0.64)	\$ (0.47)	\$ (0.50)	\$ (0.56)
Net loss per common share, diluted	(0.64)	(0.47)	(0.50)	(0.56)

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 our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15e and 15d-15e under the Exchange Act) as of the end of the period covered by this annual report. Based on this evaluation, our principal executive officer and principal financial officer concluded that these disclosure controls and procedures were effective as of June 30, 2021.

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. generally accepted accounting principles (“U.S. GAAP”).

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.

Management assessed the effectiveness of the Company’s internal control over financial reporting as of June 30, 2021. 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, 2021. As a non-accelerated filer, we are not required to comply with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) during the quarter ended June 30, 2021 that have materially affected, or are 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 2021 Annual Meeting of Stockholders (the “Proxy Statement”) 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.

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 table below provides information regarding securities authorized for issuance as of June 30, 2021 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> (a)	<u>Weighted average exercise price of outstanding options, warrants and rights</u> (b)	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u> (c)
Equity compensation plans approved by security holders	4,914,361(1)	\$ 7.60(2)	1,362,460(3)
Equity compensation plans not approved by security holders	—	—	—
Total	<u>4,914,361</u>	<u>\$ 7.60</u>	<u>1,362,460</u>

- (1) Includes 628,000 shares to be issued upon completion of the vesting periods for stock-settled restricted stock unit awards, subject to withholding to satisfy the minimum federal, state, local and/or payroll taxes of any kind required by law to be withheld with regard to the settlement of such awards, as applicable.
- (2) The calculation of the weighted average exercise price does not include outstanding restricted stock unit awards.
- (3) Includes 1,233,889 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 to our 2013 Equity and Incentive Plan by its terms, added July 1 of each 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 DIRECTOR 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 at Item 8 on page 108 of this Annual Report on Form 10-K.
- (2) **Financial Statement Schedules**—Schedules are omitted because they are not applicable or not required.
- (3) **Index to Exhibits.**

<u>Exhibit Number</u>	<u>Description</u>
3.1	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)
3.2	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)
4.1	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))
4.2	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 10-K for the year ended June 30, 2020 (File No. 001-36370))
4.3	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, event date January 28, 2021, filed with the SEC on January 29, 2021 (File No. 001-36370))
10.1	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 ended June 30, 2015 (File No. 001-36370))
10.2 [^]	Amendment to Office Lease Agreement made as of October 1, 2016 by and between Alachua Foundation Park Holding Company, LLC and Applied Genetic Technologies Corporation
10.3 [^]	Second Amendment to Office Lease Agreement made as of November 9, 2017 by and between Alachua Foundation Park Holding Company, LLC and Applied Genetic Technologies Corporation
10.4 [*]	Employment Agreement dated as of August 29, 2019 between Applied Genetic Technologies Corporation and Mark S. Shearman (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended June 30, 2019 (File No. 001-36370))
10.5 [*]	Employment Agreement dated as of August 29, 2019 between Applied Genetic Technologies Corporation and Stephen W. Potter (incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K for the year ended June 30, 2019 (File No. 001-36370))
10.6 [*]	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))
10.7 [†]	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 ended June 30, 2018 (File No. 001-36370))

Table of Contents

<u>Exhibit Number</u>	<u>Description</u>
10.8†	<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 ended June 30, 2018 (File No. 001-36370))</u>
10.9†	<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 ended June 30, 2015 (File No. 001-36370))</u>
10.10†	<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 ended June 30, 2015 (File No. 001-36370))</u>
10.11†	<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 ended June 30, 2015 (File No. 001-36370))</u>
10.12	<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>
10.13†	<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>
10.14†	<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>
10.15†	<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>
10.16†	<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>
10.17†	<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>
10.18†	<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>

Table of Contents

<u>Exhibit Number</u>	<u>Description</u>
10.19†	<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>
10.20†	<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>
10.21†	<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>
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>Form of Incentive Stock Option Agreement under the 2013 Equity and Incentive Plan (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended June 30, 2020 (File No. 001-36370))</u>
10.26*	<u>Form of Non-Statutory Stock Option Agreement under the 2013 Equity and Incentive Plan (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended June 30, 2020 (File No. 001-36370))</u>
10.27*	<u>Form of Restricted Stock Unit Agreement under the 2013 Equity and Incentive Plan (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the year ended June 30, 2020 (File No. 001-36370))</u>
10.28*^	<u>Form of Restricted Stock Unit Agreement (providing for required sale) under the 2013 Equity and Incentive Plan</u>
10.29*	<u>Form of Restricted Stock Agreement under the 2013 Equity and Incentive Plan (incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the year ended June 30, 2020 (File No. 001-36370))</u>
10.30*	<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>
10.31	<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>
10.32	<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>

Table of Contents

<u>Exhibit Number</u>	<u>Description</u>
10.33†	<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>
10.34†	<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>
10.35†	<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>
10.36*	<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 (File No. 001-36370))</u>
10.37	<u>Loan and Security Agreement, dated as of June 30, 2020, by and among Applied Genetic Technologies Corporation, the several banks and other financial institutions or entities from time to time parties to the Loan Agreement (collectively, referred to as the “Lenders”), and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and the Lenders (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed with the SEC on July 2, 2020 (File No. 001-36370))</u>
10.38*	<u>Description of additional monthly payments to Mark S. Shearman effective July 1, 2020 (incorporated by reference to Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q filed with the SEC on November 16, 2020) (File No. 001-36370)</u>
10.39^	<u>First Amendment to Loan and Security Agreement, dated as of May 13, 2021, by and among Applied Genetic Technologies Corporation, the several banks and other financial institutions or entities from time to time parties to the Loan Agreement (collectively, referred to as the “Lenders”), and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and the Lenders</u>
10.40^	<u>Lease, dated as of May 13, 2021, between Alachua Foundation Park Holding Company II, LLC and Applied Genetic Technologies Corporation</u>
10.41*^	<u>First Amendment to Employment Agreement dated as of May 14, 2021 by and between Applied Genetic Technologies Corporation and William A. Sullivan</u>
10.42	<u>Controlled Equity OfferingSM Sales Agreement, dated as of April 2, 2021, by and between Applied Genetic Technologies Corporation and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 to the Company’s Registration Statement on Form S-3 filed with the SEC on April 2, 2021)</u>
10.43*	<u>First Amendment to Employment Agreement by and between Applied Genetic Technologies Corporation and Stephen W. Potter, dated as of June 17, 2021 (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed with the SEC on June 21, 2021 (File No. 001-36370))</u>
23.1^	<u>Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm</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>

Table of Contents

<u>Exhibit Number</u>	<u>Description</u>
31.2 [^]	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
32.1 ^{^^}	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
101.1 [^]	The following interactive Data Files pursuant to Rule 405 of Regulation S-T, formatted in XBRL (eXtensible Business Reporting Language): (a) Balance Sheets as of June 30, 2021 and 2020; (b) Statements of Operations for the years ended June 30, 2021 and 2020; (c) Statements of Stockholders' Equity for the years ended June 30, 2021 and 2020; (d) Statements of Cash Flows for the years ended June 30, 2021 and 2020; and (e) Notes to such Financial Statements.

* Management contract or compensatory plan or arrangement.

[^] Filed herewith.

^{^^} Furnished herewith.

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

ITEM 16. FORM 10-K SUMMARY

None.

AMENDMENT TO OFFICE LEASE AGREEMENT

THIS AMENDMENT TO OFFICE LEASE AGREEMENT (“Amendment”) dated this 20 day of DECEMBER, 2016, but deemed effective as of October 1, 2016, is by and between ALACHUA FOUNDATION PARK HOLDING COMPANY, LLC, a Florida Limited Liability Company (“Landlord”) and APPLIED GENETIC TECHNOLOGIES CORPORATION, a Delaware corporation (“Tenant”).

WITNESSETH:

A. Landlord and Tenant are parties to that certain Standard Form of Lease for Foundation Park dated on or about April 10, 2015 (the “Lease”). Pursuant to the Lease, Tenant leases Suite 101, containing 18,309 square feet net rentable area (the “Premises”), in the building known as “Building #1”, located at 14100 N. W 113th Terrace, Alachua, Florida in the buildings known as Foundation Park (the “Project”). The initial term of the lease commenced on January 1, 2016, and currently expires on December 31, 2025.

B. Landlord and Tenant wish to modify the terms of the Lease to: (i) expand the Premises to include the Expansion Space (as defined in paragraph 64 of the Lease); (ii) grant to Tenant a further option to expand the Premises; and (iii) extend the initial Term of the Lease as more fully set forth herein; and


C. Landlord is willing to agree to such modifications provided that this agreement is entered into, but not otherwise.

NOW, THEREFORE, in consideration of the mutual promises herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, Landlord and Tenant hereby agree as follows:

1. Recitals. All recitals set forth above are true and correct and are incorporated hereby reference.

2. Premises. Effective as of January 1, 2016, the “Premises”, as such term is defined in the Lease, referred to Suite 101, containing 18,309 rentable square feet. Effective October 1, 2016 the “Premises” as such term is defined in the Lease shall hereafter refer to Suite 101, containing 18,309 rentable square feet and Suite 102, containing 3,281 rentable square feet, for a total of 21,509 rentable square feet. Tenant accepts the Premises “AS IS” and acknowledges that Landlord has no obligation to make any repairs or alterations to the Premises as a condition to this amendment.

3. Term. The initial Term of the Lease (which was 10 years) is hereby extended for an additional term of two (2) years, such that the initial term shall be twelve (12) years. The Lease term commenced on January 1, 2016, and shall now expire on December 31, 2027. The foregoing period is referred to hereafter as the “Initial Term”.



Initial



Initial

4. Operating Expenses. The parties acknowledge and agree that the Building (estimated to contain 42,460 rentable square feet) as completed contains 43,180 rentable square feet. During the term, from the period beginning on January 1, 2016 and ending on September 31, 2016, Tenant's pro rata share shall be 42.4%. Beginning on October 1, 2016, as a result of Tenant's lease of the Expansion Space, Tenant's pro rata share shall be increased from 42.4% as estimated in the Lease, to 50%. Tenant shall be responsible for its pro rata share of Operating Expenses and Additional Rent for the Premises in the same manner as set forth in the Lease, except that Tenant's obligation to pay Operating Expenses as to the Expansion Space (containing 3,281 rentable square feet) shall be limited to fifty percent (50%) of such actual Operating Expenses for the period October 1, 2016 through December 31, 2016.

5. Fixed Annual Rent for Premises. Exhibit "D" of the Lease, which sets forth the Fixed Annual Rents for the Premises, is hereby amended and restated in accordance with the revised Exhibit "D" attached hereto, and incorporated into the Lease by reference. Fixed Annual Rents shall be as set forth in such revised Exhibit "D".

6. Tenant Improvements. Tenant acknowledges that it has accepted possession of the Premises, and that all improvements to be made by Landlord as a condition to said delivery and commencement of rents under the Lease have been made.

7. Modifications to Lease. In consideration of the terms of this Amendment, Paragraphs 63 and 64 of the Lease are hereby deleted and of no further force or effect.

8. Tenant Expansion Option. Tenant shall have the one-time right by written notice to Landlord delivered anytime between the date of execution of this Lease and October 1, 2017, to expand the Premises to include the remainder of Foundation Park Building 1, containing approximately 21,590 rentable square feet (the "Second Expansion Space") on the following terms and conditions, which shall be reflected in an amendment to the Lease if such option is exercised:

a. Premises. The Premises shall be the entirety of Building 1, containing 43,180 square feet;

b. Annual Rent. Fixed Annual Rent shall be \$891,660, plus applicable sales taxes, payable in monthly installments as provided by the Lease. In the event of an increase in Interest Rates from the date of execution of this Amendment to the date of execution of an amendment referenced in this section 8, the rent shall increase in order to offset Landlord's additional interest expense. The additional expense shall be computed by calculating the cost of additional interest expenses that would be paid over the term of a traditional loan in the amount of \$6,500,000.00 amortized over 15 years. The total additional interest expense shall be divided monthly over the term of the lease. As used herein, Interest Rate shall be based on the 10 Year US Treasury Rate on December 16th 2016.



Initial



Initial

c. Rent Abatement. Tenant shall receive an abatement of \$222,915.00 (subject to adjustment in the same manner as provided in subsection (b) above) to be applied to the initial obligations for rent payment;

d. Term. The Lease shall be extended so as to have a term of 186 months from the date of the amendment. The Tenant shall be given three (3), five (5) year option periods, exercisable with 6 months prior written notice;

e. Annual Fixed Rents for option terms. Annual Fixed Rent shall increase five percent (5%) over the then applicable rent at each Option term;

f. Build out Allowance. Tenant shall be provided a build out allowance toward the cost of improvements to the Premises of \$1,001,870.00, to be disbursed for the actual cost of construction in monthly draws and consistent with construction disbursement conditions applicable to commercial lending guidelines. Tenant's contractor is subject to Landlord's reasonable approval. If Tenant chooses Concept Construction of North Florida Inc., construction shall be based upon Cost plus 7.5%;


g. Common Areas. Tenant shall have exclusive use of the parking and landscaped areas of Building 1. Tenant shall maintain all structural components, systems and equipment of Building 1, including the roof, and the interior of Building 1 at its sole expense, so long as such maintenance is performed in a manner reasonably acceptable to Landlord. Landlord shall continue to maintain the exterior (but not walls) of Building 1, subject to reimbursement by Tenant. Tenant shall pay directly for all utilities and services rendered to Building 1, but shall otherwise reimburse Landlord for all ad valorem taxes, insurance and other expenses of Landlord related to Building 1.

Tenant must take possession of the Second Expansion Space within ninety (90) days of such notice. If Tenant shall timely elect to lease the Second Expansion Space, Landlord and Tenant shall execute and deliver an amendment to this Lease memorializing the terms as reflected in Exhibit "A", and including agreed upon revised rentable area of the Premises, the Fixed Annual Fixed Rent, and Tenant's Proportionate Share. The Expansion Space shall be delivered "AS IS", "WHERE IS".


In the event Tenant (i) fails to notify Landlord in writing of its intent to exercise its Second Expansion Option; or (ii) fails to execute a lease amendment which reflects and confirms the terms of such expansion within fifteen (15) days after presentation of such document, such expansion option shall be null and void.

9. Performance by Landlord and Tenant. By execution of this Amendment, each party warrants, represents, acknowledges and agrees that the other party hereto has performed each and every obligation of such party pursuant to the Lease as same has been amended from time to time and that there are no defaults (or circumstances which with notice and passage of time would constitute defaults) by either party under the Lease.

10. Brokers. Landlord and Tenant warrant and represent to each other that neither party has had any dealings with any real estate broker, finder or other person with respect to this Amendment to Lease. Tenant covenants and agrees that to the extent Tenant has a leasing representative who is due a fee hereon (other than as disclosed herein), such fee shall be paid directly by Tenant.



Initial



Initial

11. Landlord Notice Address: Landlord's notice address (copy) shall hereafter be as follows:

David T. Abraham, Esq.
St. Johns Law Group, P.A.
104 Sea Grove Main Street
St. Augustine, Florida 32080

12. Covenants Binding. It is mutually agreed that all covenants, conditions and agreements set forth in the Lease (as hereby amended) shall remain binding upon the parties and inure to the benefit of the parties hereto and their respective successors and assigns.


13. Continuing Force and Effect. Except as modified hereby, all other terms and conditions of the Lease shall remain unchanged and in full force and effect and are hereby ratified and confirmed by the parties hereto.

14. Defined Terms. Except as otherwise expressly provided herein, all defined terms shall have the meanings ascribed to them in the Lease.


15. Conflicts/Amendment to Control. Any inconsistencies or conflicts between the terms and provisions of the Lease and the terms and provisions of this Amendment shall be resolved in favor of the terms and provisions of this Amendment.

16. Writing Required. This Amendment shall not be modified except in writing and signed by both parties hereto.

17. Address Amendment. The address shall be amended to 14193 NW 119th Terrace Alachua, FL 32615. For purposes of mailing the Suite Number for all Suites occupied by Tenant in Building#1 shall be Suite#10. For purposes of the lease the suite numbers shall remain 101 /102 as previously referenced in the lease.

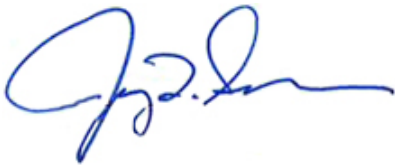


Initial



Initial

Witnesses:



Print Name: JEREMY L. SCHEER



Print Name: Brian Bloch

Witnesses:




Print Name: LARRY BULLOCK



Print Name: Tavera K. Andrews

Landlord:

ALACHUA FOUNDATION PARK HOLDING COMPANY, LLC,
a Florida Limited Liability Company



By: _____
Print Name: BRIAN S. SANFORD

Its: MANAGING MEMBER

Tenant:

APPLIED GENETIC TECHNOLOGIES CORPORATION, a Florida limited liability company



By: _____
Print Name: SUSAN BRUMBY
Its: CEO



Initial



Initial

EXHIBIT "D"

SCHEDULE OF ADJUSTMENTS IN FIXED ANNUAL RENT***

Suite Nos. 101 and 102, Building I, containing Approx. 21,590 Rentable Sq. Ft.

The initial term of this Lease shall be one hundred forty-four (144) months and shall begin on January 1, 2016.

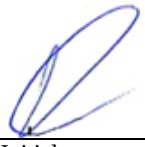
The rent rates and Fixed Annual Rent during the initial term and renewal terms, if exercised, shall be:

<u>Lease Months</u>	<u>Fixed Annual Rent*</u>	<u>Fixed Annual Rent Per Square Foot (Suite 101/102)</u>	<u>Fixed Annual Rent Monthly Payment*</u>
1 -10	\$421,107.00	\$23.00	\$37,533.86
11 - 22	\$450,406.33	\$23.00/\$8.93***	\$37,533.86
23 - 144	\$479,672.85	\$23.00/\$17.85	\$39,972.74
145 - 204**	\$546,227.00	\$25.30	\$45,518.92
205 - 264**	\$600,849.70	\$27.83	\$50,070.81
265 - 324**	\$660,869.90	\$30.61	\$55,072.49


* Does not include sales tax, which shall be paid by Tenant with each installment of Rent

** Reflects Initial Base Rent for Renewal Terms if applicable renewal option exercised by Tenant based upon the ten percent (10%) increase for illustration purposes only, but actual increase shall be based upon the methodology set forth in Section 3(G) of the Lease.

*** Fixed Annual Rent for Suite 102 is abated 50% for the initial term of the Lease for such space, and is otherwise \$17.85 per square foot.



Initial



Initial

SECOND AMENDMENT TO OFFICE LEASE AGREEMENT

THIS SECOND AMENDMENT TO OFFICE LEASE AGREEMENT (“Amendment”) dated this 9th day of November, 2017, is by and between ALACHUA FOUNDATION PARK HOLDING COMPANY, LLC, a Florida Limited Liability Company (“Landlord”) and APPLIED GENETIC TECHNOLOGIES CORPORATION, a Delaware corporation (“Tenant”).

WITNESSETH:

A. Landlord and Tenant are parties to: (i) that certain Standard Form of Lease for Foundation Park dated on or about April 10, 2015 (the “Original Lease”) as amended by (ii) that certain Amendment to Office Lease Agreement dated effective October 1, 2016 (the “First Amendment”). The Original Lease as amended by the First Amendment is referred to collectively as the “Lease”. Pursuant to the Lease, Tenant leases Suites 101 and 102, containing 21,590 square feet net rentable area (the “Premises”), in the building known as “Building #1” located at 14100 N. W 113th Terrace, Alachua, Florida in the buildings known as Foundation Park (the “Project”). The initial term of the lease commenced on January 1, 2016, and expires on December 31, 2027.

B. Landlord and Tenant wish to further modify the terms of the Lease to extend the Lease to certain adjacent space for use as storage or other allowable use permitted by the terms of the Lease in connection with Tenant’s operations as more fully set forth herein; and

C. Landlord is willing to agree to such modifications provided that this agreement is entered into, but not otherwise.

NOW, THEREFORE, in consideration of the mutual promises herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, Landlord and Tenant hereby agree as follows:

1. Recitals. All recitals set forth above are true and correct and are incorporated hereby reference.

2. Premises. The “Premises”, as such term is defined in the Lease, shall hereafter refer to Suite 101, containing 18,309 rentable square feet; Suite 102, containing 3,281 rentable square feet; and the adjacent space containing 1,994 rentable square feet as shown on Exhibit “A” attached hereto (the “Storage Space”) for a total of 23,584 rentable square feet. Landlord agrees to (i) demise the Storage Space with metal stud walls and sheet rock installed on the exterior, (ii) install reasonable lighting and electrical receptacles in mutually agreed locations, and (iii) to install two (2) sets of double doors in the locations shown on Exhibit “A”. The date that Landlord has completed such improvements and delivered the Storage Space to Tenant or the date Tenant begins using the Storage Space (whichever occurs sooner) shall be referred to as the “Storage



Space Delivery Date”, which date is estimated to be December 1, 2017. The Storage Space Delivery Date shall not occur prior to December 1, 2017. Otherwise, Tenant accepts the Storage Space and the Premises “AS IS” and acknowledges that Landlord has no obligation to make any other repairs or alterations to the Premises as a condition to this amendment.

3. Term. The Initial Term of the Lease shall not be modified, and shall continue to expire on December 31, 2027.

4. Operating Expenses. Beginning on the Storage Space Delivery Date, as a result of Tenant’s lease of the Storage Space, Tenant’s pro rata share shall be increased from fifty percent (50%) to fifty-four and six tenths percent (54.6%). Tenant shall be responsible for its pro rata share of Operating Expenses and Additional Rent for the Premises in the same manner as set forth in the Lease.

5. Fixed Annual Rent for Premises. Exhibit “D” of the Lease, which sets forth the Fixed Annual Rents for Suite 101 and 102, is hereby amended to include the supplemental rent schedule for the Storage Space attached hereto as Exhibit “D-1 (Supplement) and incorporated into the Lease by reference. Fixed Annual Rents shall be as set forth in both Exhibit “D” of the Lease and Exhibit “D-1” of this Amendment.

6. Tenant Expansion Option. Tenant acknowledges that Tenant did not elect to exercise Tenant’s Expansion Option as set forth in paragraph 8 of the First Amendment. Such option has now expired and is no longer effective.

7. Performance by Landlord and Tenant. By execution of this Amendment, each party warrants, represents, acknowledges and agrees that the other party hereto has performed each and every obligation of such party pursuant to the Lease as same has been amended from time to time and that there are no defaults (or circumstances which with notice and passage of time would constitute defaults) by either party under the Lease.

8. Brokers. Landlord and Tenant warrant and represent to each other that neither party has had any dealings with any real estate broker, finder or other person with respect to this Amendment to Lease. Tenant covenants and agrees that to the extent Tenant has a leasing representative who is due a fee hereon (other than as disclosed herein), such fee shall be paid directly by Tenant.

9. Covenants Binding. It is mutually agreed that all covenants, conditions and agreements set forth in the Lease (as hereby amended) shall remain binding upon the parties and inure to the benefit of the parties hereto and their respective successors and assigns.

10. Continuing Force and Effect. Except as modified hereby, all other terms and conditions of the Lease shall remain unchanged and in full force and effect and are hereby ratified and confirmed by the parties hereto.



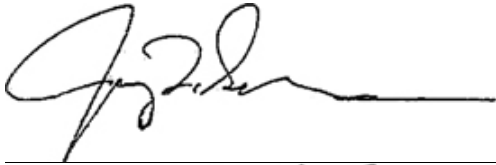
11. Defined Terms. Except as otherwise expressly provided herein, all defined terms shall have the meanings ascribed to them in the Lease.

12. Conflicts/Amendment to Control. Any inconsistencies or conflicts between the terms and provisions of the Lease and the terms and provisions of this Amendment shall be resolved in favor of the terms and provisions of this Amendment.

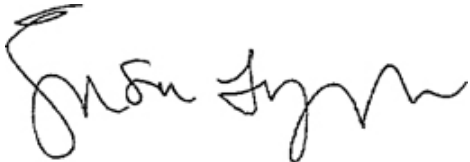
13. Writing Required. This Amendment shall not be modified except in writing and signed by both parties hereto.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment to Lease on the date indicated above.

Witnesses:



Print Name: Jeremy L. Scugel



Print Name: Susan Lynch

Witnesses:



Print Name: Rebecca WATSON



Print Name: Justin Dean

Landlord:

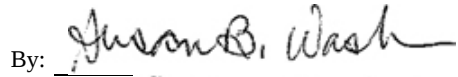
ALACHUA FOUNDATION PARK HOLDING COMPANY, LLC,
a Florida Limited Liability Company



By: _____
Print Name: Brian Cantor
Its: MANAGER

Tenant:

APPLIED GENETIC TECHNOLOGIES CORPORATION, a Delaware corporation



By: _____
Print Name: Susan B. Washer
Its: President ; CEO



EXHIBIT "D-1 (Supplement)"

SCHEDULE OF ADJUSTMENTS IN FIXED ANNUAL RENT***

Storage Space, Building I, containing Approx. 1,994 Rentable Sq. Ft.

Rents for the Storage Space shall begin on the Storage Space Delivery Date (estimated 11/15/17) and end December 31, 2027.

