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 December 31, 2019

OR

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

For the transition period from _____ to _____

Commission File Number: 001-37783

Clearside Biomedical, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware		**45-2437375**
(State or other jurisdiction of incorporation or organization)		**(I.R.S. Employer Identification No.)**
900 North Point Parkway, Suite 200 **Alpharetta, GA**		**30005**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: (678) 270-3631

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CLSD	The Nasdaq Stock Market LLC

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the 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 pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

The aggregate market value of Clearside Biomedical, Inc. voting and non-voting common equity held by non-affiliates as of June 28, 2019 (the last business day of the registrant's most recently completed second fiscal quarter) based on the closing sale price of $0.97 as reported on the Nasdaq Global Market on that date was approximately $33,200,000.

As of March 11, 2020, the registrant had 44,868,558 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's definitive proxy statement, to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, for its 2020 Annual Meeting of Stockholders are incorporated by reference in Part III of the Form 10-K.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. "Business," Part I, Item 1A. "Risk Factors," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- our plans for the development and potential commercialization of our product candidates;
- our ongoing and planned preclinical studies and clinical trials for our product candidates;
- the timing of the availability of data from our clinical trials;
- the timing of our planned regulatory filings, including the resubmission of our new drug application for XIPERE™;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- our expectation that XIPERE, if approved, would be the first drug specifically indicated for the treatment of macular edema associated with uveitis;
- the clinical utility of our product candidates;
- our manufacturing capabilities and strategy;
- our intellectual property position;
- our plans to enter into and maintain collaborations with other companies;
- our ability to identify additional product candidates with significant commercial potential that are compatible with suprachoroidal injection and which are consistent with our commercial objectives; and
- our estimates regarding future expenses and needs for additional financing.

You should refer to Item 1A. "Risk Factors" in this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that subsequent events and developments may cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

We have proprietary rights to a number of trademarks used in this Annual Report which are important to our business, including Clearside, XIPERE, SCS Microinjector and the Clearside logo. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. All other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners.

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PART I

ITEM 1. BUSINESS

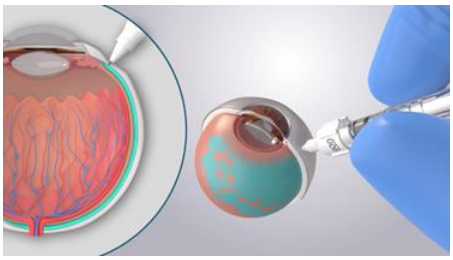
Overview

We are a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases. Our proprietary SCS Microinjector targeting the suprachoroidal space, or SCS, offers unique access to the macula, retina and choroid where sight-threatening disease often occurs. Our SCS injection platform is an inherently flexible, in-office, non-surgical procedure intended to provide targeted delivery of established and new formulations of medications, as well as future therapeutic innovations such as gene therapy, to the site of disease.

We are leveraging our SCS injection platform by building an internal research and development pipeline in areas such as novel small molecules and gene therapy, and by creating external collaborations with other companies. Using our suprachoroidal injection technology that can be used in conjunction with proprietary formulations of existing drugs as well as novel therapies, we believe that we have created a broad therapeutic platform for developing product candidates to treat serious eye diseases.

Our Technology Platform

Our suprachoroidal injection platform is a novel, patented approach for delivering pharmacotherapy to the back of the eye via the suprachoroidal space, or SCS. When fluid is injected between the choroid and sclera, the elasticity of the SCS allows the fluid to migrate and spread spherically toward the posterior regions of the eye where it is absorbed into adjacent tissue. Our proprietary microinjector is able to precisely administer drugs into the SCS utilizing a needle that is approximately one millimeter in length. This method of administration facilitates more targeted delivery of therapeutic agents to chorioretinal structures. The suprachoroidal injection procedure is depicted in the picture below.

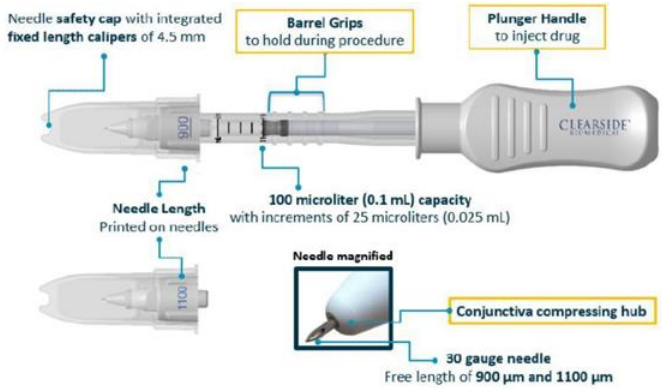


With suprachoroidal injections, product candidates are more directly administered to the retina and choroid and limit exposure to non-target tissues as compared to other ocular drug administration techniques such as injections of drug into the vitreous, a jelly-like substance that occupies the central portion of the eye. Intravitreal injections, the current standard for delivery of many drugs for eye diseases, rely on diffusion of drug outward from the vitreous to the retina and choroid. This diffusion can result in lower concentrations of drug in these targeted areas and the drug spreading to unintended parts of the eye, potentially causing significant side effects. We believe treatment of eye disease via suprachoroidal injection of product candidates may provide a number of benefits, including a non-surgical procedure, lower frequency of administration, faster onset of therapeutic effect and an improved safety profile.