The rent rates and Fixed Annual Rent for the Storage Space during the initial term and renewal terms, if exercised, shall be:

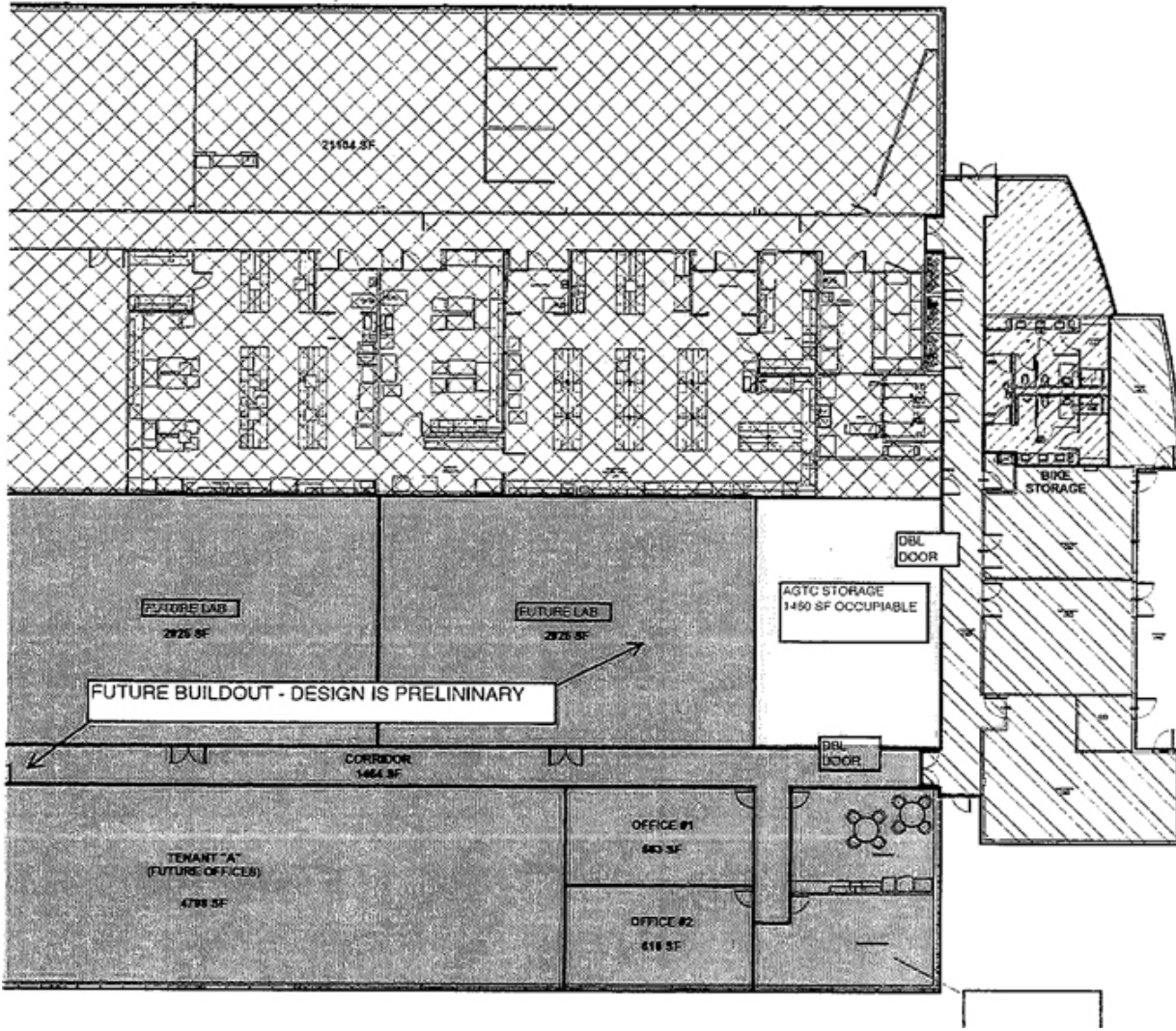
<u>Lease Months</u>	<u>Fixed Annual Rent*</u>	<u>Fixed Annual Rent Per Square Foot</u>	<u>Fixed Annual Rent Monthly Payment*</u>
23* -144	\$ 35,592.96	\$ 17.85	\$ 2,966.08
145 - 204**	\$ 39,162.12	\$ 19.64	\$ 3,263.51
205 - 264**	\$ 43,070.40	\$ 21.60	\$ 3,589.20
265 - 324**	\$ 47,377.44	\$ 23.76	\$ 3,948.12

* Rents for Storage Space estimated to begin 11/15/17, which, is the 23rd month of the Term. If the Storage Space Deliver Date occurs on a date other than the first day of a month, then the rent for such month shall be prorated based upon the foregoing monthly rent.. Does not include sales tax, which shall be paid by Tenant with each installment of Rent.

** Reflects Initial Base Rent for Renewal Terms if applicable renewal option exercised by Tenant based upon the ten percent (10%) increase for illustration purposes only, but actual increase shall be based upon the methodology set forth in Section 3(G) of the Lease.



EXHIBIT "A"



JBW

RESTRICTED STOCK UNIT AGREEMENT

Granted by

Applied Genetic Technologies Corporation

Under the 2013 Equity and Incentive Plan

Applied Genetic Technologies Corporation (the “Company”) hereby grants to the person named below (the “Recipient”) restricted stock units (“Restricted Stock Units”), with each such unit representing the right to receive one share of the Company’s common stock, par value \$0.001 per share (the “Common Stock”), pursuant to the terms set forth below (the “Award”). The Award is and shall be subject in every respect to the provisions of the Company’s 2013 Equity and Incentive Plan, as amended from time to time (the “Plan”), which is incorporated herein by reference and made a part hereof. The Recipient hereby accepts this Award subject to all the terms and provisions of the Plan and agrees that (a) in the event of any conflict between the terms hereof and those of the Plan, the latter shall prevail, and (b) all decisions under and interpretations of the Plan by the Board or the Committee shall be final, binding and conclusive upon the Recipient and his or her heirs and legal representatives. Capitalized terms used herein but not defined shall have the meaning set forth in the Plan.

1. **Name of Recipient:**
2. **Date of Grant:**
3. **Maximum Number of Restricted Stock Units:**
4. **Vesting of Restricted Stock Units:**
5. **Payment.** Upon each vesting date, the Recipient shall receive one share of Stock for each vested Restricted Stock Unit; provided, however, that the number of shares issued shall be reduced by the number of shares sufficient to satisfy the minimum tax withholding obligations as set forth in Section 6 below.
6. **Withholding Obligation; Sell to Cover.**
 - (a) The Recipient expressly acknowledges and agrees that the Recipient’s rights hereunder, including the right to be issued shares of Common Stock upon the vesting of the Award (or any portion thereof), are subject to the Recipient’s promptly paying to the Company in cash (or by such other means as may be acceptable to the Administrator in its discretion) all taxes required to be withheld, if any, relating to the Award (the “Withholding Obligation”).
 - (b) By accepting this Award, the Recipient hereby acknowledges and agrees that he or she elects to sell shares of Common Stock issued in respect of the Award and to allow the Agent to remit the cash proceeds of such sale to the Company (“Sell to Cover”) to satisfy the Withholding Obligation, to the extent that such cash proceeds are sufficient to satisfy the Withholding Obligation.

(c) In order to implement a Sell to Cover, the Recipient hereby irrevocably appoints Stifel, Nicolaus & Company, Incorporated, or such other registered broker-dealer that is a member of the Financial Industry Regulatory Authority as the Company may select, as the Recipient's agent (the "Agent"), and the Recipient authorizes and directs the Agent to: (i) sell on the open market at the then prevailing market price(s), on the Recipient's behalf, as soon as practicable on or after the date on which the shares of Common Stock are delivered to the Recipient pursuant to Section 4 hereof in connection with the vesting of the Restricted Stock Units, the number (rounded up to the next whole number) of shares of Common Stock sufficient to generate proceeds to cover (A) the satisfaction of the Withholding Obligation arising from the vesting of the Restricted Stock Units and the related issuance and delivery of shares of Common Stock to the Recipient and (B) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto; (ii) remit directly to the Company the proceeds from the sale of the shares of Common Stock referred to in clause (i) above necessary to satisfy the Withholding Obligation; (iii) retain the amount required to cover all applicable fees and commissions due to, or required to be collected by, the Agent, relating directly to the sale of the shares of Common Stock referred to in clause (i) above; and (iv) maintain any remaining funds from the sale of the shares of Common Stock referred to in clause (i) above in the Recipient's account with the Agent. The Recipient hereby authorizes the Company and the Agent to cooperate and communicate with one another to determine the number of shares of Common Stock that must be sold to satisfy the Recipient's obligations hereunder and to otherwise effect the purpose and intent of this Agreement and satisfy the rights and obligations hereunder.

(d) The Recipient acknowledges that the Agent is under no obligation to arrange for the sale of Common Stock at any particular price under a Sell to Cover and that the Agent may affect sales under any Sell to Cover in one or more sales and that the average price for executions resulting from bunched orders may be assigned to the Recipient's account. The Recipient further acknowledges that he or she will be responsible for all brokerage fees and other costs of sale associated with any Sell to Cover or transaction contemplated by this Section 6 and agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale. In addition, the Recipient acknowledges that it may not be possible to sell shares of Common Stock as provided for in this Section 6 due to various circumstances. If it is not possible to sell shares of Common Stock in a Sell to Cover, the Company will assist the Recipient in determining additional alternatives available to the Recipient. In the event of the Agent's inability to sell shares of Common Stock, the Recipient will continue to be responsible for the timely payment to the Company of all federal, state, local and foreign taxes that are required by applicable laws and regulations to be paid or withheld with respect to the Restricted Stock Units or the Award. In such event, or in the event that the Company determines that the cash proceeds from a Sell to Cover are insufficient to meet the Withholding Obligation, the Recipient authorizes the Company and its subsidiaries to withhold such amounts from any amounts otherwise owed to the Recipient, but nothing in this sentence shall be construed as relieving the Recipient of any liability for satisfying his or her obligations under the preceding provisions of this Section.

(e) The Recipient hereby agrees to execute and deliver to the Agent or the Company any other agreements or documents as the Agent or the Company reasonably deem necessary or appropriate to carry out the purposes and intent of this Agreement, including without limitation, any agreement intended to ensure the Sell to Cover and the corresponding authorization and instruction to the Agent set forth in this Section 6 to sell Common Stock to satisfy the Withholding Obligation comply with the requirements of Rule 10b5-1(c) under the Exchange Act. The Agent is a third-party beneficiary of this Section 6.

(f) The Recipient's election to Sell to Cover to satisfy the Withholding Obligation is irrevocable. Upon acceptance of the Award, the Recipient has elected to Sell to Cover to satisfy the Withholding Obligation, and the Recipient acknowledges that he or she may not change this election at any time in the future.

7. **No Rights to Shares or as a Stockholder; No 83(b) Election.** The Recipient shall not have any right in, or with respect to, any of the shares of Common Stock issuable under the Award (including voting rights) unless and until the Award vests and is settled by issuance of the shares to the Recipient. The Recipient expressly acknowledges that because the Award consists of an unfunded and unsecured promise by the Company to deliver Common Stock in the future, subject to the terms hereof, it is not possible to make a so-called "83(b) election" for tax purposes with respect to the Award.
8. **Nontransferability.** The Restricted Stock Units are personal to the Recipient and shall not be transferable or assignable, other than by will or the laws of descent and distribution, and any such purported transfer or assignment shall be null and void.
9. **Termination of Employment.** If the Recipient's employment with or service for the Company is terminated, for any reason or no reason, with or without cause, all unvested Restricted Stock Units shall immediately terminate and be of no further force or effect.
10. **Notice.** Any notice to be given to the Company hereunder shall be deemed sufficient if addressed to the Company and delivered to the office of the Company, Applied Genetic Technologies Corporation, 14193 NW 119th Terrace, Alachua, FL 32615, attention of the chief financial officer, or such other address as the Company may hereafter designate.

Any notice to be given to the Recipient hereunder shall be deemed sufficient if addressed to and delivered in person to the Recipient at his or her address furnished to the Company or when deposited in the mail, postage prepaid, addressed to the Recipient at such address.

IN WITNESS WHEREOF, the parties have executed this Award, or caused this Award to be executed, as of the Date of Grant.

Applied Genetic Technologies Corporation

By: _____

The undersigned Recipient hereby acknowledges receipt of a copy of the Plan and this Award, and agrees to the terms of this Award and the Plan.

[Name of Recipient]

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this “**Amendment**”), dated as of May 13, 2021 (the “**First Amendment Effective Date**”), is made by and among APPLIED GENETIC TECHNOLOGIES CORPORATION, a Delaware corporation, and each of its Subsidiaries (hereinafter collectively referred to as the “**Borrower**”), the several banks and other financial institutions or entities from time to time parties to this Agreement (collectively, referred to as the “**Lenders**”) and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and the Lenders (in such capacity, the “**Agent**”).

The Borrower, Lender and Agent are parties to a Loan and Security Agreement dated as of June 30, 2020 (amended, restated, modified or otherwise supplemented from time to time, the “**Loan and Security Agreement**”). The Borrower has requested that Lender agree to certain amendments to the Loan and Security Agreement. Lender has agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1. Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement.** All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation.** The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2. Amendments to the Loan and Security Agreement. The Loan and Security Agreement shall be amended as follows effective as of the First Amendment Effective Date:

(a) **New Definitions.** The following definitions are added to Section 1.1 in their proper alphabetical order:

“First Amendment Effective Date” means May 13, 2021.

“FPI” means First Patient In.

(b) **Amended and Restated Definitions.** The following definitions in Section 1.1 are hereby amended and restated as follows:

“Amortization Date” means April 1, 2022; provided however, if the Interest Only Extension Conditions are satisfied, then January 1, 2023.

“Term Loan Maturity Date” means April 1, 2024; provided that, in the event the Amortization Date is January 1, 2023, then “Term Loan Maturity Date” means July 1, 2024; provided that if such day is not a Business Day, the Term Loan Maturity Date shall be the immediately preceding Business Day.

“Performance Milestone” means satisfaction of each of the following events: (a) no default or Event of Default shall have occurred and be continuing, (b) Borrower raised at least Seventy Five Million Dollars (\$75,000,000) in unrestricted (including, not subject to any redemption, clawback, escrow or similar encumbrance or restriction) cumulative net cash proceeds from bona fide equity financings, warrant exercises, Subordinated Indebtedness and/or upfront cash payments from the consummation of corporate transactions permitted under this Agreement (or consented to by Agent), in each case after the First Amendment Effective Date but prior to March 31, 2022, subject to reasonable verification by Agent (including supporting documentation reasonably requested by Agent), and (c) Borrower announced, in a manner customary and generally accepted for a company of Borrower’s industry, size, and market, FPI for Borrower’s Phase II/III “Vista” Trial in Borrower’s XLRP program (subject to verification by Agent (including supporting documentation reasonably requested by Agent)).

(c) Section 2.2(a). Section 2.2(a) is hereby amended and restated as follows:

“(a) Advances. Subject to the terms and conditions of this Agreement, the Lenders will severally (and not jointly) make in an amount not to exceed its respective Term Commitment, and Borrower agrees to draw, a Term Loan Advance of Ten Million Dollars (\$10,000,000) on the Closing Date (the “Tranche 1 Advance”). Subject to the terms and conditions of this Agreement, as amended by the First Amendment to Loan and Security Agreement, Lenders will severally (and not jointly) make in an amount not to exceed its respective Term Commitment, and Borrower Agrees to draw, a Term Loan Advance of Ten Million Dollars (\$10,000,000) on the First Amendment Effective Date (the “Initial Tranche 2 Advance”). Subject to the terms and conditions of this Agreement, as amended by the First Amendment to the Loan and Security Agreement, and conditioned on approval by the Lenders’ investment committee in its sole and unfettered discretion, at any time after the First Amendment Effective Date but prior to the Amortization Date, Borrower may request additional Term Loan Advances in an aggregate principal amount up to Five Million Dollars (\$5,000,000) (the “Remaining Tranche 2 Advance”). The aggregate outstanding Term Loan Advances may be up to the Maximum Term Loan Amount.”

(d) References Within Loan and Security Agreement. Each reference in the Loan and Security Agreement to “this Agreement” and the words “hereof,” “herein,” “hereunder,” or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3. Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses.** The Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 5(e), and (ii) all other fees, costs and expenses, if any, due and payable as of the First Amendment Effective Date under the Loan and Security Agreement. For the avoidance of doubt, any such fees, costs and expenses shall include the Tranche 2 Facility Charge, which is payable to the Lenders in accordance with Section 4.2(d) of the Loan and Security Agreement.

(b) **This Amendment.** Agent shall have received this Amendment, executed by Agent, Lender, and the Borrower.

(c) **Representations and Warranties; Intellectual Property Claims.** Within five (5) days of the First Amendment Effective Date, or such later date as Agent shall permit in its sole discretion, Agent shall have received an updated Exhibit C in form and substance satisfactory to Agent (“**Updated Exhibit C**”). For the avoidance of doubt, Updated Exhibit C shall contain a true, correct and complete list of each of Borrower’s Patents, registered Trademarks, registered Copyrights, and material agreements under which Borrower licenses Intellectual Property from third parties (other than shrink-wrap software licenses), together with application or registration numbers, as applicable, owned by Borrower or any Subsidiary and shall replace Exhibit C of the Loan and Security Agreement in its entirety. By delivering Updated Exhibit C, Borrower will thereby confirm as of the date thereof, (a) that the representations and warranties made by it in Section 5.9 the Loan and Security Agreement are true and correct in all material respects and (b) that there has not been and there does not exist a Material Adverse Effect.

(d) **Representations and Warranties; No Default.** On the First Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct in all material respects on and as of the First Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 4. Representations and Warranties. To induce Agent and Lender to enter into this Amendment, the Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided, however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and (b) that there has not been and there does not exist a Material Adverse Effect. For the purposes of this Section 4, (i) each reference in Section 5 of the Loan and Security Agreement to “this Agreement,” and the words “hereof,” “herein,” “hereunder,” or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment, and (ii) any representations and warranties which relate solely to an earlier date shall not be deemed confirmed and restated as of the date hereof (provided that such representations and warranties shall be true, correct and complete as of such earlier date). Notwithstanding anything in the foregoing to the contrary, Borrower’s confirmation, as of the date hereof, shall not apply to the representation and warranty contained in Section 5.9 of the Loan and Security Agreement.

SECTION 5. Miscellaneous.

(a) Loan Documents Otherwise Not Affected; Reaffirmation; No Novation.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. Lender's and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) The Borrower hereby expressly reaffirms the grant of security under Section 3.1 of the Loan and Security Agreement, the Bionic Sight Pledge Instruction and Acknowledgement and any other Loan Document to which the Borrower is a party and hereby expressly reaffirms that, with effect from (and including) the First Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Secured Obligations under the Loan and Security Agreement, as amended by this Amendment, and the other Loan Documents, including without limitation any Term Loan Advances funded on or after the First Amendment Effective Date, as of the date hereof.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of the Borrower's Secured Obligations under or in connection with the Loan and Security Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Agent's security interest in, (on behalf of itself and Lender) security titles to or other liens on any Collateral for the Secured Obligations.

(b) **Conditions.** For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Agent shall have received notice from such Lender prior to the First Amendment Effective Date specifying its objection thereto.

(c) **Release.** In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and their respective successors and assigns, and their respective present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lender and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually

as a “**Releasee**”), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which the Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan and Security Agreement, or any of the other Loan Documents or transactions thereunder or related thereto (collectively, the “**Released Claims**”). The Borrower understands, acknowledges and agrees that the release set forth above (the “**Release**”) may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. The Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above. Without limiting the generality of the foregoing, the Borrower hereby waives the provisions of any statute or doctrine that prevents a general release from extending to claims unknown by the releasing party, including, without limitation, California Civil Code Section 1542, which provides:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

The Borrower acknowledges that the agreements in this Section are intended to be in full satisfaction of all or any alleged injuries or damages arising in connection with the Released Claims. The Borrower acknowledges that the Release constitutes a material inducement to Agent and Lender to enter into this Amendment and that Agent and Lender would not have done so but for Agent’s and Lender’s expectation that the Release is valid and enforceable in all events.

(d) **No Reliance.** The Borrower hereby acknowledge and confirm to Agent and Lender that the Borrower is executing this Amendment on the basis of their own investigation and for their own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(e) **Costs and Expenses.** The Borrower agrees to pay to Agent as required under the Loan Agreement, after giving effect to this Amendment, the reasonable and documented out-of-pocket fees and expenses of Agent and Lender party hereto and the reasonable and documented out-of-pocket fees and disbursements of counsel to Agent and Lender party hereto in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the First Amendment Effective Date or after such date.

(f) **Binding Effect.** This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(g) **Governing Law** THIS AMENDMENT HAS BEEN NEGOTIATED AND DELIVERED TO AGENT AND LENDER IN THE STATE OF NEW YORK, AND SHALL HAVE BEEN ACCEPTED BY AGENT AND LENDER IN THE STATE OF CALIFORNIA. PAYMENT TO AGENT AND LENDER BY THE BORROWER OF THE SECURED OBLIGATIONS IS DUE IN THE STATE OF CALIFORNIA. THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, EXCLUDING CONFLICT OF LAWS PRINCIPLES THAT WOULD CAUSE THE APPLICATION OF LAWS OF ANY OTHER JURISDICTION.

(h) **Complete Agreement; Amendments.** This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(i) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(j) **Counterparts.** This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(k) **Loan Documents.** This Amendment and the documents related thereto shall constitute Loan Documents.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

APPLIED GENETIC TECHNOLOGIES CORPORATION

By: /s/ Susan B. Washer

Name: Susan B. Washer

Title: Chief Executive Officer

AGENT:

HERCULES CAPITAL, INC.

Signature: /s/ Zhuo Huang

Print Name: Zhuo Huang

Title: Associate General Counsel

LENDER:

HERCULES CAPITAL, INC.

Signature: /s/ Zhuo Huang

Print Name: Zhuo Huang

Title: Associate General Counsel

LEASE
[Foundation Park]

THIS LEASE (this “Lease”) is made as of May 13, 2021 (the “Effective Date”) between **ALACHUA FOUNDATION PARK HOLDING COMPANY II, LLC**, a Florida limited liability company, with its office at 3324 W. University Avenue, PMB #151, Gainesville, Florida 32607 (“Landlord”), and **APPLIED GENETIC TECHNOLOGIES CORPORATION**, a Delaware corporation, whose address is Suite 101, Building I, 14100 N.W. 113th Terrace, Alachua, Florida 32615 (“Tenant”).

WITNESSETH:

SUMMARY OF LEASE PROVISIONS

Section 1—BASIC DATA; DEFINED TERMS. Certain fundamental provisions and defined terms of this Lease are presented in this summary format in this Section (sometimes hereinafter referred to as the “Summary”) to facilitate convenient reference by the parties hereto. All references in this Lease to the following terms shall be accorded the meanings or definitions given in this Section, as though such meaning or definition were fully set forth throughout the text hereof. This Section, together with the terms herein referenced, shall constitute an integral part of this Lease.

- | | |
|---------------------|--|
| A. Tenant’s Name: | Applied Genetic Technologies Corporation |
| B. Premises: | a building to be constructed in accordance with the terms hereof, and known as Foundation Park Building II at Foundation Park, Alachua, Alachua County, Florida (the “Building”), together with the land included with the Building, including driveways, parking areas, sidewalks and landscaped areas, as indicated on the Site Plan (see Exhibit A), to be developed and constructed by Landlord as Landlord’s Work (see Exhibit B-2) |
| C. Site Plan: | Site Plan showing the Premises, including the Building, proposed driveways, parking areas, sidewalks and landscaped areas, to be developed and constructed pursuant to Landlord’s Work (see Exhibit A) |
| D. Initial Term: | Two Hundred Forty (240) months from the Commencement Date |
| E. Renewal Term(s): | Three (3) consecutive renewal terms of five (5) years each, following the Initial Term |

- F. Commencement Date: Date of Landlord's delivery of written notice to Tenant that the Premises are deemed Substantially Ready for Occupancy, as evidenced by a Certificate of Occupancy or Temporary Certificate of Occupancy, as hereinafter defined or as otherwise provided in Section 3 (see Section 3B.)
- G. Anticipated Commencement Date: May 2, 2022; subject to Force Majeure and Tenant Delays (subject to Landlord's obligation as set forth in Exhibit B-2, paragraph 5 as to timing of application for permits)
- H. Outside Commencement Date: June 7, 2022; subject to Force Majeure and Tenant Delays (subject to Landlord's obligation as set forth in Exhibit B-2, paragraph 5 as to timing of application for permits)
- I. Rentable Square Feet: 21,250 square feet, subject to final determination based on actual as-built measurements of the Building (see Exhibit B-2)
- J. Fixed Annual Rent: The Fixed Annual Rents as described in Section 7 and as shown on Exhibit "C" subject to adjustment based upon final as built square footage and any cost or Allowance adjustments as agreed herein.
- K. Proportionate Share of Costs: 100% as to Premises; 100% as to Foundation Park POD A, as depicted on the site plan referenced herein (see Section 2). Operating Costs shall include all expenses incurred by Landlord in maintaining or repairing the Premises, including ad valorem taxes, insurance and other expenses so that the Fixed Annual Rent shall be net net to Landlord.
- L. Permitted Uses: As permitted by applicable land use regulations, including general office, research and development laboratory, light pharmaceutical and medical systems manufacturing and fabrication and related light manufacturing and distribution center of manufactured goods (see Section 5)
- M. REA: That certain Reciprocal Easement and Maintenance Agreement by and between Alachua Foundation Park Holding Company, Inc. and the University of Florida Foundation, Inc. dated April 15, 2015, and recorded in O.R. Book 4343, beginning at page 2227, of the public records of Alachua County, Florida, which provides access to the Premises from the public right of way.

- N. Build to Suit: The Premises is to be developed and constructed by Landlord in accordance with Site Plan and Plans and Specifications agreed to by Landlord and Tenant, in accordance with Exhibit B-2, at Landlord's cost and expense, subject to Allowances and Tenant's Cost Contribution (if any)
- O. Plans and Specifications: Plans and Specifications, as approved by Landlord and Tenant, for the development and construction of the Premises, consistent with the Site Plan and in compliance with Legal Requirements (See Exhibit E); the parties acknowledge that the Plans and Specifications as described on Exhibit E may be revised upon completion of the Plans and Specifications, and thereafter remain subject to further revisions by written change order
- P. Legal Requirements: Conditions and requirements under applicable laws, statutes, rules and regulations, and under the Declaration of Covenants, including without limitation, all licenses, permits and approvals for Landlord's Work, Landlord's delivery of the Premises Substantially Ready for Occupancy, and Tenant's use and occupancy of the Premises for the Permitted Uses
- Q. Fitout: Any portion of the Landlord's Work which is not part of the Base Building and therefore is not included in the Fixed Costs.
- R. Fitout Cost: Fitout Cost (as defined in Section 11 below), as approved by Landlord and Tenant, after completion of the final Plans and Specification, setting forth certain fixed-cost figures and certain variable cost allowances for Landlord's development and construction of the Premises, prepared in accordance with the terms and conditions of Exhibit "B". Fixed Costs are not included in the Fitout Cost. Upon completion of the final Plans and Specifications, and prior to the commencement of construction, Landlord and Tenant shall agree on the final cost associated with the Fitout Cost.

- S. Landlord's Work: Architectural design, mechanical and structural engineering, and development and construction of the Premises, including interior buildout, in accordance with the Site Plan, Plans and Specifications, Fitout Cost and Legal Requirements, Substantially Ready for Occupancy (see Exhibit B- 2)
- T. Landlord's Costs: Landlord's actual costs for Landlord's Work, which includes Fixed Costs and Fitout Costs, subject to any applicable Tenant Contribution (See Exhibit F),
- U. Base Building: That portion of Landlord's work as defined in Exhibit B-1, for which all costs are Fixed Costs. In general terms, the Base Building includes (i) the building shell, (ii) a 4 inch standard slab (or credit in lieu of such slab), and all site development, infrastructure and entitlements. In order to expedite the construction of the premises the Base Building has been derived from existing plans and specifications.
- V. Fixed Costs: Landlord's cost to construct the Base Building and related infrastructure and site improvements in accordance with the details, plans and specifications attached as Exhibit "B-1". Fixed Costs are (i) not the responsibility of Tenant; (ii) are not included in the Fitout Cost. The Fixed Costs represent the cost to complete the Base Building, as described in Exhibit B-1, general improvements and the site work, as well as the associated engineering and plan expenses. Allowance may be allocated to modifications to the Base Building or site improvements to the extent changes in the proposed Base Building, or site improvements (as described in Exhibit B-1) are requested by Tenant.

- W. Allowance: Landlord's agreed upon contribution for Landlord's Work not included in Fixed Costs. Landlord has agreed to fund \$6,000,000.00 as an Allowance toward the construction of the Fitout or toward modifications to the Base Building defined in Exhibit B-1. The Allowance represents the Landlord's contribution towards the cost to complete Tenant's interior buildout and any modifications to the Base Building. Allowance may also be utilized for changes to the Base Building as requested by Tenant. Upon completion and acceptance of the Fitout Cost the Allowance shall be applied to the cost of the Fitout. In the event that the Allowance is insufficient to fund the Fitout, a Tenant's Cost Contribution may be required per Section 11.
- X. Tenant's Cost Contribution: Any amounts in excess of Allowance and Fixed Costs, unless Landlord otherwise agrees to fund such amounts. Any additional amounts funded by Landlord would also result in an increase in the applicable Rents hereunder.
- Y. Tenant's Notice Address: Prior to Commencement Date:
Suite 101, Building I,
14100 N.W. 113th Terrace
Alachua, Florida 32615
Attn: Stephen Potter
After Commencement Date:
At the Premises address
Attn: Stephen Potter
with a copy to:
Foley Hoag LLP
Seaport West
155 Seaport Blvd.
Boston, Massachusetts 02210
Attn: Jeffrey K. Ganguly, Esq.
(see Section 33)
- Z. Landlord's Notice Address: 3324 West University Avenue, PMB #151
Gainesville, Florida 32607
Attn: Brian S. Crawford (see Section 34)
with a copy to:
Legal Department
3324 West University Avenue, PMB #151
Gainesville, Florida 32607

-
- AA. Lender: A lender which holds or will hold a mortgage and security interest encumbering Landlord's interest in the Park and the Premises. Lender to be determined during Due Diligence Period, with notice given to Tenant after selection by Landlord.
- BB. Broker: CBRE Boston (Jared Pimm) & Avison Young (Nick Banks) as "Tenant's Brokers"

STANDARD PROVISIONS OF LEASE

Section 2—PREMISES. Subject to the rent, terms and conditions herein set forth, Landlord hereby leases to Tenant and Tenant hereby rents the Premises, which constitutes a part of that certain business and research center generally known or to be known as FOUNDATION PARK (hereinafter called the “Park”), together with the use of all Common Areas of the Park, as constituted from time to time, which Tenant shall be permitted to use and occupy in accordance with the terms of this Lease. The Premises is to be developed and constructed by Landlord pursuant to Landlord’s Work as set forth on attached Exhibit B-2, to be commenced and diligently prosecuted to completion in accordance with the Site Plan as approved by Landlord and Tenant, attached hereto as Exhibit A, the Plans and Specifications as approved by Landlord and Tenant, a description of which is attached hereto as Exhibit E, the Fitout Cost as approved by Landlord and Tenant, a description of which is attached hereto as Exhibit F, and Legal Requirements (referred to generally as the “Project”). The intended Rentable Square Feet of the Building to be constructed as part of the Project, is 21,250 square feet, subject to final determination based on actual as-built measurements of the Building Prior to occupancy of the Premises by Tenant, Landlord shall deliver to Tenant, at Landlord’s expense, an “as-built” survey of the Premises, showing the actual location of the Building and all improvements then constructed or installed on the Premises. Tenant shall have the opportunity to confirm the measurement of the actual dimensions of the Building.

Section 3—TERM; RENEWAL OPTIONS.

A. Tenant shall have and hold the Premises for the Initial Term specified in Summary Section 1D. above, commencing on the date determined in the manner provided in Subsection 3B. below and expiring at the end of the Initial Term specified in Summary Section 1D. above or until such Term sooner shall terminate as hereinafter provided.

B. The term of this Lease (and Tenant’s obligation to pay rent and all forms of Additional Rent (as defined in Section 7D below) due hereunder for all of the Premises unless otherwise set forth herein) shall, commence on that date (such date being deemed to be the “Commencement Date”) when Landlord has delivered its certification as provided in Section 3C below.

C. The Premises shall be deemed substantially ready for occupancy (“Substantially Ready for Occupancy”), upon Landlord’s delivery of its written certification to Tenant that (i) Landlord has achieved substantial completion of the Base Building included within the Project in accordance with the Site Plan, the Plans and Specifications, the Project Budget and Legal Requirements, and in compliance with the Florida Construction Lien Law, and (ii) if Tenant shall have delivered detailed plans and specifications for the Fitout within one hundred twenty (120) days of the date of this lease, then also a certificate of occupancy, temporary certificate of occupancy, or equivalent instrument has been issued with respect to the Fitout located within the Building by the County of Alachua, Florida, notwithstanding that (i) minor punch list or insubstantial details of construction, decoration or mechanical adjustment remain to be performed or (ii) that the remainder of the Fitout for the Building is incomplete. For purposes of clarification, if Tenant has not delivered detailed plans and specifications for the Fitout within one hundred twenty (120) days of the date hereof, then the date of completion of the Base Building shall be the Commencement Date hereunder. Notwithstanding anything to the contrary herein, Tenant’s occupancy of the building shall serve as evidence that the Premises is substantially ready for occupancy.

D. Any reference in this Lease to the “Term of this Lease” or “Term” or “Lease Term” shall mean the initial Lease Term, as set forth in Section 3A., together with any Renewal Term(s) exercised pursuant to Section 3E. below. The Term of this Lease (and Tenant’s obligation to pay Fixed Annual Rent and all forms of Additional Rent due hereunder for all of the Premises unless otherwise set forth herein) shall commence upon the actual Commencement Date as determined in accordance with Subsection 3B. above. The Parties agree, if Landlord so requests, thereafter to execute a written memorandum confirming such Commencement Date as well as the expiration date of the Initial Term as determined based on such Commencement Date (the “Expiration Date”), which memorandum shall become a part of this Lease. The failure of the parties to execute such memorandum shall not affect the validity of the Commencement Date or the Expiration Date as fixed by the Landlord.

E. Tenant shall have three (3) options to extend the Lease Term (each, a “Renewal”) for successive five (5) year periods (each a “Renewal Term”). If this Lease is still in full force and effect and if Tenant shall not then be in default beyond applicable notice and cure periods, then Tenant may exercise a Renewal by delivering written notice of its election to Landlord not later than one hundred eighty (180) days prior to the expiration of the then current Term (Initial Term or Renewal Term, as the case may be). If a Renewal is duly exercised, then the Term automatically shall be extended for the period of the next ensuing Renewal Term, without the requirement of any further instrument, upon all of the same terms and conditions set forth in this Lease, except that the Fixed Annual Rent during the Renewal Term(s) shall be as set forth on attached Exhibit C. In the event Tenant fails to timely and properly exercise any Renewal, that Renewal and all remaining Renewals automatically shall terminate and shall be rendered null and void.

F. Provided that Tenant has not been in default beyond applicable notice and cure periods, and is not then in default hereunder, Tenant shall have a one time right to elect to terminate the term of this Lease, such termination to be effective as of the last day of the one hundred ninety-eighth (198) month of the lease term (the “Termination Effective Date”). To elect said right to terminate, Tenant shall not later than the last day of the one hundred eightieth (180th) month of the Term: (i) provide Landlord written notice of its intention to elect such termination; and (ii) pay to Landlord via wire transfer (or other form of immediate funds acceptable to Landlord), a termination fee equal to Three Million Three Hundred Fifteen Thousand U.S. Dollars (\$3,315,000.00) . Tenant shall continue to perform all obligations of Tenant arising under the Lease, including the payment of rents, through the Termination Effective Date. Failure of Tenant to satisfy all requirements of its option to terminate or to perform all obligations of Tenant arising hereunder through the Termination Effective Date shall at Landlord’ render this option void and of no further force and effect.

Section 4—PERMITTED USE. It is understood that the Premises are to be used solely for the purposes set forth in Summary paragraph H and for no other purposes. If any governmental license or permit shall be required for the proper and lawful conduct of Tenant’s business in the Premises (other than a certificate of completion or equivalent instrument issued by Alachua, Florida), Tenant shall, at its expense, duly procure and thereafter maintain such license or permit and shall at all times comply with the terms and conditions of same.

Section 5—REQUIREMENTS OF LAW.

A. Tenant shall not undertake, and shall not permit persons within Tenant's control to undertake, any act or thing in or upon the Premises, the Building, or Project which will invalidate or be in conflict with the certificate of occupancy for the Premises or the Building or violate any other zoning ordinances, and rules and regulations of governmental or quasi-governmental authorities having jurisdiction over the Premises or the Project (the "Requirements"). Tenant shall, at Tenant's sole cost and expense, take all action, including any required Alterations necessary to comply with all Requirements (including, but not limited to, applicable terms of the Alachua County Building Code and the Americans With Disabilities Act of 1990 (the "ADA"), each as modified and supplemented from time to time) which shall impose any violation, order or duty upon Landlord or Tenant arising from, or in connection with Tenant's occupancy, use or manner of use of the Premises (including, without limitation, any occupancy, use or manner of use that constitutes a "place of public accommodation" under the ADA), or any installations in the Premises, or required by reason of a breach of any of Tenant's covenants or agreements under this Lease, whether or not such Requirements shall now be in effect or hereafter enacted or issued, and whether or not any work required shall be ordinary or extraordinary or foreseen or unforeseen at the date hereof, unless such Requirement relates to a Base Building condition. Notwithstanding the preceding sentence, Tenant shall not be obligated to perform any Alterations necessary to comply with any Requirements, unless compliance shall be required by reason of: (i) any cause or condition arising out of any Alterations or installations in the Premises (whether made by Tenant or by Landlord on behalf of Tenant) other than Tenant's Work; (ii) Tenant's particular use, manner of use or occupancy on behalf of Tenant of the Premises; (iii) any breach of any of Tenant's covenants or agreements under this Lease; (iv) any wrongful act or omission by Tenant or persons within Tenant's control; or (v) Tenant's use or manner of use or occupancy of the Premises as a "place of public accommodation" within the meaning of the ADA. Landlord warrants that the Premises will comply with the Requirements (including ADA) on the Commencement Date.

B. Tenant covenants and agrees that Tenant shall, at Tenant's sole cost and expense, comply at all times with all Requirements governing its use, generation, storage, containment, transfer, transportation, treatment and/or disposal from or at the Premises of any "Hazardous Materials" (which term shall mean any Medical Waste, biologically or chemically active or other toxic or hazardous wastes, pollutants or substances, including, without limitation, asbestos, PCBs, petroleum products and by-products, substances defined or listed as "hazardous substances" or "toxic substances" or similarly identified in or pursuant to the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. § 9601 et seq., and as hazardous wastes under the Resource Conservation and Recovery Act, 42 U.S.C. § 6010, et seq., any chemical substance or mixture regulated under the Toxic Substance Control Act of 1976, as amended, 15 U.S.C. § 2601, et seq., any "toxic pollutant" under the Clean Water Act, 33 U.S.C. § 466 et seq., as amended, any hazardous air pollutant under the Clean Air Act, 42 U.S.C. § 7401 et seq., hazardous materials identified in or pursuant to the Hazardous Materials Transportation Act, 49 U.S.C. § 1802, et seq., and any hazardous or toxic substances or pollutant regulated under any

other Requirements). For purposes hereof, "Medical Waste" shall mean any solid, semisolid, gaseous, or liquid waste which is generated or utilized in the diagnosis, treatment (e.g., provisions of medical services), immunization or performance of a service to the body of human beings, and for greater certainty shall include all waste generated by the Tenant in relation to its use, and shall include the use of licensed medical waste management companies. Tenant shall agree to execute, from time to time, at Landlord's request, affidavits, representations and the like concerning Tenant's best knowledge and belief regarding the presence of Hazardous Materials in, on, under or about the Premises, the Project or the land on which the Project is located. Tenant shall indemnify and hold harmless Landlord, Landlord's officers, directors, employees, agents, successors, manager and assigns (the "Indemnitees") from and against any loss, cost, damage, liability or expense (including attorneys' fees and disbursements) arising by reason of any clean up, removal, remediation, detoxification action or any other activity required or recommended of any Indemnitees by any Governmental Authority by reason of the presence in or about the Project or the Premises of any Hazardous Materials, as a result of or in connection with the act or omission of Tenant or persons within Tenant's control or the breach of this Lease by Tenant or persons within Tenant's control. For purposes of this indemnity, a third party contracted by Tenant or on Tenant's behalf for the handling or removal of Hazardous Materials shall be deemed to be a party within Tenant's control. The foregoing covenants and indemnity shall survive the expiration or any termination of this Lease. Notwithstanding anything herein to the contrary, Tenant shall have no liability for Hazardous Materials not caused by Tenant, Tenant's agents, or persons within Tenant's control.

C. If Tenant shall receive notice of any violation of, or defaults under, any Requirements, liens or other encumbrances applicable to the Premises, Tenant shall give prompt notice thereof to Landlord.

D. Tenant shall not place a load upon any floor of the Premises exceeding the floor load per square foot area, as provided in the Plans and Specifications (as set forth in attached Exhibit E). The Plans and Specifications shall reflect the weight limitations and position of all heavy equipment and similar items, and if Tenant desires to exceed such limitations, it shall be required to obtain Landlord approval, in which event Landlord may prescribe the reinforcing necessary, if any, which, in the opinion of Landlord, may be required under the circumstances, such reinforcing to be at Tenant's expense.

Section 6—PROJECT DUE DILIGENCE.

A. Each of the parties have performed any necessary due diligence prior to entering into this Lease. The parties agree that the Base Building shall be substantially similar in exterior design and interior finishes as the building which Tenant currently occupies in the Project. A basis rendering of the building and floor plan are attached as Exhibit "A", and the parties agree that notwithstanding that the Building has not yet been fully designed, they have reached an understanding as to the material design and features of the Building so as to enter into this binding lease, subject to each party's subsequent approval of the final design.

B. Prior to the final approval of the Fitout Cost by Landlord and Tenant, Landlord shall provide a detailed cost estimate to Tenant as set forth in Section 11 herein and Exhibit B-2. At this time and upon final approval by Tenant, the Fitout Cost shall become a fixed cost to Tenant except if changes in the scope of work occur as set forth herein. The lease amendment referenced in Section 6a herein shall stipulate the fixed cost of the Fitout Cost and shall further reconcile and stipulate the Allowance, Tenant Cost Contributions or credits

Section 7—FIXED ANNUAL RENT.

A. Tenant hereby covenants and agrees to pay to Landlord in lawful United States currency, the Fixed Annual Rent (as adjusted pursuant to Exhibit C attached hereto and by this reference made a part hereof), payable in equal monthly installments in advance, beginning on the Commencement Date and continuing on the first day of each and every calendar month thereafter during the Initial Term. Landlord shall have the same rights and remedies with respect to Additional Rent as with respect to Fixed Annual Rent. The term "Rent" is hereby defined to mean the Fixed Annual Rent and any Additional Rent payable by Tenant under this Lease. All forms of Rent due under this Lease shall be paid to Landlord, together with any and all applicable sales and use taxes levied upon such Rent, without demand, setoff or deduction whatsoever, at its offices as specified in Summary Section 1V. or at such other place as Landlord shall designate in writing to Tenant. In the event that the Commencement Date is not the first day of a month, the Fixed Annual Rent shall be apportioned pro rata on a per diem basis for the period commencing on the Commencement Date and ending on the last day of the calendar month in which the Commencement Date occurs, and such apportioned sum shall be paid on the Commencement Date.

B. Landlord shall have the same rights and remedies with respect to Additional Rent as with respect to Fixed Annual Rent. The term "Rent" is hereby defined to mean the Fixed Annual Rent and any Additional Rent payable by Tenant under this Lease. In the event that any payment due Landlord under this Lease shall not be paid on the due date, Tenant agrees to pay the sum of Fifty (\$50.00) Dollars per day for each such delinquent payment until made. If any installment of Rent shall remain overdue for more than five (5) days, an additional late charge in an amount equal to one and one-half percent (1.5%) per month (18% percent per annum) of the delinquent amount may be charged by Landlord, such charge to be computed for the entire period for which the amount is overdue. In the event that any check, bank draft, order for payment or negotiable instrument given to Landlord for any payment under this Lease shall be dishonored for any reason whatsoever not attributable to Landlord, Landlord shall be entitled to make an administrative charge to Tenant of Two Hundred Fifty and 00/100 (\$250.00) Dollars. Tenant recognizes and agrees that the aforesaid charges represent, at the time this Lease is made, a fair and reasonable estimate and liquidation of the costs of Landlord in the administration of the Project resulting from the events described, which costs are not contemplated or included in any rent or other charges provided to be paid by Tenant to Landlord in this Lease. Any charges becoming due under this paragraph of this Lease shall be deemed to be Additional Rent due hereunder and shall become due with the next ensuing monthly payment of Fixed Annual Rent. Notwithstanding the foregoing to the contrary, Landlord agrees to provide to Tenant on no more than two (2) occurrences during each Lease year, a notice of nonpayment and a period of five (5) calendar days to correct same without the imposition of late payment charges or interest hereunder as provided above.

C. The term "Lease Year" as used herein shall mean consecutive twelve month periods commencing on each January 1 during the term of this Lease. In the event that the term of this Lease commences on a day other than January 1, the first and last years shall be partial Lease Years and in such case the first Lease Year shall be deemed to commence on the Commencement Date and expire on December 31 next following, and the last Lease Year shall be deemed to commence on the last January 1 occurring during the term of this Lease and shall expire on the expiration date of this Lease.

D. Any and all Operating Costs and other sums of money, assessments or charges required to be paid by Tenant under this Lease other than Fixed Annual Rent shall be considered "Additional Rent" whether or not the same be so designated and Landlord shall have all rights to enforce due and timely payment by Tenant of Additional Rent as are available to Landlord with regard to Fixed Annual Rent. If such amounts or charges are not paid at the time provided in this Lease, they shall, nevertheless, be collectible as Additional Rent with the next installment of Fixed Annual Rent thereafter falling due hereunder, but nothing herein contained shall be deemed to suspend or delay the payment of any amount of money or charges as the same become due and payable hereunder, or limit any remedy of Landlord for enforcement of the immediate collection of same, nor any other remedy available to Landlord. Terms of this Subsection shall survive the expiration or earlier termination of this Lease.

E. Tenant hereby covenants and agrees to pay monthly to Landlord, as Additional Rent, any sales, use or other tax, or any imposition in lieu thereof (excluding State and/or Federal Income Tax) now or hereafter imposed upon the rents, use or occupancy by the United States of America, the State of Florida, the County of Alachua, or any political subdivision thereof, notwithstanding the fact that such statute, ordinance or enactment imposing the same may endeavor to impose the tax on Landlord. If Tenant is exempt from such tax, Tenant shall provide to Landlord a valid exemption certificate to confirm same.

Section 8—AD VALOREM TAXES AND ASSESSMENTS.

Tenant shall pay as Operating Costs (as defined in Sections 15 below) during the term of this Lease its Proportionate Share, as provided in Summary Section 1K., of all ad valorem and real and personal property taxes levied or assessed by any lawful authority against all of the real property which is now or hereafter becomes a part of: (i) the Premises and (ii) the Common Areas of the Park, and such other costs and fees incurred by Landlord or other parties of authority over such matters in contesting any such taxes, assessments, or charges and/or costs associated with negotiating with any such lawful authority with respect thereto (collectively called "Taxes and Assessments"), which sums shall be included as Operating Costs pursuant to Paragraph 9 below. In the event any governmental authority having jurisdiction shall levy any general or special assessment against the real property which is now or hereafter becomes a part of the Common Areas for public betterments or improvements, or if the property upon which the Park or Common Areas are located are subject to assessment by any property owner's association, Tenant shall also pay to Landlord as Operating Costs its Proportionate Share of such assessments. Landlord shall have the option to take the benefit of any statute or ordinance permitting any such assessments for public betterments or improvements to be paid over a period of time, in which case Tenant shall be obligated to pay only the said fraction of the installments of any such assessments which shall become due and payable during the term of this Lease. Landlord agrees that to the extent available

from the taxing authority, any special assessment shall be paid over the longest period permitted by such taxing authority so long as the amount of such special assessment is not materially increased thereby. Unless Landlord shall elect to have Tenant pay ad valorem taxes and assessments directly under terms acceptable to Landlord, on an annual or other periodic basis, Landlord shall estimate the Taxes and Assessments which shall be payable by Tenant pursuant to this Section and Tenant shall pay one-twelfth (1/12) thereof monthly in advance, together with the payment of Fixed Annual Rent. If Landlord elects to have Tenant pay such taxes directly, Tenant shall provide evidence of payment not less than thirty (30) days prior to delinquency. After the end of each Lease Year Landlord shall furnish Tenant a statement of the actual Taxes and Assessments, and there shall be an adjustment between Landlord and Tenant with payment to or repayment by Landlord, as the case may require, to the end that Landlord shall receive the entire amount of Tenant's Proportionate Share for such annual period. Any payments due by Tenant hereunder shall be received on or before thirty (30) days following receipt of said statement. Tenant covenants and agrees that Tenant shall remain liable for and shall pay its Proportionate Share of Taxes and Assessments hereunder, notwithstanding the expiration or earlier termination of this Lease. In the event that, during any calendar year during the term of this Lease, the Project is not fully occupied by tenants, Taxes and Assessments for the Park for such year shall be adjusted to reflect the Taxes and Assessments that would have been payable had the Park been fully occupied throughout such year.

If Tenant shall reasonably believe that the Taxes and Assessments for the Premises are overstated by the taxing authority, and so notifies Landlord and furnishes Landlord with clear and convincing evidence to support such belief, and provided that Tenant funds any fees necessary for same, Landlord shall timely seek an abatement of the same, provided that pursuing same would be economically feasible based upon the anticipated outcome vs. the cost of pursuing such reduction. Tenant shall be credited with its Proportionate Share of the recovery and any costs of such contest to the extent paid by Tenant, if any, net of Landlord's reasonable costs.

Tenant's Proportionate Share represents the ratio of the rentable area of the Premises to the rentable area of the Project. Tenant's Proportionate Share shall be adjusted based upon a change in either the rentable area of the Premises or the Project.

Section 9. USE OF COMMON AREAS.

The use and occupation by Tenant of the Premises shall include the nonexclusive use, in common with others entitled thereto, of the common areas of the Park, including, without limiting the generality of the foregoing, driveways and entrances and exits thereto, pedestrian sidewalks and ramps, and landscaped areas, and other areas and improvements provided in or near the Park for the general use, in common, by tenants within the Park, their officers, agents, employees and customers (hereinafter collectively "Common Areas") as such Common Areas now exist or as may hereafter be constructed for the benefit of or as a part of the Park, subject, however, to the terms and conditions of this Lease and the rules and regulations for the use thereof as prescribed from time to time by Landlord. Tenant acknowledges that the Common Areas shall at all times be subject to the exclusive control and management of the owner or other entity controlling the Common Areas, which shall have the right to do and perform such acts in and to the Common Areas and improvements thereon as it shall determine to be advisable with a view to the improvement of the convenience and use thereof by authorized users of the Common Areas, but

provided such acts do not materially adversely affect Tenant's ability to access and operate the Premises. Tenant shall comply with the terms and conditions governing the use of the Common Areas and occupation with the Park as provided in any Declaration of Covenants which may exist from time to time; provided that no such Declaration of Covenants shall prohibit Tenant's use as provided herein, nor materially diminish any rights of Tenant hereunder as to the Premises. If requested by Landlord, Tenant agrees to execute such documents as may be requested to create said Declaration based upon the foregoing.

Section 10. REA. In connection with its use of the Premises pursuant to this Lease, Landlord assigns to Tenant the joint use of the roadway improvements as described in the REA for ingress to and egress from the Premises to the public right of way. Any expenses related to such use shall be chargeable to Tenant as Additional Rent hereunder. Tenant further acknowledges that pursuant to the REA, any damage to the roadway caused by Tenant, its employees or invitees shall be chargeable to Tenant and shall be subject to Indemnification pursuant to Section 30 below. If Landlord shall elect to or is required to incur any such expenses in connection with the REA, then such expenses shall be deemed "Operating Costs" hereunder.

Section 11—CONSTRUCTION OF PREMISES.

A. Landlord's Work. Subject to Section 11(C) below, Landlord shall perform the work and obligations ("Landlord's Work") as determined in accordance with Exhibit B-2, substantially in accordance with the Site Plan, the Plans and Specifications, the Fitout Cost and Legal Requirements, and in a good and workmanlike manner, and shall deliver possession of the Premises as Substantially Completed for Occupancy on the Commencement Date. Subject to Section 11(C) below, all Landlord's Work shall be done at Landlord's sole cost and expense (including, without limitation, the cost of preparation of the Site Plan, the Plans and Specifications, the Fitout Cost and compliance with Legal Requirements), subject, however, to Tenant's Cost Contribution (as hereinafter defined) as may be applicable.

B. Fitout Cost. Landlord's Work shall be subject to the line item cost figures, estimates and allowances as set forth in the Fitout Cost to be approved by the parties as described in Exhibit B-2 (the "Fitout Cost"), and to be made a part hereof once approved (and thereafter attached hereto as Exhibit F). The Fitout Cost shall provide for estimated costs of: (i) any revisions to the Base Building requested by Tenant (and reflected in a Change Order) and (ii) Interior Buildout. Landlord agrees to fund up to \$6,000,000.00 toward payment of the Fitout Cost (the "Allowance"). In addition, provided that the Building is delivered to Tenant for Fitout with a dirt floor, Landlord shall also contribute to the Fitout Cost Landlord's cost of a typical 4 inch slab for that portion of the Building without a slab (that assumes that the QC Lab is being constructed by Landlord and will therefore include a slab). The total project cost is expected to exceed the Allowance by a minimum of approximately \$500,000 (plus or minus) based upon preliminary estimates obtained by Tenant which excess would be funded by Tenant, and may further exceed the Allowance, as a result of changes requested by Tenant, standards required for Tenant's Fitout or necessary revisions to plans based upon applicable Legal Requirements, revisions to the Plans and Specifications or architectural issues. Accordingly, the Fitout Cost shall be subject to adjustment from time to time upon agreement of Landlord and Tenant, to reflect changed costs due to Plans and Specifications revisions and to the final Plans and Specifications approved by Landlord and Tenant, and to address unanticipated requirements, inconsistencies, errors or

omissions in the design of the Fitout approved by Landlord, change orders or other cost increases for Landlord's Work, in each case as approved by Landlord and Tenant in writing, such approval to not be unreasonably withheld, conditioned or delayed; except that to the extent that any such changes, deletions or additions are required in order to complete the Fitout in accordance with applicable codes, laws or regulations (and are not discretionary) (each referred to as a "Nondiscretionary Change Order"), then Landlord shall provide written notice to Tenant of such change and the resulting increase in the Fitout or Tenant Cost Contribution, but such matters shall not require the approval of the Tenant. To the extent that actual Project Costs exceed the Allowance, Landlord's obligation to complete the Project shall be subject to Tenant's agreement to fund that portion of the Fitout Cost in excess of \$6,000,000.00.

C. Tenant's Cost Contribution. As an inducement for Landlord's entry into this Lease and to incur the expense of and undertake Landlord's Work, on the dates as set forth below, Tenant shall be obligated to reimburse Landlord for its demonstrated costs for Landlord's Work in excess of the Allowance and Base Building, consistent with the Fitout Cost or as otherwise set forth in Change Orders requested by Tenant and approved by Landlord or as required as to Nondiscretionary Change Orders. Tenant's Cost Contribution shall be determined either: (i) as a result of completion of the original Plans and Specifications agreed by Landlord and Tenant; or (ii) as a result of changes from or additions to the Plans and Specifications requested by Tenant, or requested by Landlord during construction of the Project, or Nondiscretionary Change Orders. Notwithstanding the foregoing, once the parties have agreed to the Fitout Cost and the Tenant Cost Contribution, except as to Nondiscretionary Change Orders, Tenant shall not be required to contribute additional amounts to the cost of construction solely as a result of cost overruns or project expenses being in excess of the amounts anticipated by Landlord as reflected in the Project Budget approved by the parties.

Once a Tenant's Cost Contribution has been determined, whether in connection with the original Fitout Cost or as a result of change orders, within ten (10) days following the date of such determination, Landlord and Tenant shall upon request of either party, establish an escrow account with an escrow agent reasonably acceptable to the parties (the "Escrow Agent"). If an escrow account is established, then (i) Tenant shall deposit Tenant's Cost Contribution and (ii) Landlord shall deposit the Allowance into such account. If no escrow account has been established, then Tenant shall upon request deposit the Tenant's Cost Contribution with Landlord. Tenant's Cost Contribution shall be released only in connection with payment of construction costs incurred in accordance with construction of the Project as approved by Tenant, the Project Architect, and Landlord each month based upon a percentage of completion. Release of Tenant's Cost Contribution and the Allowance shall be made on a *pari passu* basis. Tenant shall not be entitled to occupy the Premises until Tenant's Cost Contribution and Additional Tenant Contribution as to work then invoiced and completed (subject only to "punch list" items), have been paid.

D. A "Landlord Delay" shall be determined by adherence with the time frames requiring Landlord action or consent as reflected in the Project schedule attached to Exhibit B-2. A "Tenant Delay" shall mean any delay in the progression of Landlord's Work resulting from: (i) any requested material change by Tenant in Landlord's Work (even though Landlord may approve such change); (ii) any negligent or willful acts or omissions of Tenant, its contractors, agents or employees; (iii) Tenant's failure to timely respond to Landlord's requests for approvals or information necessary for the prosecution of Landlord's Work; (iv) Tenant's failure to timely

approve the Plans and Specifications or to execute any written Change Order, to the extent reflecting a change requested by Tenant, or to deposit funds with the Escrow Agent or directly with Landlord as required hereunder; or (iv) any breach of Tenant's obligations hereunder. A "Tenant Delay" shall be determined by adherence with the time frames requiring Tenant action or consent as reflected in this Lease, including without limitation, the Project schedule attached to Exhibit B-2.

E. If for any reason other than Tenant Delay or a Force Majeure event, the Premises is not delivered by the Outside Commencement Date, then Tenant shall be entitled to a rent credit of Two Thousand Five Hundred Dollars (\$2,500.00) for each day of Landlord's delay as its sole remedy for such delay, except as may be provided in subparagraphs (F) and (G) below.

F. If the Commencement Date has not occurred by July 23, 2022 except as a result of a Tenant Delay or a Force Majeure event, then commencing on July 24, 2022, Tenant shall, in lieu of the rent credit as described in Subparagraph 11(E) above, be entitled to a rent credit of Five Thousand Dollars (\$5,000.00) for each day of Landlord's Delay as its sole remedy for such delay, except as provided in subparagraph (G) below.

G. If the Commencement Date has not occurred by December 31, 2022 except as a result of a Tenant Delay or a Force Majeure event, then Tenant may, as its sole remedies, either: (i) extend the Outside Commencement Date to the actual Commencement Date, continuing to receive the rent credit as provided in subparagraph (F) above until the occurrence of the Commencement Date; or (ii) terminate this Lease; such termination to be exercised by providing written notice to Landlord of such election no later than 5:00 P.M. on such date. Upon Tenant's exercise of its right of termination hereunder, each of the parties shall be relieved of any further obligation hereunder.

H. The Anticipated Commencement Date or Outside Commencement Date may be extended on a day-for-day basis as a result of a Force Majeure event, by Landlord's written notice to Tenant of the Force Majeure event and the anticipated impact on the timely performance of Landlord's Work.

Section 12—ALTERATIONS. Tenant shall make no decorations, additions, improvements or other Alterations in the Premises, without the prior written consent of Landlord, which consent shall not be unreasonable withheld, and then only at its sole cost and expense and by contractors or mechanics and in such manner and with such materials as may be approved by Landlord. All decorations, additions, improvements or other Alterations to the Premises, except movable office furniture, trade fixtures and equipment installed at the expense of Tenant, shall, unless Landlord elects otherwise in writing at the time of its approval or consent, become the property of Landlord upon the installation thereof, and shall be surrendered with the Premises at the expiration of this Lease. Notwithstanding the foregoing, Tenant may install art work and decorate the Premises (and remove such art work or decorations at the end of the Term) without Landlord's consent provided that such decoration are not installed with screws and Tenant shall repair any damage caused by such removal. If required by Landlord in accordance with the foregoing, any such Alteration, addition or improvement to the Premises shall be removed at Tenant's expense upon the expiration or sooner termination of the term of this Lease and Tenant, at its expense, shall also repair any damage to the Premises caused by such removal and restore the Premises to a commercially reasonable standard; provided, however, Tenant shall have no obligation to repaint the walls of the Premises at the expiration or earlier termination of this Lease.

Section 13.—LIENS. Nothing contained in this Lease shall be construed as a consent on the part of Landlord to subject the estate of Landlord to liability under the Construction Lien Law of the State of Florida, it being expressly understood that the Landlord's estate shall not be subject to such liability. Tenant shall strictly comply with the Construction Lien Law of the State of Florida as set forth in Chapter 713, Florida Statutes. Other than the Landlord's Work, Tenant agrees to obtain and deliver to Landlord prior to the commencement of any work or Alteration or the delivery of any materials, written and unconditional waivers of contractors' liens with respect to the Premises, the Project and the Common Areas for all work, service or materials to be furnished at the request or for the benefit of Tenant to the Premises, and any Notice of Commencement filed by Tenant shall contain, in bold print, the first sentence of this Section 13. Such waivers shall be signed by all architects, engineers, designers, contractors, subcontractors, materialmen and laborers to become involved in such work. Notwithstanding the foregoing, Tenant at its expense shall cause any lien filed against the Premises, the Building or the Project, or any portion thereof, for work, services or materials claimed to have been furnished to or for the benefit of Tenant to be satisfied or transferred to bond within ten (10) days after Tenant's having received notice thereof. In the event that Tenant fails to satisfy or transfer to bond such claim of lien within said ten (10) day period, Landlord may do so and thereafter charge Tenant as Additional Rent, all costs incurred by Landlord in connection with the satisfaction or transfer of such claim, including attorneys' fees and an administrative charge not exceeding fifteen percent (15%) of all sums incurred by Landlord in the satisfaction or transfer of such claim. Further, Tenant agrees to indemnify, defend, and save the Landlord harmless from and against any damage to and loss incurred by Landlord as a result of any such contractor's claim of lien. If so requested by Landlord, Tenant shall execute a short form or memorandum of this Lease, which may, in Landlord's sole reasonable discretion be recorded in the Public Records of Alachua County for the purpose of protecting Landlord's estate from contractors' Claims of Lien, as provided in Chapter 713.10, Florida Statutes. In the event such short form or memorandum of this Lease is executed, Tenant shall simultaneously execute and deliver to Landlord an instrument in recordable form terminating Tenant's interest in the real property upon which the Premises are located, which instrument may be recorded by Landlord at the expiration or earlier termination of the term of this Lease. In the event Tenant fails to satisfy or bond over any Contractor's Claim of Lien within the time period specified above, the security deposit paid by Tenant may be used by Landlord for the satisfaction or transfer of any Contractor's Claim of Lien, as provided in this Section. This Section shall survive the termination of this Lease.

Section 14—CHANGES TO BUILDING AND COMMON AREAS. Landlord hereby reserves the right, at any time, to perform maintenance operations and to make repairs to the Common Areas and to those elements of the Premises that are Landlord's obligations pursuant to Section 15A. below, and to modify the Common Areas, and to construct other buildings or improvements within the Park, including, but not limited to, structures for motor vehicle parking. Tenant agrees to cooperate with Landlord, permitting Landlord to accomplish any such maintenance, repairs, alterations, additions or construction, and waives any claim against Landlord in association with any disruptions experienced during the course of such activities.

Section 15—MAINTENANCE, REPAIRS AND REPLACEMENTS.

A. Landlord covenants and agrees throughout the Term to: (i) maintain the structural components of the Building, including exterior walls and the roof, all landscaped areas and the parking lot; (ii) remedy any defects in Landlord's Work during the period as specified in paragraph 7 of Exhibit B-2, upon written notice of such defects from Tenant; provided, however, so long as Landlord has assigned to Tenant all warranties obtained by Landlord with respect to improvements installed by or on behalf of Landlord as part of Landlord's Work, each such obligation with respect to improvements that are the subject of and covered by such warranties shall expire on the third (3rd) anniversary of the Commencement Date, unless a longer warranty period is provided by any component or materials manufacturer. All expenses incurred by Landlord hereunder shall be deemed Operating Costs, which shall be subject to reimbursement by Tenant as Additional Rent. Notwithstanding the foregoing to the contrary, Landlord shall not be obligated to make any repairs necessitated by the negligence or willful misconduct of Tenant, its agents, employees, contractors, invitees or customers. Except as otherwise expressly provided in this Lease, Landlord shall not be obligated perform any maintenance or to make any other repairs, replacements or improvements of any kind in or to the Premises, or upon any equipment, facilities or fixtures located in the Premises, including all signage. The provisions of this Section 15A. shall not apply in the case of damage or destruction by fire or other casualty or by eminent domain, in which event the obligations of Landlord shall be controlled by Section 18 and Section 19 of this Lease. Landlord shall have no obligation to repair until a reasonable time after the receipt by Landlord of written notice of the need for repairs.

In the event that Landlord has elected to maintain the Premises as provided in Section 15(C), Landlord may elect to estimate Tenant's Operating Costs. In such event, upon request of Landlord, Tenant shall pay one-twelfth (1/12) thereof monthly in advance, together with the payment of Fixed Annual Rent. After the end of each Lease Year, Landlord shall furnish Tenant, upon request, a statement of the actual Operating Costs. Tenant shall have thirty (30) days from receipt of such statement to review same and to submit to Landlord in writing any objections of Tenant thereto. If no written objections are received by Landlord within said thirty (30) day period, such statement shall be conclusively deemed to be correct as between the parties, and there shall be an adjustment with payment by or refund or credit to Tenant, as the case may require, to the end that Tenant shall pay the entire amount of Tenant's Proportionate Share for such period but not in excess thereof. Any payments due by Tenant hereunder shall be received by Landlord on or before thirty (30) days following receipt by Tenant of said statement. Tenant covenants and agrees that Tenant shall remain liable for and shall pay its Proportionate Share of Operating Costs in the amounts and times as set forth herein, notwithstanding the expiration or earlier termination of this Lease. Tenant acknowledges that Operating Costs or any item or component of assessment or charge thereunder may be made or assessed by either Landlord and/or the owner or other entity controlling the Common Areas, and Tenant shall pay such charge to the party making such assessment. Landlord shall retain its records regarding Operating Costs for a period of at least twelve (12) months following the final billing for the Lease Year in question.

In the event that Landlord elects to undertake maintenance and repair of the Premises, then Landlord agrees that the following costs shall not be chargeable to Tenant as Operating Costs:

(1) Leasing commissions, rent concessions to lessees, tenant improvements and allowances and advertising expenses;

(2) Expenditures for capital improvements, except those which under generally accepted accounting principles are expenses or regarded as deferred expenses and except for capital expenditures required by changes in law after the date of this Lease, in either of which cases the cost thereof shall be included in expenses for the calendar year in which the costs are incurred and subsequent years, appropriately allocated to such years on a straight-line basis, to the extent that such items are amortized over an appropriate period, consistent with general accepted accounting principles, with an interest factor equal to the prime rate of The Wall Street Journal, but in no event greater than the highest rate of interest permitted to be charged by law at the time of Landlord's having incurred said expenditure;

(3) Painting, redecorating or other work which Landlord performs for any lessee or prospective lessee;

(4) Repairs or other work (including rebuilding) occasioned by fire, windstorm or other casualty or condemnation;

(5) Depreciation;

(6) Interest on, amortization of, and fees and expenses in connection with any mortgages placed upon the Project by Landlord;

(7) Rent payable under any lease to which this Lease is subject;

(8) Costs and expenses of negotiating and enforcing leases against lessees, including attorneys' fees;

(9) Penalties for the late payment of any Real Estate Taxes or other Operating Costs and penalties and fines incurred due to Landlord's violation of any applicable law;

(10) Landlord's general corporate overhead and administrative expenses;

(11) Expenses for any item or service not available to Tenant but to certain other tenant(s) of the Project;

(12) Expenses for any item or service which Tenant pays directly to a third party or separately pays to Landlord and expenses incurred by Landlord to the extent the same are chargeable to any other tenant or occupant of the Project, or third party;

(13) Salaries of (i) employees above the grade of building superintendent or building manager, and (ii) employees whose time is not spent directly in the operation of the Project (which may be allocated by Landlord to account for the extent utilized for the Project).

(14) Any cost incurred by the gross negligence or willful misconduct of the Landlord, its agents and employees;

(15) Capital reserves;

(16) The cost of correcting defects in the initial construction of the Building or other portions of the Project;

(17) Costs and expenses of investigating, monitoring and remediating hazardous material on, under or about the Project, except as otherwise provided in this Lease; and

(18) Any costs reimbursed directly to Landlord by its insurers or other third parties.

If Landlord shall purchase any item of capital equipment or make any capital expenditure designed to result in savings or reductions in any of the elements of Operating Costs, then the costs for such capital equipment or capital expenditure are to be included within the definition of "Operating Costs" for the Lease Year in which the costs are incurred and subsequent years, on a straight-line basis, to the extent that such items are amortized over such period of time as reasonably can be estimated as the time in which such savings or reductions in Operating Costs are expected to equal Landlord's costs for such capital equipment or capital expenditure, with an interest factor equal to the prime rate of The Wall Street Journal, but in no event greater than the highest rate of interest permitted to be charged by law at the time of Landlord's having incurred said costs. If Landlord shall lease any such item of capital equipment designed to result in savings or reductions in Operating Costs, then the rentals and other costs paid pursuant to such leasing shall be included in Operating Costs for the year in which they are incurred.

B. As provided in Paragraph 7 of Exhibit B-2, Landlord hereby assigns to Tenant (to the extent assignable) all warranties, if any, received by Landlord from contractors, subcontractors, suppliers and manufacturers for materials and construction of that portion of the Premises which is the Landlord's Work but which shall be Tenant's responsibility to maintain. To the extent not assigned to Tenant, Landlord shall enforce such warranties, if any, for Tenant's benefit at no cost or liability to Landlord. Landlord's assignment of warranties shall be on a non-exclusive basis, such that Landlord shall have the right, independent of Tenant, to enforce such warranties.

C. Except to the extent of Landlord's obligations pursuant to Section 15A. above, Tenant shall keep the Premises in good repair and condition, including, without limitation, maintenance, repair, and capital repair and replacement of: (i) the interior of the Building; (ii) re-paving of the parking lot in keeping with best practices; and (iii) all Premises systems including electrical, plumbing, HVAC and life safety systems, and the fixtures and appurtenances therein, except to the extent subject to warranty hereunder, and including repairs or replacement which would otherwise be an obligation of Landlord under subparagraph A above when those are necessitated by the act, omission or negligence of Tenant or its agents, employees or invitees. Notwithstanding the foregoing, Tenant shall not be responsible for the capital cost to replace any

item constituting a part of the Base Building, the useful life of which exceeds the remaining Term of this Lease; in the event of such required replacement, Landlord shall be responsible for the cost of such replacement and Tenant shall reimburse the item pursuant to the capital expense provisions of Operating Expenses set forth above. Tenant shall also be responsible for janitorial services for the Premises consistent with best practices for property maintenance of class "A" commercial buildings. Tenant shall not suffer any damage, waste or deterioration to occur to the Premises. In the event that Tenant shall fail to properly maintain the Premises, such failure, after expiration of applicable notice and cure periods, if any, shall constitute an event of default hereunder. Upon such event, in addition to any right or remedy otherwise provided pursuant to this Lease, Landlord may, at its option, if such failure has not been corrected after thirty (30) days written notice to Tenant, (i) elect to perform such necessary maintenance or make such necessary repairs or replacement as Tenant shall have failed to make or perform, and the cost thereof shall be payable to Landlord on demand as Additional Rent, and (ii) thereafter, perform such maintenance at Tenant's expense with the cost thereof, including a fifteen percent (15%) administrative expense, chargeable to Tenant as Operating Costs. Tenant shall maintain a quarterly service contract on all HVAC systems, and shall provide Landlord evidence of the continuation of such contract during the term of this Lease. So long as Tenant is directly maintaining the Premises as provided above, Landlord agrees that its management fee shall be reduced to one percent (1%).

Section 16 – Reserved

Section 17— Reserved

Section 18—EMINENT DOMAIN.

A. If (i) the whole of the Premises or (ii) a material portion of the Project so as to render the Project unsuitable for Landlord's operations (as determined in Landlord's sole discretion), shall be acquired or condemned by eminent domain for any public or quasi-public use or purpose, then the term of this Lease shall cease and terminate as of the date of title vesting in the condemning governmental body or other authority pursuant to such proceeding and all rentals and other charges shall be paid up to that date and Tenant shall have no claim against Landlord for the value of any unexpired term of this Lease.

B. If a part of the Premises shall be acquired or condemned by eminent domain for any public or quasi-public use or purpose, and such partial taking or condemnation shall render the Premises unsuitable for the business of Tenant, then the term of this Lease shall cease and terminate as of the date of title vesting in the condemning governmental body or other authority pursuant to such proceeding and Tenant shall have no claim against Landlord for the value of any unexpired term of this Lease. In the event of a partial taking or condemnation which is not extensive enough to render the Premises unsuitable for the business of Tenant, then Landlord shall promptly restore the Premises to a condition comparable to its condition at the time of such condemnation less the portion lost in the taking, and this Lease shall continue in full force and effect except that the Fixed Annual Rent shall be reduced in proportion to the portion of the Premises lost in the taking; provided, however, there shall be no reduction of Landlord's assessment of Additional Rent as a result of such partial taking or condemnation; provided that any actual reductions in the expenses included within Additional Rent shall result in reductions of Tenant's obligations toward Additional Rent.

C. In the event of any condemnation or taking as hereinbefore provided, whether whole or partial, except as specifically provided herein, Tenant shall not be entitled to any part of the award, as damages or otherwise, for such condemnation and Landlord is to receive the full amount of such award. Tenant hereby expressly waives any right or claim to any part thereof. Although all damages in the event of any condemnation are to belong to Landlord whether such damages are awarded as compensation for diminution in value of the leasehold or the fee of the Premises, Tenant shall have the right to claim and recover from the condemning authority, but not from Landlord, such compensation as may be separately awarded or recoverable by Tenant in Tenant's own right on account of any damage to Tenant's business by reason of the condemnation and for or on account of any cost or loss to which Tenant might be put in removing or relocating Tenant's merchandise, furniture, fixtures, leasehold improvements and equipment from the Premises, provided that recovery by Tenant shall not reduce the award otherwise available to Landlord. A sale by Landlord to any authority having the power of eminent domain, either under threat of condemnation or while condemnation proceedings are pending, shall be deemed a taking under the power of eminent domain for all purposes under this Section.

Section 19—DAMAGE AND DESTRUCTION.

A. If the Premises shall be damaged by fire, the elements, unavoidable accident or other casualty, without the fault of Tenant, but are not thereby rendered untenable (including as a result of a loss of necessary access or essential service from the remainder of the Project) in whole or in part, Landlord shall at its own expense cause such damage to be repaired and the Fixed Annual Rent and Additional Rent payable by Tenant hereunder shall not be abated. If by reason of such occurrence, the Premises shall be rendered untenable only in part, Landlord shall cause the damage to be repaired, and the Fixed Annual Rent meanwhile shall be abated proportionately as to the portion of the Premises rendered untenable, until the Premises has been restored to the extent required to be restored by Landlord as required hereby. Landlord shall use commercially reasonable efforts to commence restoration and to complete restoration as soon as possible after receipt of insurance proceeds, if applicable. If the Premises shall be rendered wholly untenable by reason of such occurrence, Landlord shall cause such damage to be repaired, and the Fixed Annual Rent meanwhile shall be abated in whole, until the Premises has been restored to the extent required to be restored by Landlord as required hereby, except that Landlord shall have the right, to be exercised by notice in writing delivered to Tenant within ninety (90) days after said occurrence, to elect not to reconstruct the destroyed Premises, and in such event this Lease and the tenancy hereby created shall cease as of the date of the said occurrence. Nothing in this Section shall be construed to permit the abatement in whole or in part of Additional Rent, including without limitation charges for Operating Costs and Taxes and Assessments attributable to any period during which the Premises shall be in untenable condition, nor shall there be any abatement in Additional Rent nor the Fixed Annual Rent if such damage is caused by a negligent or intentional act or omission of Tenant. In the event Landlord elects not to repair the destroyed Premises but fails to provide notice of its election not to reconstruct the Premises as prescribed herein, Tenant may at its option cancel and terminate this Lease, as its sole and exclusive remedy against Landlord.

B. In the event that eighty percent (80%) or more of the total rentable square feet of the Building shall be damaged or destroyed by fire or other cause, notwithstanding any other provisions contained herein and that the Premises may be unaffected by such fire or other cause, Landlord shall have the right, to be exercised by notice in writing delivered to Tenant within one hundred eighty (180) days after said occurrence, to elect to cancel and terminate this Lease, provided that Landlord terminates all other similarly affected leases of the Project. Upon the giving of such notice to Tenant, the term of this Lease shall expire by lapse of time upon the third day after such notice is given, and Tenant shall vacate the Premises and surrender the same to Landlord.

C. If the Premises are destroyed or damaged during the last eighteen (18) months of the term of this Lease and the estimated cost of repair exceeds fifty percent (50%) of the Fixed Annual Rent then remaining to be paid by Tenant for the balance of the term and Landlord does not intend to reconstruct the Building, Landlord may at its option cancel and terminate this Lease as of the date of occurrence of such damage by giving written notice to Tenant of its election to do so within thirty (30) days after the date of occurrence of such damage. In the event Landlord provides such notice to terminate the Lease, Tenant shall have thirty (30) days to provide notice of its intent to extend the lease pursuant to other provisions of this Lease whereupon such Landlord notice to terminate shall be deemed rescinded. If Landlord shall not so elect to terminate this Lease, the repair of such damage shall be governed by other provisions of this Section

D. If the Premises, or portions of the Building providing access or essential services to the Premises, are destroyed or damaged by fire or other casualty, and the expected time to restore the same will exceed two hundred forty (240) days, or Landlord fails to complete restoration of the Premises, or such portions of the Building within three hundred sixty (360) days after the occurrence of the fire or other casualty. Tenant shall have the right by written notice to Landlord received by Landlord within thirty (30) days of such event, to either (i) cancel and terminate this Lease or (ii) at its sole expense, expedite repairs or reconstruction of the Premises, as its sole and exclusive remedies against Landlord. In the event of any reconstruction of the Premises under this Section, Landlord's obligation with regard to said reconstruction shall be only to the extent of Landlord's original obligation to construct and deliver the Premises pursuant to this Lease. Tenant, at its sole cost and expense, shall be responsible for all repairs and restorations in excess of that required of Landlord, such that the Premises shall be restored to its improved condition prior to such destruction. Tenant shall additionally be responsible for the replacement of its stock in trade, trade fixtures, furniture, furnishings and equipment. Tenant shall commence the installation of fixtures, equipment, and stock in trade promptly upon redelivery to it of possession of the Premises and shall diligently prosecute such installation to completion.

E. Upon any termination of this Lease under any of the provisions of this Section, each party shall be released thereby without further obligation to the other party coincident with the surrender of possession of the Premises to the Landlord except for items which have theretofore accrued and are then unpaid and for such of the other obligations of Tenant and/or Landlord as are expressly provided herein to survive the termination of this Lease, for which each party shall remain liable to the other.

Section 20—QUIET ENJOYMENT. Landlord warrants, covenants and agrees that, upon Tenant's paying on a monthly installment basis the Fixed Annual Rent and any Additional Rent required hereunder and performing all of the other covenants herein on its part to be performed, Tenant shall and may peaceably and quietly hold and enjoy possession of the Premises without hindrance by Landlord or persons claiming through or under Landlord, subject to the terms, covenants and conditions of this Lease and all existing or future underlying leases or mortgages encumbering the Park and Common Areas.

Section 21—RIGHT OF ENTRY. Upon reasonable prior notice to Tenant, Landlord and Landlord’s agents shall have the right to enter the Premises at all reasonable times, to examine and make inspections of the same, and to show them to prospective purchasers, lenders or lessees of the Building, and to make such repairs, alterations, improvements or additions as Landlord may deem reasonably necessary or desirable, and Landlord shall be allowed to take all material into and upon the Premises that may be required without the same constituting an eviction of Tenant in whole or in part, and the Rent reserved shall in no way abate while said repairs, alterations, improvements, or additions are being made unless Tenant is prevented from operating in the Premises in whole or in part, in which event Fixed Annual Rent shall be proportionately abated during said period. At Tenant’s request, such access shall be in the presence of a representative of Tenant. During the six (6) months prior to the expiration of the term of this Lease or any renewal term, Landlord may exhibit the Premises to prospective tenants or purchasers. If Tenant shall not be personally present to open and permit entry into the Premises, at any time, when for any reason an entry therein shall be necessary or permissible, Landlord or Landlord’s agents may enter the same without in any manner affecting the obligations and covenants of this Lease. Nothing herein contained, however, shall be deemed or construed to impose upon Landlord any obligation, responsibility or liability whatsoever, for the care, maintenance or repair of the Premises or the Project or any part thereof, except as otherwise herein specifically provided; except that Landlord agrees to correct any damage to the Premises or Tenant’s personal property caused by reason of Landlord’s exercise of its right of entry hereunder.

Section 22—SERVICES AND UTILITIES. Tenant shall be solely responsible for and promptly pay all charges for water, gas, electricity or any other utility used or consumed in the Premises, all of which shall be separately metered. If any such charges are not paid when due, Landlord may, at its option, pay the same, and any amount so paid by Landlord shall thereupon become due to Landlord from Tenant as Additional Rent. Unless Landlord has elected to maintain the Premises as provided in Section 15(c) above, and such interruption or failure is caused by the willful act or gross negligence of Landlord, Landlord not be liable for an interruption or failure in the supply of any such utilities to the Premises and same shall in no manner constitute an actual or constructive eviction of Tenant, nor entitle Tenant to any abatement of any Rent under this Lease.

Section 23—FORCE MAJEURE. Except as otherwise expressly provided in this Lease, if either party to this Lease, as the result of any (i) strikes, lockouts or labor disputes, (ii) inability to obtain labor or materials or reasonable substitutes therefor, (iii) war, emergency governmental regulation or delay, condemnation or civil commotion, pandemic or other public health concern regulating commerce, personal or business activities, including regulations or limitations arising from such concerns (iv) acts of God, fire, earthquake or other casualty, or (v) other conditions similar to those enumerated in this Section 23 beyond the reasonable control, other than financial, of the party obligated to perform, fails punctually to perform any obligation on its part to be performed under this Lease, after exercising its best efforts to do so, then such failure shall be excused and not be a breach of this Lease by the party in question, but only to the extent occasioned by such event. If the right of either party to take any action under or with respect to this Lease is conditioned upon the same being exercised within any prescribed period of time or at or before a named date, then such prescribed period of time and such named date shall be deemed to be extended or delayed, as the case may be, on a day-for-day basis as measured by the duration of such Force Majeure event.

Section 24—ASSIGNMENT OR SUBLETTING.

A. Tenant may not assign this Lease in whole or in part, nor sublet, or permit the use or occupancy by a party other than Tenant of, all or any portion of the Premises, without the prior written consent of Landlord in each instance, which consent shall not be unreasonably withheld, conditioned or delayed. Any attempted assignment or sublease by Tenant in violation of the terms and covenants of this provision shall constitute a default hereunder and shall be void ab initio. The consent by Landlord to any assignment or subletting shall not constitute a waiver of the necessity for such consent to any subsequent assignment or subletting. Landlord's basis for such refusal may include, without limitation, the fact that the proposed sublessee or assignee, or any person or entity which directly or indirectly, controls, is controlled by, or is under common control with, the proposed sublessee or assignee, either (i) occupies space in the Project at the time of the request for consent, or (ii) is negotiating with Landlord or has negotiated with Landlord during the six (6) month period immediately preceding the date Landlord receives Tenant's request for consent, to lease space in the Project. In the event Tenant desires to assign this Lease or sublet, or permit such occupancy of, the Premises, or any portion thereof, Tenant shall provide written notice thereof to Landlord at least sixty (60) days prior to the proposed commencement date of such subletting or assignment, which notice shall set forth the name of the proposed subtenant or assignee, the relevant terms of any sublease or assignment and copies of financial reports and other relevant financial reports and other relevant financial information of the proposed subtenant or assignee.

B. If this Lease be assigned, or if the Premises or any part thereof be underlet or occupied by any party other than Tenant, Landlord may collect rent from the assignee, subtenant or occupant, and apply the net amount collected to the rent herein reserved, but no such assignment, underletting, occupancy or collection shall be deemed a waiver of this covenant, or the acceptance of the assignee, subtenant or occupant as Tenant, or a release of Tenant from the further performance by Tenant of the covenants on the part of Tenant herein contained. Tenant shall pay as additional rents hereunder, any increase in the insurance for the Project directly attributable to Tenant's assignment or Tenant's assignee's occupancy of the Premises. This prohibition against assignment or subletting shall be construed to include a prohibition against any assignment or subleasing by operation of law, legal process, receivership, bankruptcy or otherwise, whether voluntary or involuntary, and a prohibition against any encumbrance of all and any part of Tenant's leasehold interest.

C. Notwithstanding any assignment or sublease, Tenant shall remain fully liable on this Lease and shall not be released from performing any of the terms, covenants and conditions hereof or any rents or other sums to be paid hereunder.

D. Upon any request to assign or sublet, Tenant will pay to Landlord, on demand, a sum equal to all of Landlord's costs, including reasonable attorney's fees, incurred in investigating and considering any proposed or purported assignment or pledge of this Lease or sublease of any of the Premises, regardless of whether Landlord shall consent to, refuse consent, or determine that Landlord's consent is not required for, such assignment, pledge or sublease. Provided that Tenant promptly provides to Landlord all relevant information to consider such request, such payment to Landlord hereunder shall not exceed \$2,000.00.

E. If the Tenant is a corporation whose shares are not publicly traded or is a partnership, if there shall be any change in the ownership of and/or power to vote the controlling interest of Tenant, whether such change of ownership is by sale, assignment, bequest, inheritance, operation of law or otherwise, same shall constitute an assignment of this Lease subject to Landlord's consent as above provided.

F. Anything contained in the foregoing provisions of this Section to the contrary notwithstanding, neither Tenant nor any other person having an interest in the possession, use, occupancy or utilization of the Premises shall enter into any lease, sublease, license, concession or other agreement for use, occupancy or utilization of space in the Premises which provides for rental or other payment for such use, occupancy or utilization based, in whole or in part, on the net income or profits derived by any person from the Premises leased, used, occupied, or utilized (other than an amount based on a fixed percentage or percentages of receipts or sales), and any such purported lease, sublease, license, concession or other agreement shall be absolutely void and ineffective as a conveyance of any right or interest in the possession, use occupancy or utilization of any part of the Premises.

G. Any purported sale, assignment, mortgage, transfer of this Lease or subletting of the Premises which does not comply with the provisions of this Section 24 shall be void.

H. Tenant acknowledges and agrees that any and all right and interest of Landlord in and to the Premises, the Project and the Property, and all right and interest of Landlord in this Lease, may be conveyed, assigned or encumbered at the sole discretion of Landlord at any time, provided that such conveyance, assignment or encumbrance is subject to this Lease and the rights, privileges and easements granted herein..

I. In the event Tenant desires to assign this Lease or to sublease a portion of the Premises, Landlord shall have the right and option to terminate this Lease, or the portion to be subleased for the proposed term of the sublease, which right or option shall be exercisable by written notice from Landlord to Tenant within thirty (30) days from the date Tenant gives Landlord written notice of its desire to assign or sublease. In the event Landlord elects not to terminate this Lease (within the time period described above), then such right shall be null and void. Additionally, Landlord agrees to waive such right of recapture in the event that Tenant shall have funded at least fifty percent (50%) of the initial cost of the build out of the Premises.

J. Notwithstanding the foregoing, Landlord's consent shall not be required for any assignment or sublet to a validly existing entity controlling, controlled by, in common control with Tenant, nor to any entity that succeeds to Tenant's interest in this Lease by reason of merger, or sale/acquisition of all or substantially all of the stock or assets), consolidation or reorganization; provided, however, with respect to an assignment or a sublease of all or substantially all of the Premises, such successor entity must (i) have a net worth comparable to Tenant as of the date of such assignment and/or sublet; and (ii) not conflict with any exclusive use granted to other tenants of the Project, or (iii) make any use of the Premises for other than the Permitted Use.

Section 25—LANDLORD’S REPRESENTATIONS AND WARRANTIES.

Landlord, in order to induce Tenant to enter into this Lease, hereby represents or warrants, as the case may be, as follows as of the date hereof:

A. Landlord is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Florida, and has full power and authority to enter into and perform the obligations of “Landlord” under this Lease

B. Landlord is, or prior to the Commencement Date will be, the sole fee simple owner of the Premises and such title is not subject to any exception which prohibits or limits the Landlord’s rights to enter into this Lease in accordance with its terms or prohibits or materially limits Tenant’s rights as granted under the Lease . If Landlord does not currently have fee simple title to the Premises, then Landlord has a contractual right to acquire the Premises. There is no mortgage or deed of trust encumbering the Premises as of the Effective Date, except in favor of Lender. Landlord will, upon request, deliver to Tenant at or before the completion of the Plans and Specifications, a copy of Landlord’s owner title insurance policy for the real property which includes the Premises.

C. Landlord is not a party to any agreement or litigation which could adversely affect its ability to perform its obligations under this Lease or which would constitute a default on the part of Landlord under this Lease, or otherwise adversely affect Tenant’s rights or entitlements under this Lease.

D. Landlord has not granted to any third party (other than Tenant) the authority or right to use, or otherwise permit the use of any portion of the Premises, and no part of the Premises constitutes Common Areas under the Declaration of Covenants or any other lease within the Park.

Section 26—HAZARDOUS SUBSTANCES.

A. Representations and Warranties of Landlord. Landlord hereby makes the following warranties and representations to Tenant, each of which is made to the best of Landlord’s current and actual knowledge as of the Effective Date:

(1) To the best of Landlord’s knowledge, there are no Hazardous Substances (as defined below), including, without limitation, polychlorinated biphenyls (PCB), hydrocarbons or asbestos materials, located in, on, under or about the Premises as of the Effective Date. In addition, the Premises and Landlord’s operations concerning the Premises are in compliance with all Legal Requirements regarding Hazardous Substances.

(2) There are no underground petroleum, fuel oil or other storage tanks located on or under the Property.

(3) Any handling, transportation, storage, treatment, disposal, release or use of Hazardous Substances that has occurred on the Property by Landlord on or prior to the Effective Date has been in compliance with all Legal Requirements regarding Hazardous Substances.(4) No litigation has been brought or threatened, nor any settlements reached with any governmental or private party, concerning the actual or alleged presence of Hazardous Substances on or about the Property or any disposal, release or threatened release of Hazardous Substances in or about the Property prior to the Effective Date, nor has Landlord received any notice of any violation, or any alleged violation of any Legal Requirements regarding Hazardous Substances, pending claims or pending investigations with respect to the presence of Hazardous Substances on or about the Property.

B. Indemnity by Landlord. Landlord shall indemnify, defend upon demand with counsel reasonably acceptable to Tenant, and hold Tenant harmless from and against any and all (i) liabilities, lawsuits, claims, damages, interest, penalties, fines, monetary sanctions, attorneys' fees, experts' fees and court costs, and (ii) incurred remediation costs, investigation costs and other expenses which result from or arise in any manner whatsoever out of the following: (1) the breach of any warranty or inaccuracy of any representation by Landlord contained in this Section 26, (2) the use, storage, release or disposal of Hazardous Substances in or on the Premises prior to the Effective Date in amounts that exceed minimum action levels or other minimum standards imposed by Legal Requirements regarding Hazardous Substances (except only if such presence of Hazardous Substances is the result of the acts of Tenant, its agents, employees, contractors or invitees) during the Lease Term by Landlord, and (3) Hazardous Substances affecting the Premises as identified in the ESA Report. To the extent that Tenant is held strictly liable by a court or other governmental agency of competent jurisdiction under any Legal Requirements regarding Hazardous Substances solely with respect to any of the matters specified in sub-clauses (1) to (3) above, Landlord's obligation to Tenant and the other indemnitees under the foregoing indemnification shall likewise be without regard to fault on Landlord's part with respect to the violation of any Legal Requirements regarding Hazardous Substances which results in liability to the indemnitee. Landlord's obligations and liabilities pursuant to this Section 25 shall survive the expiration or earlier termination of this Lease

C. Tenant's Covenants. Tenant covenants and agrees that Tenant shall, at Tenant's sole cost and expense, comply at all times with all Legal Requirements regarding Hazardous Substances on or about the Premises of the Park including, without limitation, Medical Waste. Tenant shall not use, store, transport, release or dispose of Hazardous Substances in or from the Premises except for such substances that are necessary components of Tenant's Permitted Use, and in such case in strict compliance with Legal Requirements regarding Hazardous Substances. Tenant agrees to execute, from time to time, at Landlord's request, affidavits, representations and the like concerning Tenant's best knowledge and belief regarding the presence of Hazardous Materials in, on, under or about the Premises, the Park or the land on which the Park is located, and Tenant's compliance with Legal Requirements regarding Hazardous Substances.

D. Indemnity by Tenant. Tenant shall indemnify, defend upon demand with reasonably acceptable counsel, and hold Landlord harmless from and against any and all (i) liabilities, lawsuits, claims, damages, interest, penalties, fines, monetary sanctions, attorneys' fees, expert's fees and court costs and (ii) reasonably incurred remediation costs, investigation costs and other expenses which result from or arise in any manner whatsoever out of the following: (1) the

use, storage, release, transportation or disposal on or about the Premises of Hazardous Substances after the Delivery Date; or (2) the exposure of any person to a Hazardous Substance stored, used, released, transported, or disposed by Tenant, its agents, employees, subtenants, assignees, licensees or contractors in or about the Premises or the Park. Except to the extent of the preceding indemnity obligation, Tenant shall have no further liability to Landlord or any other party pursuant to the Lease as a result of the presence of Hazardous Substances on or about the Premises. To the extent that Landlord is held strictly liable by a court or other governmental agency of competent jurisdiction under any Legal Requirements regarding Hazardous Substances with respect to any of the matters specified in sub-clauses (1) to (2) above, Tenant's obligation to Landlord and the other indemnitees under the foregoing indemnification shall likewise be without regard to fault on Tenant's part with respect to the violation of any Legal Requirements regarding Hazardous Substances which results in liability to the indemnitee. Tenant's obligations and liabilities pursuant to this Section 26D. shall survive the expiration or earlier termination of this Lease.

E. Notification. Landlord and Tenant shall each give written notice to the other as soon as reasonably practicable of (i) all matters required to be disclosed to the other party under applicable Legal Requirements regarding Hazardous Substances, (ii) any communication received from any governmental authority concerning any Hazardous Substances which relates to the Premises; and (iii) any release of Hazardous Substances known by such party to have occurred on the Premises and which constitutes a violation of any Legal Requirements regarding Hazardous Substances.

G. Delay or Interference of Use. If, during the performance of Landlord's Work, Hazardous Substances are discovered which must be Remediated (as defined below) to comply with all applicable Legal Requirements regarding Hazardous Substances, Landlord shall as a condition to Tenant's obligations under this Lease, at its sole cost and expense, perform, or cause to be performed, such Remediation and any other work required to bring the Premises into compliance with all applicable Legal Requirements regarding Hazardous Substances (including the execution of any and all waste manifests or other documents required by the applicable governmental authorities in connection therewith) and if required to be performed by Landlord during the Term after completion of Landlord's Work, Landlord shall perform such work in a manner that minimizes interference with Tenant's use of the Premises. If Remediation is required during Landlord's Work pursuant to this Section 26(F)., Landlord shall use reasonable efforts to complete such Remediation on or before the Commencement Date and shall use its best efforts to minimize any delays to the construction of Landlord's Work. Notwithstanding the foregoing, any actual delay in the completion of Landlord's Work resulting from the presence of Hazardous Substances or Landlord's Remediation pursuant hereto shall delay the Commencement Date commensurately, but in no event later than the Outside Commencement Date

H. Defined Terms.

(1) "Hazardous Substance" shall mean any substance or material defined or designated as hazardous or toxic waste, hazardous or toxic material, a hazardous or toxic substance, or other similar term, by any federal, state or local environmental statute, regulation or ordinance presently in effect or which may be promulgated in the future, as such statutes, regulations and/or ordinances may be supplemented or amended from time to time, including without limitation, any substance (a) containing petroleum, crude oil or any fraction thereof; (b) containing polychlorinated biphenyls (PCBs); (c) containing asbestos; (d) containing mold-producing organisms; or (e) which is radioactive. For purposes of Tenant's Permitted Use, Hazardous Substances also shall include Medical Waste.

(2) "Legal Requirements regarding Hazardous Substances" shall mean any Legal Requirements applicable to the use, storage, handling, disposal or removal of Hazardous Substances, including, without limitation, the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. § 9601 et seq., and as hazardous wastes under the Resource Conservation and Recovery Act, 42 U.S.C. § 6010, et seq., any chemical substance or mixture regulated under the Toxic Substance Control Act of 1976, as amended, 15 U.S.C. § 2601, et seq., any "toxic pollutant" under the Clean Water Act, 33 U.S.C. § 466 et seq., as amended, any hazardous air pollutant under the Clean Air Act, 42 U.S.C. § 7401 et seq., hazardous materials identified in or pursuant to the Hazardous Materials Transportation Act, 49 U.S.C. § 1802, et seq., and any hazardous or toxic substances or pollutant regulated under any other Requirements).

(3) "Medical Waste" shall mean any solid, semisolid, gaseous, or liquid waste which is generated or utilized in the diagnosis, treatment (e.g., provisions of medical services), immunization or performance of a service to the body of human beings, and for greater certainty shall include all waste generated by Tenant in relation to its use, and shall include the use of licensed medical waste management companies.

(4) "Remediated" or "Remediation" shall mean the necessary actions to comply with applicable Legal Requirements with respect to the unlawful presence of, or suspected discharge of, a Hazardous Substance. Remediation may include, without limitation: environmental investigation, monitoring and sampling; installation, maintenance and removal of monitoring wells; removal, treatment, neutralization or containment of any Hazardous Substance; storage of excavated materials; and installation, maintenance, storage and removal of machinery and equipment used in connection with Remediation.

Section 27—DEFAULT.

A. Events of Default. Upon the happening of one or more of the events set forth below in (1) to (7), inclusive (any of which is referred to hereinafter as an "Event of Default"), Landlord shall have any and all rights and remedies hereinafter set forth:

(1) If Tenant shall default in the payment of Fixed Annual Rent, any Additional Rent or any other sums payable by Tenant for more than five (5) days after written notice from Landlord, provided that Landlord shall have no obligation to give more than two (2) such notices in any consecutive 12-month period;

(2) If Tenant shall default in the performance of any non-monetary covenants or agreements of this Lease and said default shall continue for thirty (30) days after written notice thereof, or in the event that the default be of such a nature as cannot with diligent effort be cured within said thirty (30) day period, if Tenant shall not commence to cure within said period and diligently prosecute remedial efforts to completion within a reasonable time thereafter, not to exceed one hundred eighty (180) days;

(3) If a petition in bankruptcy under any present or future bankruptcy laws (including but not limited to reorganization proceedings) be filed by or against the Tenant or any other entity responsible for the obligations of Tenant under this Lease, and such petition is not dismissed within thirty (30) days from the filing thereof, or in the event Tenant or any other entity responsible for the obligations of Tenant under this Lease is adjudged a bankrupt;

(4) If an assignment for the benefit of creditors is made by Tenant or any other entity responsible for the obligations of Tenant under this Lease;

(5) If an appointment by any court of a receiver or other court officer of Tenant's property or of the property of any other entity responsible for the obligations of Tenant under this Lease, and such receivership is not dismissed within thirty (30) days from such appointment;

(6) If without thirty (30) days' prior written notice to Landlord, Tenant removes, attempts to remove, or permits to be removed from the Premises, except in the usual course of trade, substantially all or a material portion of the goods, furniture, effects or other property of the Tenant brought thereon; or

(7) If Tenant, before the expiration of the term of this Lease, and without the written consent of the Landlord, uses the same for purposes other than the permitted use for which the same are hereby leased.

B. Remedies of Landlord. If any Event of Default occurs, Landlord shall have the right, at the option of Landlord, to exercise the following remedies:

(1) Declare the entire balance of all forms of Rent due hereunder for the remainder of the term of this Lease (reduced to present value on such date utilizing the Prime Rate as reflected in The Wall Street Journal on the date of such default) (the "Accelerated Rent") to be due and payable and may collect the same by distress or otherwise. Notwithstanding the foregoing, Landlord agrees that provided Tenant pays the Accelerated Rent within thirty (30) days of written demand (which shall be accompanied by a calculation of the Accelerated Rent in accordance with this Lease), then Landlord agrees that for a period of two (2) years after such payment, Landlord shall (i) seek to mitigate Tenant's damages by re-letting the Premises to a tenant acceptable to Landlord, and in the event of re-letting during such period, shall refund to Tenant that portion of the Accelerated Rent which has been mitigated as then so determined (which shall take into account all expenses incurred as a result of such re-letting, including without limitation, any brokerage, attorney fees, tenant improvements, rent concessions or other expenses); or (ii) upon written request of Tenant, shall permit Tenant access to the Premises, through a licensed broker acting on Tenant's behalf, and shall cooperate with Tenant so that Tenant may mitigate its damages directly by presenting to Landlord, a tenant acceptable to Landlord, in Landlord's sole but reasonable judgment, who thereafter enters into a lease of the Premises with Landlord, in which event Landlord shall refund to Tenant in the same manner as subsection (i) above

(2) Terminate this Lease and any right of renewal thereof, and retake possession of the Premises; or

(3) Without terminating this Lease, re-enter and re-let the Premises, or any part thereof, as the agent and for the account of Tenant, upon such terms and conditions as Landlord may deem advisable or satisfactory, in which event the rents received on such re-letting shall be applied first to the expenses of such re-letting and collection including but not limited to, necessary renovation and alterations of the Premises, reasonable attorney's fees, any real estate commissions paid, and thereafter toward payment of all sums due or to become due Landlord hereunder, and if a sufficient sum shall not be thus realized or secured to pay such sums and other charges, (i) at Landlord's option, Tenant shall pay Landlord any deficiency immediately upon demand, notwithstanding Landlord may have received periodic rental in excess of the periodic rental stipulated in this Lease in previous or subsequent rental periods, and Landlord may bring an action to recover same as such deficiency shall arise, or (ii) at Landlord's option, the entire deficiency which is subject to ascertainment for the remaining term of this Lease, shall be immediately due and payable by Tenant. Nothing herein, however, shall be construed to require Landlord to reenter and re-let in any event. Landlord shall not, in any event, be required to pay Tenant any surplus of any sums received by Landlord on a re-letting of said Premises in excess of the rent provided in this Lease. Once Landlord has collected the accelerated amount owed by Tenant to Landlord, Tenant shall automatically be released from all liability under the terms of this Lease.

C. If any Event of Default occurs, Landlord, in addition to other rights and remedies it may have, shall have the right to remove all or any part of Tenant's property from the Premises and any property removed may be stored in any public warehouse or elsewhere at the cost of, and for the account of Tenant and except as provided under Florida law, the Landlord shall not be responsible for the care or safekeeping thereof whether in transport, storage or otherwise, and Tenant hereby waives any and all claim against Landlord for loss, destruction and/or damage or injury which may be occasioned by any of the aforesaid acts.

D. No such re-entry or taking possession of the Premises by Landlord shall be construed as an election on Landlord's part to terminate this Lease unless a written notice of such intention is given to Tenant. Notwithstanding any such re-letting without termination, Landlord may at all times thereafter elect to terminate this Lease for such previous default. To the extent permitted under the laws of the state of Florida, any such re-entry shall be allowed by Tenant without hindrance (except as provided by any and all applicable laws of the State of Florida), and Landlord shall not be liable in damages for any such re-entry, or guilty of trespass or forcible entry.

E. In the event of a breach or threatened breach of any covenant of this Lease, Landlord shall have the right of injunction. Any and all rights, remedies and options given in this Lease to Landlord shall be cumulative and in addition to and without waiver of, or in derogation of, any right or remedy given to it under any law now or hereafter in effect or in equity .

F. If Tenant shall default in the performance of any provision of this Lease on Tenant's part to be performed (after giving account for any notice or cure period as may be provided with respect to Tenant's performance), Landlord may perform the same for the account of Tenant and Tenant shall promptly reimburse Landlord for any expense incurred, which expenses shall be deemed to be Additional Rent.

G. It is expressly agreed that the forbearance on the part of the Landlord in the institution of any suit or entry of judgment for any part of the Rent herein reserved to the Landlord, shall in no way serve as a defense against nor prejudice a subsequent action for such Rent. The Tenant hereby expressly waives Tenant's right to claim a merger or waiver of such subsequent action in any previous suit or in the judgment entered therein. Furthermore, it is expressly agreed that claims for liquidated Fixed Annual Rent may be regarded by the Landlord, if it so elects, as separate and independent claims capable of being separately assigned.

H. Default by Landlord. In the event of any default by Landlord under this Lease, Tenant shall promptly give written notice of such default to Landlord. Landlord agrees to use reasonable diligence to complete the cure of such default within thirty (30) days after receipt of written notice from Tenant, provided that in the event any default is of such a nature that it cannot be cured within the thirty (30) day period, Landlord shall have a reasonable time in which to complete the cure thereof. Notwithstanding the foregoing, if Landlord fails to cure, or to initiate reasonable efforts to cure, said default within a sixty (60) day period, then Tenant may either (i) elect to perform Landlord's obligation in a commercially reasonable manner so as to cure such default and recover from Landlord the reasonable expenses incurred by Tenant completing such cure and seek reimbursement within thirty (30) days or if not paid by Landlord within said thirty (30) days, be entitled to offset Rent in the amount so expended, or (ii) elect to terminate this Lease by delivering written notice thereof to Landlord; provided, however, Tenant may elect this termination remedy only if Tenant is unable, as a result of the Landlord's Default, to operate its business in the Premises in a commercially reasonable manner.

Section 28—LEGAL EXPENSES.

A. In the event that after notice to Tenant and expiration of any Cure Period provided for in this Lease, it shall become necessary for Landlord to employ the services of an attorney to enforce any of its right under this Lease or to collect any sums due to it under this Lease or to remedy the breach of any covenant of this Lease on the part of Tenant to be kept or performed, regardless of whether suit be brought, Tenant shall pay to Landlord such reasonable fee as shall be charged by Landlord's attorney for such services. Should Landlord prevail in a suit brought for the recovery of possession of the Premises, or for rent or any other sum due Landlord under this Lease, or because of the default of any of Tenant's covenants under this Lease, Tenant shall pay to Landlord all expenses of such suit and any appeal thereof, including reasonable attorneys' fees.

B In the event that it shall become necessary for Tenant to employ the services of an attorney to judicially enforce any of its rights under this Lease or to collect any sums due to it under this Lease or to remedy the material breach of any covenant of this Lease on the part of Landlord to be kept or performed which is not corrected by Landlord within a reasonable period after written notice from Tenant to Landlord, Landlord shall pay to Tenant such reasonable fee as shall be charged by Tenant's attorney for such services. Should Tenant prevail in a suit brought, because of the default of any of Landlord's covenants under this Lease, Landlord shall pay to Tenant all expenses of such suit and any appeal thereof, including reasonable attorneys' fees.

Section 29—INSURANCE

A. Property Insurance on Premises. Tenant shall keep the buildings, improvements, and equipment constituting the Premises continuously insured throughout the Lease Term (and any other period during which Tenant is in possession of the Premises), for the benefit of Landlord against loss or damage by fire and other hazards included in a standard fire insurance policy with extended coverage endorsement in an amount equal to the greater of (i) 80% of the then replacement value of the Premises with an inflation rider or (ii) the full insurable value of the Premises.

B. Liability and other coverages. Tenant agrees to maintain, throughout the Lease Term (and any other period during which Tenant is in possession of the Premises), at Tenant's sole cost and expense, (i) comprehensive general public liability insurance in standard form against claims for bodily injury or death or property damage occurring in or upon the Premises, effective from the date Tenant enters into possession and during the term of this Lease and having a combined single limit amount of not less than One Million Dollars (\$1,000,000.00) per occurrence and Two Million Dollars (\$2,000,000.00) in the aggregate in primary coverage and Ten Million Dollars (\$10,000,000.00) in excess liability coverage for injury to one person in one accident, occurrence or casualty, or for injuries to more than one person in one accident, occurrence or casualty; (ii) property damage insurance on Tenant's alterations and personal property, including furniture, fixtures, and equipment located in the Premises in an amount at not less than their full insurable value, but not less than One Million Dollars (\$1,000,000.00) for damage to property on any one occurrence; (iii) worker's compensation and employer's liability insurance in compliance with applicable legal requirements; (iv) business interruption insurance with limit of liability representing loss of at least approximately six (6) months of income ; and (v) any other form of insurance or endorsements which Landlord or any mortgagee of the Premises shall reasonably require from time to time, in form, in amounts and for risks against which are consistent with commercially reasonable terms and Tenant's use.

C. Any insurance policies required hereunder shall name Landlord, Lender, Landlord's property manager and service provider as an additional insured and shall provide that they may not be modified or terminated without thirty (30) days advance notice to Landlord, and Tenant shall provide a certificate of insurance to Landlord adding Landlord as an additional insured to its primary liability and excess liability policies. Tenant may provide for replacement policies through different insurers or insurance brokers from time to time, subject, however, to Tenant's obligation to continuously maintain such insurance as provided in this subsection, and provided that such insurers meet all requirements of this provision. All insurance required to be carried by Tenant pursuant to the terms of this Lease shall be effected under policies issued by insurers permitted to do business in the State of Florida and rated in Best's Insurance Guide, or any successor thereto (or, if there be none, an organization having a national reputation) as having a general policyholder rating of "A-" and a financial rating of at least "X". Tenant shall furnish to Landlord within thirty (30) days from the date hereof evidence of such insurance coverage by way of a copy of the declarations page of the insurance policy signed by the underwriter, and any amendments and endorsements thereto, and a certificate of insurance clearly evidencing each of the coverages and provisions set forth in this paragraph. Upon (i) thirty (30) days prior written notice without cause or (ii) immediately upon Tenant's default in obtaining or delivering the policy or certificate for any such insurance or Tenant's failure to pay the charges, Landlord may procure or pay the charges for any such policy or policies and charge Tenant for such expenses as Additional Rent. The limits of insurance specified in this Section may be adjusted upward by Landlord, if consistent with commercially reasonable standards, in the event that Landlord shall determine that because of: (i) the lapse of time, (ii) any unexpected rates of inflation, (iii) the size of the Premises, (iv) the use of the Premises by Tenant or (v) for any reason similar to those specified in clauses (i) through (iv) immediately above in this paragraph, the limits specified offer inadequate protection to Landlord.

D. Tenant shall at all times during the term hereof, and at its cost and expense, maintain in effect policies of insurance covering all Alteration made by or on behalf of Tenant and Tenant's fixtures and equipment located on the Premises, in an amount not less than their full replacement value, including any Alterations made by Tenant, in amount and with such deductibles as determined by Tenant and Landlord based upon commercially reasonable terms, providing protection against any peril included within the standard classification of "All Risk Coverage," together with insurance against sprinkler damage, vandalism, theft and malicious mischief. The proceeds of such insurance, so long as this Lease remains in effect, shall be used to repair or replace such fixtures and equipment and Alterations so insured.

E. Landlord and Tenant waive, unless said waiver should invalidate any such insurance, their right to recover damages against each other for any reason whatsoever to the extent the damaged party recovers indemnity from its insurance carrier. Any insurance policy procured by either Tenant or Landlord which does not name the other as a named insured shall, if obtainable, contain an express waiver of any right of subrogation by the insurance company, including but not limited to Tenant's workers' compensation insurance carrier, against Landlord or Tenant, whichever the case may be.

F. Tenant at its expense shall comply with all requirements of the Board of Fire Underwriters, or any other similar body affecting the Premises, and shall not use the Premises in a manner which shall increase the rate of fire insurance or other insurance of Landlord or of any other tenant, over that in effect as of the Commencement Date and applicable to the Permitted Use.

G. Tenant shall provide certificates of insurance (Accord Form #27) to Landlord for all vendors and contractors authorized by Tenant to provide services for the Premises in connection with the Alterations, evidencing the general liability and workers compensation coverages of such vendors and contractors. Landlord must be added as additional insured to the general liability and excess liability policies of such vendors and contractors, and the minimum limit of liability insurance for such vendors and contractors shall be One Million Dollars (\$1,000,000.00) and the minimum limit of excess liability coverage for such vendors and contractors shall be Two Million Dollars (\$2,000,000.00).

Section 30—INDEMNIFICATION OF LANDLORD. Tenant shall not do or permit any act or thing to be done in, on or about the Premises, the Building or the Project that may subject Landlord to any liability or responsibility for injury, damage to persons or property or to any liability by reason of the existence or application of, compliance with or violation of any Requirement, but shall exercise such control over the Premises as to protect the Landlord fully against any such liability and responsibility. Tenant shall indemnify and save harmless the Landlord from and against (a) all claims of whatever nature against the Landlord arising from any negligent act or omission of Tenant, its employees, customers, invitees, vendors, or persons within Tenant's control, (b) all claims against the Landlord arising from any accident, injury or damage whatsoever caused to any person or to the property of any person and occurring in or about the Premises during the Term or during Tenant's occupancy of the Premises, (c) all claims against the Landlord arising from any accident, injury or damage occurring outside of the Premises but anywhere within or

about the Premises, Building or the Project, where such accident, injury or damage results or is claimed to have resulted from a negligent act or omission of Tenant, its employees, customers, invitees, vendors, or persons within Tenant's control, and (d) any breach, violation or non-performance of any covenant, condition or agreement contained in this Lease to be fulfilled, kept, observed and performed by Tenant. This indemnity and hold harmless agreement shall include indemnity from and against any and all liability, fines, suits, demands, costs and expenses of any kind or nature (including, without limitation, attorneys' fees and disbursements), including those arising from the Landlord's negligence, (but excluding Landlord's gross negligence and/or willful misconduct), incurred in or in connection with any such claim or proceeding brought thereon, and the defense thereof.

If any claim, action or proceeding is made or brought against the Landlord, against which claim, action or proceeding Tenant is obligated to indemnify Landlord pursuant to the terms of this Lease, then, upon demand by the Landlord, Tenant, at its sole cost and expense, shall resist or defend such claim, action or proceeding in the Landlord's name, if necessary, by such attorneys as the Landlord may select, including, without limitation, attorneys for the Landlord's insurer. Notwithstanding the foregoing, if such attorneys shall be defending both Tenant or any persons within Tenant's control and Landlord, the Landlord may retain its own attorneys to defend or assist in defending any claim, action or proceeding, and Tenant shall pay the reasonable fees and disbursements of such attorneys. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

Section 31—END OF TERM At the expiration of this Lease, Tenant shall peaceably give up and surrender the Premises (including any alterations and additions made by Tenant or Landlord to the Premises during the Term) to Landlord, broom clean and in good order, repair and condition, excepting only reasonable wear and tear, damage by casualty or condemnation and other causes beyond Tenant's reasonable control, and damage that is Landlord's responsibility to repair hereunder, provided that Tenant shall, at Landlord's option (unless Landlord shall have agreed at the time of approval of such alterations that removal would not be required) remove any alterations and additions made to the Premises during the Lease Term by Tenant (or by Landlord on Tenant's behalf) and Tenant shall remove all personal property and trade fixtures of Tenant from the Premises at the termination of this Lease. Unless Landlord provides written notice prior to approval of the Fitout that Landlord reserves the right to require Tenant to remove any portion of such Fitout as a condition to its approval, all Fitout shall be surrendered with the Premises at the end of the Term and Tenant shall not be required to remove same nor shall Tenant have the right to remove same. Should Tenant fail to remove any of its trade fixtures, whether permanently attached or not, and other personalty, Landlord may have them removed and disposed of in any manner permitted by Legal Requirements at the risk of Tenant; the expense of such removal, disposal and repair necessitated by such removal shall be borne by Tenant or reimbursed by Tenant to Landlord. If Tenant remains in possession of the Premises after the expiration or sooner termination of this Lease, then in the absence of an agreement in writing between the Parties, Tenant shall be deemed a tenant at sufferance. Tenant shall indemnify, defend and save Landlord harmless against all costs, claims, loss or liability resulting from delay by Tenant in so surrendering the Premises, including, without limitation, any claims made by any succeeding tenant founded on such delay. The parties recognize and agree that the damage to Landlord resulting from any failure by Tenant timely to surrender possession of the Premises as aforesaid will be substantial, will exceed the amount of the Fixed Annual Rent theretofore payable hereunder, and accurate

measurement will be impossible. Tenant therefore agrees that if possession of the Premises is not surrendered to Landlord on the date of the expiration or sooner termination of this Lease, then, unless Landlord shall have consented to Tenant's holding over, Tenant shall pay Landlord as liquidated damages for each month and for each portion of any month prorated on a daily basis, during which Tenant holds over in the Premises after expiration or termination of the term of this Lease without consent, a sum equal to one hundred fifty percent (150%) of the Fixed Annual Rent and Additional Rent which was payable per month under this Lease during the last month of the terms thereof. The aforesaid provision of this Section shall survive the expiration or sooner termination of this Lease.

Section 32—SIGNS. Tenant shall not place any signs or other advertising matter or material on the exterior of the Building, anywhere upon the Common Areas, or in any portion of the interior of the Premises which is visible beyond the Premises (except for Tenant's name and logo in the Tenant's reception area inside the Premises), without the prior written consent of Landlord, which consent shall not be unreasonably withheld. Landlord conceptually approved Tenant's installation of one sign on the south side of the Building with Tenant's identifying logo or other identification, subject to Landlord's approval as to size, installation and design. Any lettering or signs placed on the interior of said Building shall be for directional purposes only, and such signs and lettering shall be of a type, kind, character and description first approved by Landlord.

Section 33—NOTICES. All notices, demands or other writings in this Lease provided to be given, made or sent by either party hereto to the other shall be deemed to have been fully given, if made in writing and delivered in person or by public courier (or any nationally recognized overnight delivery service such as Fed Ex or UPS) or deposited in the United States mail certified or registered, return receipt requested and postage prepaid and addressed to the parties at their respective post office addresses, as listed in Summary Section 1Y. and Section 1Z. hereof, or with respect to Tenant, at the Premises. The address to which any notice, demand or other writing may be given, made or sent to either party may be changed by written notice given by such party as above provided.

Section 34—NON-WAIVER. No references to any specific right or remedy shall preclude either party from exercising any other right or from having any other remedy or from maintaining any action to which it may otherwise be entitled at law or in equity. The failure of, or delay by, either party in one or more instances to insist upon strict performance or observance of one or more of the covenants or conditions hereof or to exercise any remedy, privilege or option reserved to either party, shall not be construed as a waiver of such covenant or condition or of the right to enforce the same or to exercise such privilege, option or remedy. The receipt by Landlord of Rent or any other payment required to be made by Tenant, or any part thereof, shall not be a waiver of any other Additional Rent or payment then due, nor shall such receipt, though with knowledge of the breach of any covenant or condition hereof, operate as or be deemed a waiver by Landlord of any of the provisions hereof, or of any of Landlord's rights, remedies, privileges or options hereunder. No waiver by Landlord of any breach by Tenant under this Lease or any breach by any other tenant under any other lease of any portion of the Building shall affect or alter this Lease in any way whatsoever. Any such waiver must be in writing and signed by Landlord. No act or omission of Landlord or its agents shall constitute an actual or constructive eviction, unless Landlord shall have first received written notice of Tenant's claim and shall have had a reasonable opportunity to remedy to such claim.

Section 35—SUBORDINATION AND ATTORNMENT. Tenant hereby subordinates its rights hereunder to the lien of any ground or underlying leases, any mortgage or mortgages, or the lien resulting from any other method of financing or refinancing, now or hereafter in force against the property or Park of which the Premises are a part, upon the Common Areas and any buildings hereafter placed upon the Property of which the Premises are a part, and to all advances made or hereafter to be made upon the security thereof; provided that the holder thereof executes a commercially reasonable non-disturbance agreement providing that this Lease shall not terminate as long as Tenant is not in default under this Lease, in the event of the foreclosure of such lien, or any conveyance in lieu thereof and that Tenant's rights under this Lease shall continue in full force and effect and its possession shall be undisturbed, except in accordance with the provisions of this Lease. Except as provided above, this Section shall be self-operative and no further instrument of subordination shall be required by any mortgagee, but Tenant agrees upon request of Landlord, from time to time, to promptly execute and deliver any and all documents evidencing such subordination, and failure to do so (following any applicable notice and cure period hereunder) shall constitute a default under this Lease. In the event any proceedings are brought for the foreclosure of, or in the event of exercise of the power of sale under, any mortgage made by Landlord covering the Premises or Common Areas, or in the event a deed is given in lieu of foreclosure of any such mortgage, Tenant shall attorn to the purchaser, or grantee in lieu of foreclosure, upon any such foreclosure or sale and recognize such purchaser, or grantee in lieu of foreclosure, as Landlord under this Lease and said party shall assume the obligations of Landlord provided that Tenant's occupancy hereunder shall not be disturbed.

Section 36—ESTOPPEL CERTIFICATES. From time to time, Tenant, within ten (10) days after written request by Landlord, will deliver to Landlord a statement in writing certifying that this Lease is unmodified and in full force and effect (or if there shall have been modification, that the same is in full force and effect as modified and stating the modification), the dates to which rent and other charges have been paid and stating whether or not the Landlord is in default in performance of any covenant, agreement, or condition contained in this Lease and, if so, specifying each such default of which Tenant may have knowledge, and such additional information as any mortgagee or purchaser of the Project may require. The failure of Tenant to execute, acknowledge and deliver to the Landlord a statement in accordance with the provisions of this Section within said ten (10) day period and within an additional five (5) days after notice of such failure, shall constitute an acknowledgment by the Tenant, which may be relied on by any person holding or proposing to acquire an interest in the Project or any party thereof or the Premises or this Lease from or through the other party, that this Lease is unmodified and in full force and effect and shall constitute, as to any person entitled as aforesaid to rely upon such statements, waiver of any defaults which may exist prior to the date of such notice. It is agreed that nothing contained in the provisions of this Section shall constitute waiver by Landlord of any default in payment of rent or other charges existing as of the date of such notice and, unless expressly consented to in writing by Landlord, and Tenant shall still remain liable for the same.

Section 37—RULES AND REGULATIONS. Tenant agrees to fully comply with all rules and regulations shown in Exhibit G attached hereto and by this reference incorporated herein, and such amendments or revisions as shall be uniformly applied to all occupants of the Park from time to time during the Lease term; provided the same do not unreasonably affect Tenant's rights and obligations under this Lease in any materially negative way, including use of the Premises for the Permitted Use.

Section 38—BROKER. Each Party represents and warrants to the other that it has neither consulted nor negotiated with any broker or finder with respect to the Premises other than Avison Young and CBRE Boston with respect to Tenant, and such representing Party agrees to indemnify, defend and save the other Party harmless from and against any claims for fees or commissions from anyone with whom such representing Party has dealt in connection with the Premises or this Lease, including without limitation any attorney's fees incurred by the other Party in connection with said claims. Brokerage commissions shall be paid to Avison Young and CBRE Boston by Landlord per separate agreement between Concept Development, Inc and such parties.

Section 39—SUCCESSORS AND ASSIGNS. All rights and liabilities herein given to, or imposed upon, the respective parties hereto shall extend to and bind the several respective heirs, executors, administrators, successors, and permitted assigns of the said parties; and if there shall be more than one Tenant, they shall be bound jointly and severally by the terms, covenants and agreements herein. No rights, however, shall inure to the benefit of any assignee of Tenant unless the assignment to such assignee has been approved by Landlord in writing as provided herein. Nothing contained in this Lease shall in any manner restrict Landlord's right to assign or encumber this Lease and, in the event Landlord sells its interest in the Building and the purchaser expressly assumes in writing Landlord's obligations and covenants in this Lease, Landlord shall thereupon be relieved of all further obligations hereunder.

Section 40—NO RECORDING; MEMORANDUM OF LEASE. This Lease shall not be recorded; however, a memorandum of this Lease shall be executed, in recordable form, by both parties concurrently with their execution of this Lease and recorded by Landlord, at Landlord's expense, with the Clerk of Circuit Court of Alachua County, Florida. The Parties agree to execute and record a modification of such memorandum to establish the actual Commencement Date and Expiration Date of this Lease, as applicable. Such memorandum of this Lease shall include, without limitation, a statement of the Term, Renewal Terms, Commencement Date, Expiration Date, the Purchase Option (as herein defined) and the Right of First Refusal (as herein defined).

Section 41—PARKING. Subject to Section 60 below, Tenant shall have the exclusive use of the driveways and footways and all parking areas located on the Premises, which shall contain no less than 47 spaces for Tenant's use. Landlord shall not be liable for any loss, damage, theft or injury occurring to person or property within the parking areas of the Building or Park.

Section 42—CONSTRUCTION OF LANGUAGE. The terms "Lease", "Lease Agreement" or "Agreement" shall be inclusive of each other, and shall include renewals, extensions or modifications of this Lease. The word "Tenant" shall be deemed and taken to mean each and every person or party mentioned as a Tenant herein, and the permitted sublessees, assigns and successors thereof. The use of the neuter singular pronoun to refer to Landlord or Tenant shall be deemed a proper reference even though Landlord or Tenant may be an individual, a partnership, a corporation, or a group of two or more individuals or corporations. The necessary grammatical changes required to make the provisions of this Lease apply in the plural sense where there is more than one Landlord or Tenant and to either corporations, associations, partnerships, or individuals, males or females, shall in all instances be assumed as though in each case fully expressed.

Section 43—CAPTIONS AND SECTION NUMBERS. The captions, section numbers, and article numbers appearing in this Lease are inserted only as a matter of convenience and in no way define, limit, construe, or describe the scope or intent of such sections or articles of this Lease nor in any way affect this Lease.

Section 44—LANDLORD’S CONSENT. Except as otherwise expressly stated in this Lease, any consent or approval required to be obtained from Landlord may be granted by Landlord in its sole discretion. In any instance in which Landlord agrees not to act unreasonably, Tenant hereby waives any claim for damages against or liability of Landlord which is based upon a claim that Landlord has unreasonably withheld or unreasonably delayed any consent or approval requested by Tenant, and Tenant agrees that its sole remedy shall be an action or proceeding to enforce any declaratory judgment. If with respect to any required consent or approval Landlord is required by the express provisions of this Lease not to unreasonably withhold or delay its consent or approval, and if it is determined in any such proceeding referred to in the preceding sentence that Landlord acted unreasonably, the requested consent or approval shall be deemed to have been granted; however, Landlord shall have no liability whatsoever to Tenant for its refusal or failure to give such consent or approval. Tenant’s sole remedy for Landlord’s unreasonably withholding or delaying consent or approval shall be as provided in this Section.

Section 45—LIABILITY OF LANDLORD. Tenant shall look solely to the estate and property of Landlord in the land and building improvements comprising the Project for the collection of any judgment, or in connection with any other judicial process, requiring the payment of money by Landlord in the event of any default by Landlord with respect to any of the terms, covenants and conditions of this Lease to be observed and performed by Landlord, including without limitation any and all policies of insurance maintained in connection with Landlord’s ownership, operation and construction of the Project, and no other property or estates of Landlord shall be subject to levy, execution or other enforcement procedures for the satisfaction of Tenant’s remedies and rights under this Lease. The word “Landlord” as used in this Lease shall mean only the owner from time to time of Landlord’s interest in this Lease. In the event of any assignment of Landlord’s interest in this Lease, the assignor shall no longer be liable for the performance or observation of any agreements or conditions on the part of Landlord to be performed or observed accruing after the effective date of such assignment.

Section 46—TIME OF ESSENCE. Time is of the essence with respect to the performance of every provision of this Lease in which time of performance is a factor.

Section 47—ACCORD AND SATISFACTION. No payment by Tenant or receipt by Landlord of a lesser amount than the Rent herein stipulated to be paid shall be deemed to be other than on account of the earliest stipulated Rent, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as rent be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord’s right to recover the balance of such rent or pursue any other remedy provided herein or by law. No acceptance of any Rent by Landlord shall constitute a waiver by Landlord of any prior or subsequent default of Tenant, notwithstanding any knowledge of such default by Landlord at the time of receipt of such Rent.

Section 48—ENTIRE AGREEMENT. The Exhibits attached to this Lease and the terms and conditions set forth therein are incorporated in this Lease as if fully set forth herein. This Lease and such Exhibits constitute all the covenants, promises, agreements, conditions and understandings between Landlord and Tenant concerning the Premises and the Park and there are no covenants, promises, conditions or understandings, either oral or written, between them other than are herein set forth. Neither Landlord nor Landlord's agents have made nor shall be bound to any representations with respect to the Premises, the Park or the Common Areas except as expressly set forth in this Lease and such Exhibits, and all representations, either oral or written, shall be deemed to be merged into this Lease and such Exhibits. Except as herein otherwise provided, no subsequent alteration, change or addition to this Lease or such Exhibits shall be binding upon Landlord or Tenant unless reduced to writing and signed by both Landlord and Tenant.

Section 49—TENANT'S AUTHORITY AND FINANCIAL REPORTING. Tenant represents and warrants that Tenant maintains its good standing with the State of its incorporation, and has been and is qualified to do business in the state in which the Park is located, that the corporation has full right and authority to enter into this Lease, and that all persons signing on behalf of the corporation sign only in their official capacity and not personally, but said persons were authorized to do so by appropriate corporate actions. Tenant agrees to furnish promptly upon request a corporate resolution, proof of due authorization by directors, or other appropriate documentation evidencing the due authorization of Tenant to enter into this Lease.

In addition to the forgoing, in the event that Tenant shall cease to be a publicly traded company, or if Tenant's financial information is no longer publicly available, Tenant further agrees that Tenant will deliver or cause to be delivered to Landlord such financial statements, tax returns, and information as may be requested by Landlord from time to time, including, without limitation, the following:

- (i) Annual Reports: Within one hundred twenty (120) days after the end of each calendar year, a profit and loss statement and financial statement of Tenant and each guarantor for such year, and a balance sheet as of the end of such year, in a form reasonably satisfactory to Landlord. Tenant agrees to provide to Landlord an update or amendment to such information when reasonably requested by Landlord, which shall include execution of such certification statements as may be requested by Landlord or any lender to Landlord.
- (ii) Tax Returns: Within thirty (30) days after filing, but in any case within ninety (90) days of the standard filing date, including any applicable extensions thereof, copies of all federal and state, as appropriate, income tax returns on Tenant and guarantor, including all schedules and accompanying materials, each prepared by a certified public accountant reasonably acceptable to Landlord.
- (iii) All financial statements must be prepared in accordance with generally accepted accounting principles consistently applied, include balance sheets, income information, contingent liabilities, and be in form and content acceptable to Landlord.
- (iv) All financial statements shall be (a) utilized solely for the purposes of this Lease and the underwriting of Landlord's loan for the Premises, and (b) subject to strict confidentiality. Any party entitled to review such statements shall be likewise subject to strict confidentiality.

Section 50—NO PARTNERSHIP. Landlord does not, in any way or for any purpose, become a partner of Tenant in the conduct of its business, or otherwise, or joint adventurer or a member of a joint enterprise with Tenant, nor does anything in this Lease confer any interest in Landlord in the conduct of Tenant's business. Nothing contained herein shall be deemed or construed by the parties hereto, or by any third party, as creating the relationship of principal and agent, or of partnership or of joint venture between the parties hereto, it being understood and agreed that neither the method of computation of rent nor any other provision contained herein, nor any acts of the parties hereto, shall be deemed to create any relationship between the parties hereto other than the relationship of landlord and tenant.

Section 51—PARTIAL INVALIDITY. If any term, covenant or condition of this Lease or the application thereof to any person or circumstances shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such term, covenant or condition to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition of this Lease shall be valid and enforceable to the fullest extent permitted by law.

Section 52—RADON DISCLOSURE. In accordance with the requirements of Florida Statutes Section 404.056(6), the following notice is hereby given:

RADON GAS: Radon is a naturally occurring radioactive gas that, when it has accumulated in a building in sufficient quantities, may present health risks to persons who are exposed to it over time. Levels of radon that exceed federal and state guidelines have been found in buildings in Florida. Additional information regarding radon testing may be obtained from your county public health unit.

Section 53—CONFIDENTIALITY. Text intentionally Deleted

Section 54—EFFECT OF DELIVERY OF LEASE. Landlord has delivered a copy of this Lease to Tenant for Tenant's review and execution only and the delivery hereof does not constitute an offer to Tenant or an option to lease the Premises. This Lease shall not be effective until a copy executed by both Landlord and Tenant is delivered to Tenant.

Section 55—GOVERNING LAW. This Lease shall be governed by, and construed and enforced in accordance with, the laws of the State of Florida.

Section 56—WAIVERS BY TENANT. Tenant expressly waives any rights it may have in the selection of venue in the event of suit by or against Landlord, it being understood that the venue of such suit shall be in Alachua County, Florida.

Section 57—WAIVER OF JURY TRIAL. Landlord and Tenant shall and they hereby do waive trial by jury in any action, proceeding or counterclaim brought by either of them against the other on any matters whatsoever arising out of or in any way connected with this Lease, the relationship of Landlord and Tenant, Tenant's use or occupancy of the Premises, whether during or after the Term, or for the enforcement of any remedy under any statute, emergency or otherwise. The foregoing waiver is made knowingly, voluntarily and intentionally by the parties. If Landlord shall commence any summary proceeding against Tenant, Tenant shall not interpose any counterclaim of whatever nature or description in

any such proceeding (unless failure to impose such counterclaim would preclude Tenant from asserting in a separate action the claim which is the subject of such counterclaim), and shall not seek to consolidate such proceeding with any other action which may have been or shall be brought in any other court by Tenant or Landlord.

Section 58—SECURITY DEPOSIT. No Security Deposit is being required by Landlord at the initial execution of this Lease. However, in the event that the Tenant shall be in default hereunder that is continuing beyond any applicable grace or cure period, then Landlord may require that the Tenant post a Security Deposit not exceeding three (3) months' base rent and Tenant's share of Additional Rent with Landlord as a condition to cure of such default. In such instance, Tenant shall make such deposit within ten (10) days of written demand by Landlord. Said Security Deposit shall be held by Landlord, and Tenant's obligation to pay said Security Deposit is Additional Rent hereunder. Said Security Deposit may be commingled with other funds of Landlord and transferred out of state, and Landlord shall have no liability for the accrual or payment of any interest thereon. If at any time during the term of this Lease any of the rent herein reserved shall be overdue and unpaid, or any other sum payable by Tenant to Landlord hereunder shall be overdue and unpaid, then Landlord may, at the option of Landlord, appropriate and apply all or any portion of said Security Deposit to the payment of any such overdue rent or other sum. In the event of the failure of Tenant to keep and perform any of the terms, covenants and conditions of this Lease to be kept and performed by Tenant, then Landlord, at its option, may appropriate and apply said Security Deposit, or so much thereof as Landlord may deem necessary, to compensate Landlord for all loss or damage sustained or suffered by Landlord due to such default or failure on the part of Tenant. Should the entire Security Deposit, or any portion thereof, be appropriated and applied by Landlord for the payment of overdue Fixed Annual Rent or Additional Rent or other sums due and payable by Tenant hereunder, then Tenant shall, upon the demand of Landlord, forthwith remit to Landlord a sufficient amount in cash to restore said security to the original sum deposited, and Tenant's failure to do so within five (5) days after receipt of such demand shall constitute a default of this Lease. Should Tenant comply with all of said terms, covenants and conditions and promptly pay all of the Fixed Annual Rent and Additional Rent herein provided for as it falls due, and all other sums payable by Tenant to Landlord hereunder, the said Security Deposit shall be returned in full to Tenant at the end of the term of this Lease, or upon the earlier termination hereof. Landlord may deliver the Security Deposit to the purchaser of Landlord's interest in the Premises, in the event that such interest be sold, and thereupon Landlord shall be discharged from any further liability with respect to such Security Deposit. No mortgagee acquiring title to the Premises by foreclosure or deed in lieu of foreclosure shall be responsible for the return of any Security Deposit not received by it.

Section 59—SECURITY INTEREST. Except for the specific equipment and personal property of Tenant described on Exhibit "H" attached hereto (the "Excluded Assets"), Tenant hereby grants to Landlord a lien and security interest on all property owned by Tenant now or hereafter placed in or upon the Premises, and such property shall be and remain subject to such lien and security interest of Landlord for payment of all rent and other sums agreed to be paid by Tenant herein. The provisions of this paragraph relating to such lien and security interest shall constitute a security agreement under and subject to the Uniform Commercial Code of the State of Florida so that Landlord shall have and may enforce a security interest on all property of Tenant now or hereafter placed in or on the Premises, in addition to and cumulative of the Landlord's liens and rights provided by law or by the other terms and provisions of this Lease. Tenant hereby appoints

Landlord as its attorney-in-fact to execute any financing statement Landlord deems prudent to perfect the security interest granted hereby and such other documents as Landlord may now or hereafter require in order to protect or further perfect Landlord's security interest. Within thirty (30) days following Tenant's request and provided that Tenant is not then in default under this Lease beyond any applicable cure period, Landlord will execute and deliver to Tenant a subordination agreement (in a form reasonably satisfactory to counsel for Landlord and Tenant) whereby Landlord subordinates its security interest in Tenant's personal property, trade fixtures, and movable equipment existing in the Premises (or to be located in the Premises) other than (i) any such personal property, trade fixtures or equipment which would constitute fixtures under applicable law (ii) any personal property, trade fixtures or equipment funded by Landlord, to the lien of any lender of Tenant, which lender is not affiliated with Tenant and that is providing inventory, equipment, or operating-capital financing. For purposes of clarification, Tenant acknowledges that Landlord shall not consent to any additional security interest or subordinate its security interest in any personal property which may otherwise constitute fixtures under applicable law.

SECTION 60—EXPANSION. Prior to the expiration of the fifth (5th) anniversary of the Commencement Date, and provided that Tenant has not been in default hereunder beyond any applicable notice and cure periods, Tenant shall have the right to request that Landlord construct an additional space of approximately 21,250 immediately adjacent to and incorporated into the Premises as an expansion of the existing Building. Such right shall be subject to Landlord's ability to comply with all legal requirements necessary for such expansion, and the amendment to this Lease on terms and conditions acceptable to Landlord and Tenant, which shall address term, rents, buildout, Tenant contribution and other material terms and conditions. The parties agree to act in good faith to complete the negotiation of such amendment and construction of the expansion space. Landlord agrees that notwithstanding any term or condition herein to the contrary, except for any expansion to serve Tenant, Landlord shall not undertake any expansion of the Building or any additional buildings on the Premises prior to the expiration of the fifth anniversary of the Commencement Date hereunder.

(END OF TEXT ON THIS PAGE. SIGNATURE PAGE FOLLOWS)

TENANT:

APPLIED GENETIC TECHNOLOGIES CORPORATION,
a Delaware corporation

DocuSigned by:
Susan Washer
D43C2ED382464C6...

By: _____
Name: Susan Washer
Its: Chief Executive Officer

LANDLORD:

ALACHUA FOUNDATION PARK HOLDING COMPANY II, LLC,
a Florida limited liability company

DocuSigned by:
Brian Crawford
40DB08BEA94945D...

By: _____
Name: Brian Crawford
Its: Manager

Schedule of Attachments:

Consent and Joinder of Expansion Owner

Exhibit A – Site Plan

Exhibit B-1 – Fixed Cost and Base Building Specifications

Exhibit B-2 – Landlord's Work

Exhibit C – Schedule of Fixed Annual Rent

Exhibit D – reserved

Exhibit E – Schedule of Plans and Specifications

Exhibit F – Fitout Cost (pro forma)

Exhibit G – Park Rules and Regulations

Exhibit H – Tenant's Excluded Assets

EXHIBIT A - SITE PLAN

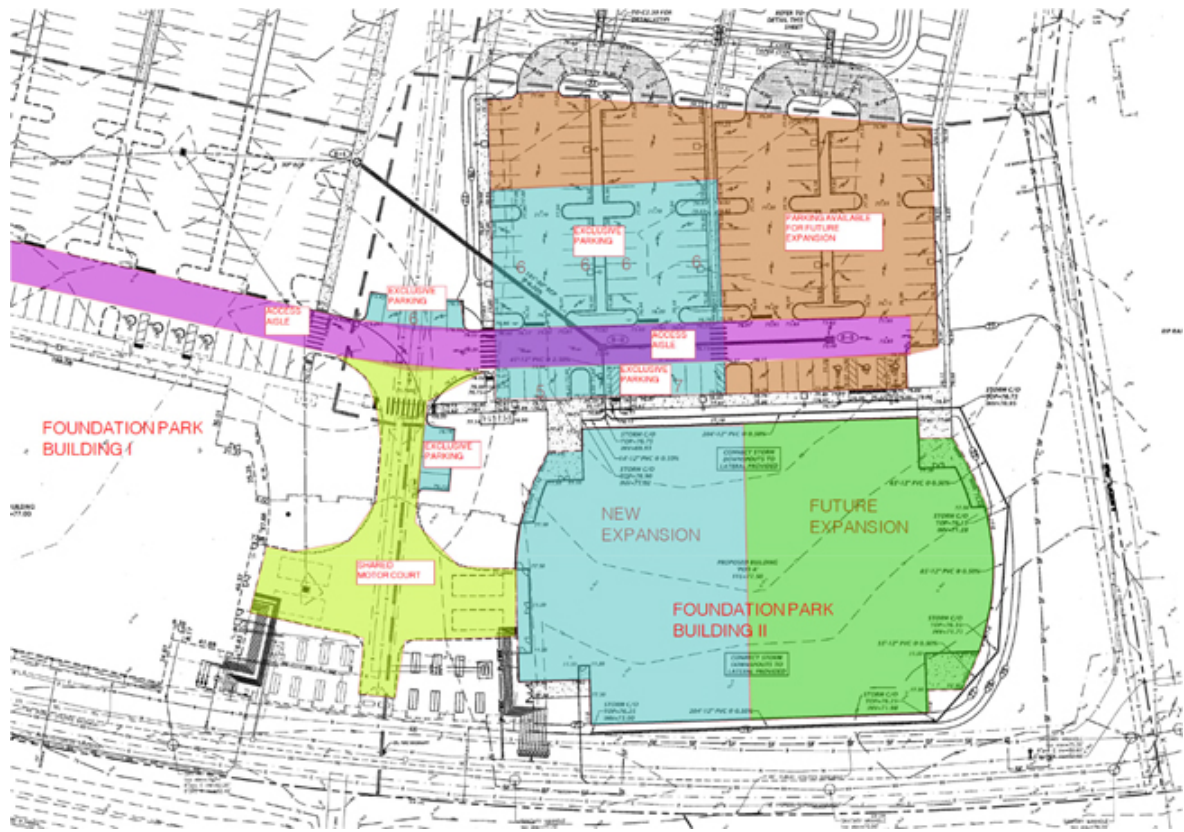


EXHIBIT B-1 – FIXED COST AND BASE BUILDING SPECIFICATIONS

In order to expedite the commencement of construction of the Premises the Base Building has been budgeted based on the acquisition and development according to the plans and specifications for a similar facility constructed by Landlord or an affiliated entity. The Base Building which includes the vacant unimproved land, building shell, site work, infrastructure, and landscaping shall be based on the plans and specifications specified herein. Upon completion of the final Plans and Specifications for the Premises the Landlord and Tenant will compare the specifications outlined in this section to the final Plans and Specifications. Any variance between the documents in Exhibit B-1 reducing the Fixed Cost shall result in a credit which shall be applied to the Fitout Cost. Likewise, variance resulting in an overage shall increase the Fitout Cost.

Landlord shall provide the Base Building as a Fixed Cost at Landlord's risk in form consistent with plans and specifications attached hereto via reference. Variances shall be permitted as mutually agreed by Landlord and Tenant set forth herein. Fixed Costs shall include:

- Vacant unimproved land
- All site development, infrastructure, and entitlements.
- Architectural / civil design for the building shell and infrastructure.
- All exterior windows, doors, and storefronts
- All exterior insulation.
- Building shell.
- The Building will be delivered with dirt floor to allow for ease of under slab rough for Tenant Fitout. Landlord will increase the Tenant Improvement Allowance to account for Landlord's cost of a typical 4 inch slab, unless otherwise agreed.
- The Premises will be delivered with improved parking for 47 parking spaces.
- The parties acknowledge that the Base Building shall not include a back-up generator, and any requested back-up generator shall be paid from Tenant's Fitout Costs
- Landlord shall pay for the cost of bringing primary electrical service to the Building. The sizing and specifications of the services provided as part of the base building shall be consistent with that of Foundation Park Building I.

In the absence of final plans and specifications the plans and specifications for Foundation Park Building I shall act as the standard guideline for Base Building components subject to the limitations provided in this section.

The Plans and Specifications are incorporated by reference herein.

EXHIBIT B-2 – LANDLORD’S WORK

Capitalized Terms not otherwise expressly defined in this Exhibit B-2 shall have the meanings assigned to such terms in the Lease.

1. Landlord’s Work Generally. Landlord shall, at Landlord’s expense, subject to Allowances and costs as a result of changes to the Base Building / Fixed Costs referenced in Exhibit B-1, perform Landlord’s Work in accordance with the Plans and Specifications, or if not otherwise specified in the Plans and Specifications. Landlord agrees that the Building shall be located so as not to violate any easement or other right of record as contained within Landlord’s title insurance policy or otherwise actually known to Landlord. Landlord shall bear all costs and expenses of Landlord’s Work, subject however, to Tenant’s obligation to fund Tenant’s Cost Contribution.

2. Plans and Specifications.

a. Landlord’s Work shall be completed in accordance with Plans and Specifications as described in the Lease. A conceptual plan with a basic layout is attached to this Schedule B-2 and is incorporated herein by reference. While subject to likely further revision by the parties, such preliminary plan presently serves as a basic layout acceptable to the parties. The cost associated with the preparation of the Plans and Specifications for the Building shell, geotechnical investigations and site plans shall be deemed a part of the Base Building and Landlord’s Fixed Cost, all other design expenses shall be deemed a part of the Fitout Cost. Any further expenses associated with modifications to the Plans and Specifications to allow consistency with the Fitout Cost as described in the Lease, including the contract price for the Landlord’s Work as agreed by Landlord’s contractor, Concept Construction of North Florida, Inc. dba Theory Construction (“Landlord’s Contractor”), and compliance with Legal Requirements and Nondiscretionary Change Orders, shall also be deemed a part of the Fitout Cost. As to any clean rooms included in the Plans, Landlord agrees that Tenant may request to have Whiting Turner provide construction services for such portion of the Premises, subject to agreement of Landlord and Tenant, and with the understanding that Landlord may require a performance and payment bond from Whiting Turner, the cost of which shall be subtracted from the Fitout Allowance.

b. Within fifteen (15) days following Landlord’s submittal of the final Plans and Specifications to Tenant for review, Tenant shall provide written notice to Landlord of Tenant’s approval of the Plans and Specifications, or of any objections that Tenant may have to the Plans and Specifications, stated in sufficient detail so as to allow necessary modification by Landlord. Once accepted by Tenant and Landlord in final form, the Plans and Specifications may be modified only with Landlord’s and Tenant’s written approval, and Tenant shall be liable for any additional

costs incurred as a result of any such change unless such change was requested by, or due to acts or omissions of, Landlord. Should Tenant fail within the time period specified in this Section to either (i) approve the Plans and Specifications to Landlord or (ii) make any reasonable modifications to same and resubmit to Landlord as so specified, then such failure shall be construed as an acceptance of the Plans and Specifications.

c. In conjunction with Landlord's review of the Plans and Specifications, Landlord shall advise Tenant of any special material, finish or fixture requested by Tenant that will result in a delay in Landlord's construction schedule beyond the Anticipated Commencement Date. In such event, Tenant shall either modify its specifications so as not to delay construction or be deemed to have accepted responsibility for any resulting delay. Prior to final approval of the Plans and Specification, the parties shall cooperate to identify any potential cost-saving measures, which may include alternative materials, equipment or fixturing; provided that if such alternatives are expected to delay completion of the Project, any such delays shall extend the Commencement Date, Anticipated Commencement Date and Outside Commencement Date hereunder. The foregoing efforts by Landlord and Tenant shall include, without limitation, special attention to the methods and materials proposed for concrete sub-flooring as necessary or appropriate to allow installation of flooring materials per the Plans and Specifications or as otherwise determined by Landlord and Tenant upon evaluation of costs and time factors.

d. The parties acknowledge that based upon current market conditions, there may be unavailability of certain supplies, materials or equipment. Landlord shall undertake to obtain such supplies, materials or equipment as may be specified in the Plans and Specifications. However, in the event that such requested supplies, materials or equipment either (i) materially increase the cost of the Base Building or (ii) result in a delay in completion of the Project, then Landlord shall present reasonable substitutes so as to minimize any cost overruns or delays in the Completion Date. In the event that Tenant shall not approve such substitutes, then any cost increase shall be deemed a Tenant expense, increasing Tenant's Contribution and any delay resulting from the delays in receiving Tenant's preferred supplies, materials or equipment shall be deemed a Tenant Delay hereunder.

3. Bid Procedure as to Allowance and Fitout (including any Tenant Contribution). Within thirty (30) days after receipt of the final completed Plans and Specifications, Landlord will procure a bid from Landlord's Contractor, which shall reflect any value engineering or potential costs savings recommended by Landlord's Contractor, to be reviewed by Landlord and Tenant with respect to performance of that portion of the Landlord's Work referred to as the Fitout Cost. The bid submitted by Landlord's Contractor shall be based upon the estimated cost of the Landlord's Work plus reasonable overhead and profit based on industry standards for the project size and scope. Landlord will provide Tenant a true and correct copy of Landlord's Contractor's detailed list of the cost of Landlord's Work. Once the final plans and specifications have been agreed to and any applicable bids received, Landlord will prepare a final Fitout Cost for approval by Tenant. Once approved, such Fitout Cost shall govern the obligation of the parties as to Allowance and Tenant Contribution, subject to Change Orders as set forth below or as required by the Lease. The Parties acknowledge that time is of the essence for this project. As such, there may be some major scopes of work that, for time's sake, requires early selection of qualified and fair contractors without competitively bidding the scope. This may be done by mutual agreement.

4. Change Orders.

a. If Tenant requires a change in the Landlord's Work as set forth in the Plans and Specifications, other than due to acts or omissions of Landlord, then Tenant may request that Landlord provide to Tenant information regarding the feasibility, cost, and time delay, if any (a "Change Order Proposal"), associated with any modification, addition, change, or deletion to the scope of the Landlord's Work. Tenant shall be responsible for any and all delays necessitated by any halting or pacing of the Landlord's Work to allow for preparation of such Change Order Proposal and implementation of the change in the Landlord's Work. Further, Tenant shall pay for the costs, if any, incurred with respect to obtaining and furnishing such Change Order Proposal including, but not limited to, costs related to obtaining governmental approvals, architectural/engineering fees, subcontractor costs and costs of materials.

b. Tenant shall review such Change Order Proposal and Tenant shall promptly approve or disapprove such information in writing. Landlord's Contractor's designee shall only implement changes to the scope of the Landlord's Work that are specifically authorized in writing by Landlord and Tenant. Tenant shall be responsible for the cost to implement or complete any Change Order or Change Order Proposal, or any delay(s) and/or increase in the cost of the improvements to the Premises resulting from changes to the scope of the Landlord's Work. **NO CHANGE ORDERS SHALL BE EFFECTIVE UNLESS SIGNED BOTH BY LANDLORD AND TENANT, AND ACKNOWLEDGED BY LANDLORD'S CONTRACTOR.** As a condition to its obligation to perform any Change Order, Tenant shall reimburse Landlord for the cost to complete such Change Order to the extent that it results in an increase in the Tenant's Cost Contribution, and shall deposit with the Escrow Agent, the amount necessary to implement and construct the construction or material changes as reflected in such Change Order. Tenant's failure to pay all of such costs within ten (10) days after execution of such Change Order shall, at Landlord's option, terminate the force and effect of such Change Order. In the event of such election to terminate, Tenant shall nonetheless be responsible for the reimbursement to Landlord for the cost to complete and prepare such Change Order.

5. Contractor(s); Permits. Landlord shall use Landlord's Contractor and shall obtain all licenses, permits and approvals in compliance with applicable Legal Requirements to commence and diligently prosecute to completion Landlord's Work. Landlord agrees that it shall make application for necessary permits within fifteen (15) days of: (i) receipt of all final approvals from Tenant as to the Plans and Specifications and Tenant Fitout Costs, and (ii) payment of any Tenant Contribution as may be required, and shall diligently pursue issuance of such permits thereafter.

6. Punchlist Items. Following completion of the Project to a condition of Substantially Ready for Occupancy and not later than three (3) days prior to the Commencement Date, Landlord's Contractor, Landlord and Tenant shall perform a walk-through of the Premises to identify and agree upon any "punchlist" or insubstantial details of construction, decoration, or mechanical adjustment remaining to be performed, completed, repaired, or adjusted (based upon construction standards prevailing in Alachua County for similar property). Landlord thereafter shall diligently continue Landlord's Work to final completion of the Project to address all such identified punchlist items not later than thirty (30) days following the Commencement Date. The existence of such punchlist items shall not in any event constitute a basis for postponing the Commencement Date or the accrual of rent pursuant to the Lease, provided, however, that none of the punchlist items would materially interfere with Tenant's ability to open for and conduct its business.

7. Warranties. Upon final completion of Landlord's Work, Landlord shall cause Landlord's Contractor to issue: (i) a three (3) year warranty on all patent defects, (ii) a five (5) year warranty on all latent defects, and (iii) a ten (10) year warranty on the roof, foundation and structure, or in each case for such longer period(s) as may be required under Florida law. All warranties provided by Landlord's Contractor, its subcontractors and providers of the roofing, heating, ventilation and air conditioning systems and the other fixtures and equipment specified in the Plans and Specifications shall be expressly assignable to Tenant, and shall be assigned to Tenant, to the extent that Tenant is obligated to repair or replace the applicable component of the Premises in accordance with the terms of the Lease, or if Tenant acquires title to the Premises pursuant to any option available to Tenant in accordance with the terms of the Lease. In addition, Landlord represents and warrants that (a) the Landlord's Work will (i) conform to the Plans and Specifications in all material respects, and (ii) be of good material and workmanship and free from defects; and (b) all Landlord's Work will delivered shall be free from liens and encumbrances except in favor of Lender; and (c) all Landlord's Work performed under this Lease will be performed in a workmanlike manner in accordance with all applicable laws, rules and regulations.

8. All amounts in excess of Allowance and Base Building necessary for completion of the Building in accordance with the Plans and Specifications and any Change Order shall be paid by Tenant as Tenant's Cost Contribution. Unless otherwise agreed by the parties in writing, Tenant's Cost Contribution shall be funded to Landlord by Tenant no later than ten (10) days after determination of a Tenant Cost Contribution. Landlord agrees that Tenant's funds shall not be disbursed for construction until such time as Allowance Costs have been disbursed for the payment of the Fitout Cost.

9. Management of Allowance (including Tenant's Cost Contribution). Landlord's Allowance shall be subject to the following account and expenditure management terms and conditions, to be exercised by each of Landlord and Tenant on a commercially reasonable good faith basis:

a. If Landlord shall request an Additional Tenant Cost Contribution, at Tenant's reasonable request, Landlord shall provide Tenant with a copy of an account ledger showing amounts paid (or to be paid) under the Allowance and the Tenant Cost Contribution.

b. Landlord shall maintain a record of Tenant's proposed specifications for interior build-out materials, equipment or fixturing, and provide Tenant with reasonable cost estimates of such specifications in advance of Tenant's approval or Change Order for such specified items

c. During all phases of construction, Landlord shall allow Tenant or Tenant's authorized representatives, reasonable access to the construction site for the purpose of observation and inspection of Landlord's Work in progress and evaluation of the stage of construction and time for completion. For purposes hereunder, Tenant's authorized representative (i) shall be a licensed architect, contractor, licensed professional inspector mutually agreed to by the parties, and (ii) shall not be compensated on a contingency or other fee under which such party's compensation is

EXHIBIT C—SCHEDULE OF FIXED ANNUAL RENT

(See next page)

Exhibit C—Schedule of Fixed Annual Rent

Lease Month	Fixed Annual Rent	Fixed Annual Rent Per Square Foot	Fixed Annual Rent Monthly Payment
1	\$ 0.00	\$ 0.00	\$ 0.00
2	\$ 0.00	\$ 0.00	\$ 0.00
3	\$ 0.00	\$ 0.00	\$ 0.00
4	\$ 0.00	\$ 0.00	\$ 0.00
5	\$ 0.00	\$ 0.00	\$ 0.00
6	\$ 0.00	\$ 0.00	\$ 0.00
7	\$ 0.00	\$ 0.00	\$ 0.00
8	\$ 0.00	\$ 0.00	\$ 0.00
9	\$ 0.00	\$ 0.00	\$ 0.00
10	\$ 0.00	\$ 0.00	\$ 0.00
11	\$ 0.00	\$ 0.00	\$ 0.00
12	\$ 0.00	\$ 0.00	\$ 0.00
13	\$ 637,500.00	\$ 30.00	\$ 53,125.00
14	\$ 637,500.00	\$ 30.00	\$ 53,125.00
15	\$ 637,500.00	\$ 30.00	\$ 53,125.00
16	\$ 637,500.00	\$ 30.00	\$ 53,125.00
17	\$ 637,500.00	\$ 30.00	\$ 53,125.00
18	\$ 637,500.00	\$ 30.00	\$ 53,125.00
19	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
20	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
21	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
22	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
23	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
24	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
25	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
26	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
27	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
28	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
29	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
30	\$ 1,253,750.00	\$ 59.00	\$ 104,479.17
31	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
32	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
33	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
34	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
35	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
36	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
37	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
38	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
39	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
40	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
41	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
42	\$ 1,272,556.25	\$ 59.89	\$ 106,046.35
43	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05

Exhibit C—Schedule of Fixed Annual Rent

Lease Month	Fixed Annual Rent	Fixed Annual Rent Per Square Foot	Fixed Annual Rent Monthly Payment
44	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05
45	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05
46	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05
47	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05
48	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05
49	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05
50	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05
51	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05
52	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05
53	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05
54	\$ 1,291,644.59	\$ 60.78	\$ 107,637.05
55	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
56	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
57	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
58	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
59	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
60	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
61	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
62	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
63	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
64	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
65	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
66	\$ 1,311,019.26	\$ 61.70	\$ 109,251.61
67	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
68	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
69	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
70	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
71	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
72	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
73	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
74	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
75	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
76	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
77	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
78	\$ 1,330,684.55	\$ 62.62	\$ 110,890.38
79	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73
80	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73
81	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73
82	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73
83	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73
84	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73
85	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73
86	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73
87	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73
88	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73

Exhibit C—Schedule of Fixed Annual Rent

Lease Month	Fixed Annual Rent	Fixed Annual Rent Per Square Foot	Fixed Annual Rent Monthly Payment
89	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73
90	\$ 1,350,644.82	\$ 63.56	\$ 112,553.73
91	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
92	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
93	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
94	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
95	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
96	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
97	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
98	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
99	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
100	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
101	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
102	\$ 1,370,904.49	\$ 64.51	\$ 114,242.04
103	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
104	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
105	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
106	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
107	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
108	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
109	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
110	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
111	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
112	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
113	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
114	\$ 1,391,468.06	\$ 65.48	\$ 115,955.67
115	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
116	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
117	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
118	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
119	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
120	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
121	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
122	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
123	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
124	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
125	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
126	\$ 1,412,340.08	\$ 66.46	\$ 117,695.01
127	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43
128	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43
129	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43
130	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43
131	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43
132	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43
133	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43

Exhibit C—Schedule of Fixed Annual Rent

Lease Month	Fixed Annual Rent	Fixed Annual Rent Per Square Foot	Fixed Annual Rent Monthly Payment
134	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43
135	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43
136	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43
137	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43
138	\$ 1,433,525.18	\$ 67.46	\$ 119,460.43
139	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
140	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
141	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
142	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
143	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
144	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
145	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
146	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
147	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
148	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
149	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
150	\$ 1,455,028.06	\$ 68.47	\$ 121,252.34
151	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
152	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
153	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
154	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
155	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
156	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
157	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
158	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
159	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
160	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
161	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
162	\$ 1,476,853.48	\$ 69.50	\$ 123,071.12
163	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
164	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
165	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
166	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
167	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
168	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
169	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
170	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
171	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
172	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
173	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
174	\$ 1,499,006.28	\$ 70.54	\$ 124,917.19
175	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95
176	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95
177	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95
178	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95

Exhibit C—Schedule of Fixed Annual Rent

Lease Month	Fixed Annual Rent	Fixed Annual Rent Per Square Foot	Fixed Annual Rent Monthly Payment
179	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95
180	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95
181	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95
182	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95
183	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95
184	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95
185	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95
186	\$ 1,521,491.38	\$ 71.60	\$ 126,790.95
187	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
188	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
189	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
190	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
191	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
192	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
193	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
194	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
195	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
196	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
197	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
198	\$ 1,544,313.75	\$ 72.67	\$ 128,692.81
199	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
200	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
201	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
202	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
203	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
204	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
205	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
206	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
207	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
208	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
209	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
210	\$ 1,567,478.45	\$ 73.76	\$ 130,623.20
211	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
212	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
213	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
214	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
215	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
216	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
217	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
218	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
219	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
220	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
221	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
222	\$ 1,590,990.63	\$ 74.87	\$ 132,582.55
223	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29

Exhibit C—Schedule of Fixed Annual Rent

Lease Month	Fixed Annual Rent	Fixed Annual Rent Per Square Foot	Fixed Annual Rent Monthly Payment
224	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29
225	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29
226	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29
227	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29
228	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29
229	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29
230	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29
231	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29
232	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29
233	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29
234	\$ 1,614,855.49	\$ 75.99	\$ 134,571.29
235	\$ 1,639,078.32	\$ 77.13	\$ 136,589.86
236	\$ 1,639,078.32	\$ 77.13	\$ 136,589.86
237	\$ 1,639,078.32	\$ 77.13	\$ 136,589.86
238	\$ 1,639,078.32	\$ 77.13	\$ 136,589.86
239	\$ 1,639,078.32	\$ 77.13	\$ 136,589.86
240	\$ 1,639,078.32	\$ 77.13	\$ 136,589.86

Option Period 1

The parties acknowledge a 1.5% annual increase has been used for illustration. However, renewals are subject to an annual increase of 1.5% or CPI, whichever is greater.

241	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
242	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
243	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
244	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
245	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
246	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
247	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
248	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
249	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
250	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
251	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
252	\$ 1,663,664.50	\$ 78.29	\$ 138,638.71
253	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29
254	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29
255	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29
256	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29
257	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29
258	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29
259	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29
260	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29
261	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29
262	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29
263	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29
264	\$ 1,688,619.46	\$ 79.46	\$ 140,718.29

Exhibit C—Schedule of Fixed Annual Rent

Lease Month	Fixed Annual Rent	Fixed Annual Rent Per Square Foot	Fixed Annual Rent Monthly Payment
265	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
266	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
267	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
268	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
269	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
270	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
271	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
272	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
273	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
274	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
275	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
276	\$ 1,713,948.76	\$ 80.66	\$ 142,829.06
277	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
278	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
279	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
280	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
281	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
282	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
283	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
284	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
285	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
286	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
287	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
288	\$ 1,739,657.99	\$ 81.87	\$ 144,971.50
289	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
290	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
291	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
292	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
293	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
294	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
295	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
296	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
297	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
298	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
299	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
300	\$ 1,765,752.86	\$ 83.09	\$ 147,146.07
Option Period 2			
The parties acknowledge a 1.5% annual increase has been used for illustration. However, renewals are subject to an annual increase of 1.5% or CPI, whichever is greater.			
301	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26
302	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26
303	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26
304	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26
305	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26

Exhibit C—Schedule of Fixed Annual Rent

Lease Month	Fixed Annual Rent	Fixed Annual Rent Per Square Foot	Fixed Annual Rent Monthly Payment
306	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26
307	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26
308	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26
309	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26
310	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26
311	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26
312	\$ 1,792,239.15	\$ 84.34	\$ 149,353.26
313	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
314	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
315	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
316	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
317	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
318	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
319	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
320	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
321	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
322	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
323	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
324	\$ 1,819,122.74	\$ 85.61	\$ 151,593.56
325	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
326	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
327	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
328	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
329	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
330	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
331	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
332	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
333	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
334	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
335	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
336	\$ 1,846,409.58	\$ 86.89	\$ 153,867.46
337	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
338	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
339	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
340	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
341	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
342	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
343	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
344	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
345	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
346	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
347	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
348	\$ 1,874,105.72	\$ 88.19	\$ 156,175.48
349	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11
350	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11

Exhibit C—Schedule of Fixed Annual Rent

Lease Month	Fixed Annual Rent	Fixed Annual Rent Per Square Foot	Fixed Annual Rent Monthly Payment
351	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11
352	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11
353	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11
354	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11
355	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11
356	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11
357	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11
358	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11
359	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11
360	\$ 1,902,217.31	\$ 89.52	\$ 158,518.11

Option Period 3

The parties acknowledge a 1.5% annual increase has been used for illustration. However, renewals are subject to an annual increase of 1.5% or CPI, whichever is greater

361	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
362	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
363	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
364	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
365	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
366	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
367	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
368	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
369	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
370	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
371	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
372	\$ 1,930,750.57	\$ 90.86	\$ 160,895.88
373	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
374	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
375	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
376	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
377	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
378	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
379	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
380	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
381	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
382	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
383	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
384	\$ 1,959,711.83	\$ 92.22	\$ 163,309.32
385	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96
386	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96
387	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96
388	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96
389	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96
390	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96
391	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96

Exhibit C - Schedule of Fixed Annual Rent

Lease Month	Fixed Annual Rent	Fixed Annual Rent Per Square Foot	Fixed Annual Rent Monthly Payment
392	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96
393	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96
394	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96
395	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96
396	\$ 1,989,107.50	\$ 93.61	\$ 165,758.96
397	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
398	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
399	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
400	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
401	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
402	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
403	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
404	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
405	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
406	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
407	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
408	\$ 2,018,944.12	\$ 95.01	\$ 168,245.34
409	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02
410	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02
411	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02
412	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02
413	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02
414	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02
415	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02
416	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02
417	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02
418	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02
419	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02
420	\$ 2,049,228.28	\$ 96.43	\$ 170,769.02

EXHIBIT E—SCHEDULE OF PLANS AND SPECIFICATIONS

See Exhibit B-1 for Base Building Plans and Specifications.

See Exhibit B-2 for preliminary Plans and Specifications.

A preliminary or “conceptual” draft of the Plans and Specifications have been developed by RS&H Architects and incorporated into Exhibit B-2.

The final Plans and Specifications shall be incorporated by amendment to this agreement upon approval of the Fitout Cost.

EXHIBIT F—FITOUT COST (pro forma)

Intentionally Omitted.

The Fitout Cost shall be established under the terms of the lease and as described in detail under Section 11 therein.

EXHIBIT G—PARK RULES AND REGULATIONS

FOUNDATION PARK

1. The sidewalks and public portions of FOUNDATION PARK, such as entrances, passages, courts, parking areas, elevators, vestibules, stairways, corridors or halls shall not be obstructed or encumbered by Tenant or its employees, agents, invitees or guests nor shall they be used for any purpose other than ingress and egress to and from the Premises.

2. No cigarette, cigar or pipe smoking shall be permitted in the Project at any time, except in areas as may be designated by Landlord for such purpose, if any.

3. No awnings or other projections shall be attached to the outside walls of the Building. No curtains, blinds, shades, louvered openings or screens shall be attached to or hung in, or used in connection with, any window or door of the Premises, without the prior written consent of Landlord, unless installed by Landlord. No aerial or antenna shall be erected on the roof or exterior walls of the Premises or on the Project without the prior written consent of Landlord in each instance.

4. Unless approved in writing by Landlord, no sign, advertisement, notice or other lettering shall be exhibited, inscribed, painted or affixed by Tenant on any part of the outside of the Premises or Project or on corridor walls or doors or mounted on the inside of any windows without the prior written consent of Landlord. Signs on any entrance door or doors shall conform to Project standards and shall, at Tenant's expense, be inscribed, painted or affixed for Tenant by sign makers approved by Landlord. In the event of the violation of the foregoing by Tenant, Landlord may install and/or remove same without any liability and may charge the expense incurred to Tenant.

5. The sashes, sash doors, skylights, windows, heating, ventilating and air conditioning vents and doors that reflect or admit light and air into the halls, passageways or other public places in the Project shall not be covered or obstructed by Tenant, or its employees, agents, invitees or guests nor shall any bottles, parcels, or other articles be placed outside of the Premises.

6. No showcases or other articles shall be put in front of or affixed to any part of the exterior of the Building, nor placed in the public halls, corridors or vestibules without the prior written consent of Landlord.

7. The water and wash closets and other plumbing fixtures shall not be used for any purposes other than those for which they were constructed, and no sweepings, rubbish, rags, or other substances shall be thrown therein. All damages resulting from any misuse of fixtures shall be borne by the Tenant who, or whose employees, agents, invitees or guests shall have caused the same.

8. Tenant shall not in any way deface any part the Premises or the Building. Tenant shall not lay linoleum, or both similar floor covering, so that the same shall come in direct contact with the floor of the Premises, and, if linoleum or other similar floor covering is desired to be used, an interlining of builder's deadening felt shall be first affixed to the floor, by a paste or other material, soluble in water, the use of cement or other similar adhesive material being expressly prohibited.

9. No pets of any kind (except seeing eye dogs) shall be brought upon the Premises or Building. No cooking shall be done or permitted by Tenant on the Premises except in conformity to law and then only in the utility kitchen (if a utility kitchen was provided for in the approved plans for the Premises or if Landlord has consented in writing thereto), which is to be primarily used by Tenant's employees for heating beverages and light snacks. Tenant shall not cause or permit any unusual or objectionable odors to be produced upon or permeate from the Premises.

10. No office space in the Project shall be used for the sale at auction or otherwise of merchandise, goods or property of any kind.

11. Tenant shall not make or permit to be made, any unseemly or disturbing noises or disturb or interfere with occupants of the Project or neighboring Premises or those having business with them, whether by the use of any musical instrument, radio, talking machine, unmusical noise, whistling, singing, or in any other way. Tenant shall not throw anything out of the doors or windows or down the corridors, stairwells or elevator shafts of the Building.

12. Neither Tenant nor any of Tenant's employees, agents, invitees or guests shall at any time bring or keep upon the Premises any inflammable, combustible or explosive substance or any chemical substance, except in compliance with requirements of applicable laws, rules and regulations.

13. Landlord shall have a valid pass key to all spaces within the Premises at all times during the term of this Lease unless such spaces are restricted by law or safety practice as reasonably agreed by Landlord. No additional locks or bolts of any kind shall be placed upon any of the doors or windows by Tenant, nor shall any changes be made in existing locks or the mechanism thereof, without the prior written consent of the Landlord and unless and until a duplicate key is delivered to Landlord. Tenant must, upon the termination of its tenancy, restore to the Landlord all keys to stores, offices and toilet rooms, either furnished to or otherwise procured by such Tenant, and in the event of the loss of any keys so furnished, Tenant shall pay Landlord for the cost thereof.

14. All deliveries, removals and/or the carrying in or out of any safes, freights, furniture or bulky matter of any description may be accomplished only with the prior approval of Landlord and then only in approved areas, through the approved loading/service area doors and during approved hours. Tenant shall assume all liability and risk with respect to such movements. Landlord may restrict the location where such heavy or bulky matters may be placed inside the Premises. Landlord reserves the right to inspect all freight to be brought into the Project and to exclude from the Project all freight which can or may violate any applicable law, rule or regulation, these Rules and Regulations or the Lease of which these Rules and Regulations are a part.

15. Tenant shall not, unless otherwise approved by Landlord, occupy or permit any portion of the Premises demised to it to be occupied as, by or for a public stenographer or typist, barber shop, bootblacking, beauty shop or manicuring, beauty parlor, telephone or telegraph agency, telephone or secretarial service, messenger service, travel or tourist agency, employment agency, public restaurant or bar, commercial document reproduction or offset printing service, public vending machines, discount shop for sale of merchandise, retail service shop, labor union, school or classroom, governmental or quasi-governmental bureau, department or agency, including an autonomous governmental corporation, or a company engaged in the business of renting office or desk space; or for a public finance (personal loan) business.. Tenant shall not engage or pay any employees on the Premises, except those actually working for Tenant on said Premises, nor advertise for labor giving an address at said Premises.

16. Tenant shall not create or use any advertising mentioning or exhibiting any likeness of FOUNDATION PARK without the prior written consent of Landlord. Landlord shall have the right to prohibit any such advertising which, in Landlord's reasonable opinion, tends to impair the reputation of the Project or its desirability as a building for offices, and upon written notice from Landlord, Tenant shall discontinue such advertising.

17. Intentionally Deleted.

18. The Premises shall not be used for lodging or sleeping, or for any immoral, disreputable or illegal purposes, or for any purpose which may be dangerous to life, limb or property.

19. Any maintenance requirements of Tenant will be attended to by Landlord only upon application at the Landlord's office at the Building. Landlord's employees shall not perform any work or do anything outside of their regular duties, unless under specific instructions from the office of Landlord.

20. Canvassing, soliciting and peddling within the Project or in Common Areas is prohibited and Tenant shall cooperate to prevent the same.

21. There shall not be used in any space, or in the public halls of the Building, either by Tenant or by jobbers or others, in the delivery or receipt of merchandise to Tenant, any hand trucks, except those equipped with rubber tires and side guards. No hand trucks shall be used in elevators other than those designated by Landlord as service elevators. All deliveries shall be confined to the service areas and through the approved service entries.

22. In order to obtain maximum effectiveness of the cooling system, Tenant shall make reasonable efforts to promote efficiency in the use of utilities.

23. In the event that, in Landlord's reasonable opinion, the replacement of ceiling tiles becomes necessary after they have been removed on behalf of Tenant by telephone company installers or others (in both the Premises and the public corridors), the cost of such replacements shall be charged to Tenant on a per-tile basis.

24. All paneling or other wood products not considered furniture which Tenant shall install in the Premises shall be of fire-retardant materials. Prior to the installation of any such materials, Tenant shall submit to Landlord a satisfactory (in the reasonable opinion of Landlord) certification of such materials' fire-retardant characteristics.

25. Usage of parking spaces shall be in common with all other lessees of the Project and their employees, agents, invitees and guests. All parking spaces usage shall be subject to such reasonable rules and regulations for the sale and proper use thereof as Landlord may prescribe. Tenant's employees, agents, invitees and guests shall abide by all posted roadway signs in and about the parking facilities.

26. All trucks and delivery vans shall be parked in designated areas only and not parked in spaces reserved for cars. All delivery service doors are to remain closed except during the time that deliveries, garbage removal or other approved uses are taking place therein. All loading and unloading of goods shall be done only at such times, in the areas and through the entrances designated for such purposes by Landlord.

27. Tenant shall be responsible for the removal and proper disposition of all crates, oversized trash, boxes and garbage from the Premises. The corridors, parking and delivery areas are to be kept clean from such items. Tenant shall provide convenient and adequate receptacles for the collection of standard items of trash and shall facilitate the removal of such trash by Landlord. Tenant shall ensure that liquids are not disposed of in such receptacles.

28. Tenant shall not conduct any business, loading or unloading, assembling or any other work connected with Tenant's business in any public areas.

29. If and when requested by Landlord, Tenant shall, at its sole cost and expense, promptly cause the Premises to be treated for pests by a licensed pest extermination contractor.

30. Landlord shall not be responsible for lost or stolen personal property, equipment or money occurring within the Premises or Building, regardless of how or when the loss occurs.

31. Neither Tenant, nor its employees, agents, invitees or guests, shall paint or decorate the Premises, or mark, paint or cut into, drive nails or screw into nor in any way defect any part of the Premises or Project without the prior written consent of Landlord. If Tenant desires a signal, communications, alarm or other utility or service connection installed or changed, such work shall be done at the expense of Tenant, with the approval and under the direction of Landlord.

32. Tenant shall give Landlord prompt notice of all accidents to or defects in air conditioning equipment, plumbing, electric facilities or any part or appurtenance of the Premises.

33. Whenever and to the extent that the above rules conflict with any of the rights or obligations of Tenant pursuant to the provisions of the Sections of this Lease, the provisions of the Sections shall govern.

EXHIBIT "H"

Tenant's Excluded Assets

(Schedule to be completed upon completion of final plans and specifications)

FIRST AMENDMENT TO EMPLOYMENT AGREEMENT
(William A. Sullivan)

THIS FIRST AMENDMENT AGREEMENT TO EMPLOYMENT AGREEMENT (this "First Amendment") is entered into as of the 14th day of May 2021 by and between Applied Genetic Technologies Corporation, a Delaware corporation, including its successors and assigns (the "Employer" or "Company") and William A. Sullivan ("Executive").

WHEREAS, the Company and Executive are parties to a letter employment agreement dated July 26, 2017 (the "Employment Agreement"); and

WHEREAS, the parties desire to amend certain provisions of the Employment Agreement in the manner set forth herein.

NOW, THEREFORE, in consideration of the premises and the covenants set forth herein and in the Employment Agreement, the parties hereby agree as follows:

1. Defined Terms. Capitalized terms used, but not defined, herein shall have the meanings ascribed to them in the Employment Agreement.

2. Effective Date. This First Amendment shall become effective on the date that it is approved by the Compensation Committee of the Company's Board of Directors (the "Effective Date").

3. Employment Term and Notice of Termination. The last paragraph of page 3 of the Employment Agreement is hereby amended and replaced with the following:

Notwithstanding the foregoing provisions of this Employment Agreement, you agree to continue your employment, and the Company agrees to employ you, until June 9, 2021 (the "Termination Date"), provided, however, that the Company may terminate your employment for Cause before June 9, 2021 immediately upon providing you with written notice. Upon the termination of your employment for any reason other than by the Company for Cause, provided that you execute and do not revoke a Release and Settlement Agreement in the form reasonably acceptable to the Company (the "Release"), you shall be entitled to receive the following:

- (a) a payment equal to six (6) months of your current base salary, less all applicable deductions, to be paid within 14 days of the Release becoming effective;
- (b) a prorated bonus for the fiscal year ending June 30, 2021, less all applicable deductions, based on Employee's performance and the overall performance and status of the Company as determined by the Compensation Committee in accordance with the Company's normal practice;
- (c) if you elect to continue your participation in the Company's medical, dental, and vision benefit plans pursuant to COBRA, the Company will reimburse you for COBRA premiums to the extent required so that your premium cost for the coverage is substantially the same as the cost immediately prior to the Termination Date, until

the earlier to occur of six months immediately following the Termination Date or the date on which you obtain other employment which provides the same type of benefit; provided, however, that if the Company determines, in its reasonable judgment, that providing medical, dental, and/or vision benefits in accordance with this section 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 reimbursement with respect to you and instead pay to you taxable cash payments at the same time and in the same amounts as the Company would have paid as COBRA premium reimbursements to provide such coverage;

- (d) stock options previously granted to you by the Company that are unvested as of the Termination Date will continue to vest through and including December 31, 2021; and
- (e) the period during which you will be permitted to exercise any vested stock options held by you will be extended to the later to occur of (i) December 31, 2022 and (ii) the date that is 90 calendar days after the date on which the Company issues a press release that reports the 6-month masked interim analysis in the Phase 2/3 Vista trial (the "Vista Release Date"),

4. Ratification. The Employment Agreement, as amended hereby, is hereby ratified and confirmed in all respects and shall continue in full force and effect. The Employment Agreement shall, together with this First Amendment, be read and construed as a single agreement.

5. Nondisparagement. 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. The Company agrees that its officers and directors will not disparage or encourage or induce others to disparage Executive. Nothing herein is intended to or shall prevent either party from providing testimony in response to a valid subpoena, court order, regulatory request or other judicial, administrative or legal process or otherwise as required by law. In response to inquiries from third parties concerning Executive's departure from the Company, the Company and Executive will respond consistently with mutually-agreed upon talking points.

6. Governing Law. This First Amendment shall be construed and enforced in accordance with the laws of the State of Delaware, without regard to its principles of conflicts of laws.

7. Counterparts. This First Amendment may be executed in two counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this First Amendment to Employment Agreement as of the date first written above.

APPLIED GENETIC TECHNOLOGIES CORP.

By: /s/ Susan Washer
Susan Washer
President and CEO

EXECUTIVE:

/s/ William Sullivan
William A. Sullivan

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) pertaining to the Applied Genetic Technologies Corporation 2001 Stock Option Plan, 2011 Stock Incentive Plan, 2013 Equity and Incentive Plan and the 2013 Employee Stock Purchase Plan,
- (2) Registration Statement (Form S-3 No. 333-225286) of Applied Genetic Technologies Corporation,
- (3) Registration Statement (Form S-8 No. 333-233955) pertaining to the Applied Genetic Technologies Corporation 2013 Equity and Incentive Plan,
- (4) Registration Statement (Form S-8 No. 333-248900) pertaining to the Applied Genetic Technologies Corporation 2013 Equity and Incentive Plan, and
- (5) Registration Statement (Form S-3 No. 333-255008) of Applied Genetic Technologies Corporation;

of our report dated September 23, 2021, with respect to the financial statements of Applied Genetic Technologies Corporation included in this Annual Report (Form 10-K) of Applied Genetic Technologies Corporation for the year ended June 30, 2021.

/s/ Ernst & Young LLP

Tampa, Florida
September 23, 2021

CERTIFICATION

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 23, 2021

By: /s/ Susan B. Washer
Susan B. Washer
Chief Executive Officer and President
(Principal Executive Officer)

CERTIFICATION

I, Jonathan I. Lieber, 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 23, 2021

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
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, 2021, 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 her or his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 23, 2021

By: /s/ Susan B. Washer
Susan B. Washer
Chief Executive Officer and President
(Principal Executive Officer)

Date: September 23, 2021

By: /s/ Jonathan I. Lieber
Jonathan I. Lieber
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.