Our extensive patent portfolio provides us with exclusive rights to develop and commercialize pharmacological agents for treatment of eye diseases via suprachoroidal injection. We believe this proprietary method of administration has the potential to become the standard for the delivery of therapies intended to treat retinal and choroidal diseases. Our drug candidates, SCS Microinjector and method of drug administration into the SCS are protected by 19 issued U.S. patents broadly directed to methods of administering drugs into the SCS by injection, including one design patent.

Our SCS Microinjector

Our proprietary SCS Microinjector, shown in the picture below, can be used to inject a wide variety of drugs into the SCS. Our internally developed and our collaborators' drug candidates are specifically formulated to be injected via suprachoroidal injection with our SCS Microinjector in order to flow to the back of the eye. The SCS Microinjector is composed of a syringe and two 30-gauge hollow microneedles of varying lengths, each less than 1.2 millimeters, within a custom-designed hub that optimizes insertion and suprachoroidal administration of drugs.



Current intravitreal injections are performed in a procedure similar to that of suprachoroidal injections, except that the hypodermic needles and syringes used in intravitreal injection procedures are designed so that the needle penetrates through all of the layers of the eye and drug is injected into the vitreous cavity, where the precise spatial location of the needle is not as important as when injecting into the SCS. Intravitreal injections are typically performed using a needle that is approximately five millimeters in length, or four times the length of our microneedle. Using a needle of this length, the physician penetrates past the sclera, choroid and retina until reaching the vitreous and does not receive any tactile feedback as to when the needle reaches one of the layers between the sclera and the vitreous.

By contrast, our SCS Microinjector is designed to inject drug into the suprachoroidal space. This suprachoroidal injection is designed to be carried out perpendicular to the sclera, at a site similar to an intravitreal injection, under local anesthesia. Once the microneedle penetrates the sclera and reaches the SCS, the boundary between the sclera and the choroid, the open bevel of the needle releases the drug between these two layers. Once drug is injected into the SCS, it spreads within the SCS to the back of the eye, targeting the cells of interest. The preparation and injection will require minimal training for the administering retinal specialist and can be accomplished in an in-office setting.

Our Pipeline

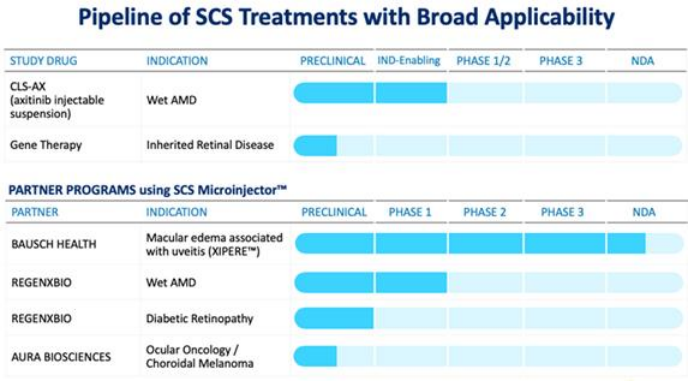
We have research capabilities focused on developing proprietary therapeutic formulations to utilize with our SCS Microinjector. Our internal research and development initiatives are focused on small molecules and gene therapy to address unmet needs in back-of-the-eye diseases. After evaluation of our prior work and based on recently presented data in the scientific community, we have decided to advance our proprietary suspension of axitinib, a tyrosine kinase inhibitor, or TKI, for suprachoroidal injection, which we refer to as CLS-AX, into further preclinical development. We expect to submit an Investigational New Drug application, or IND, to the U.S. Food and Drug Administration, or FDA, for CLS-AX in mid-2020. This would potentially enable us to initiate a Phase 1/2a clinical trial by the end of 2020.

In addition to growing our internal pipeline, we are also focused on collaborating with other companies to provide access to the suprachoroidal space.

During the second half of 2019, we entered into three license and other agreements that we believe validate and expand the reach of our suprachoroidal injection platform. In October 2019, we announced that Bausch + Lomb, a division of Bausch Health Companies, Inc., or Bausch, acquired an exclusive license for the commercialization and development of XIPERE (triamcinolone acetonide suprachoroidal injectable suspension) in the United States and Canada. In October 2019, REGENXBIO Inc., or REGENXBIO, exercised its option to license our SCS Microinjector technology for in-office delivery of adeno-associated virus (AAV)-based therapeutics to the SCS to potentially treat wet age-related macular degeneration, or AMD, diabetic retinopathy, and other conditions for which chronic anti-vascular endothelial growth factor, or anti-VEGF, treatment is currently the standard of care. In July 2019, Aura Biosciences, or Aura, licensed our SCS Microinjector to deliver Aura's proprietary drug candidates into the SCS for the potential treatment of certain ocular cancers, including choroidal melanoma.

By entering into these partnerships and expanding the use of our suprachoroidal injection platform to other indications, we eliminated the inherent risks and investment related to building and maintaining a commercial infrastructure for XIPERE. Under these license agreements, we received $7.0 million of non-dilutive capital in the form of upfront payments during 2019, and we are eligible to receive over $200 million in potential future development and sales milestones and royalties from net sales of covered products.

The current development status of our pipeline, including programs licensed to third parties, is summarized in the chart below:



XIPERE (triamcinolone acetonide suprachoroidal injectable suspension)

Our first candidate, XIPERE, formerly known as CLS-TA, is a proprietary, preservative-free suspension of the corticosteroid triamcinolone acetonide, or TA, formulated for administration via suprachoroidal injection. Corticosteroids are the standard of care in uveitis. They are effective at treating the inflammatory aspect of ocular disease, but when delivered locally, either topically as drops, intravitreally, or by periocular injection, they have been associated with significant side effects, such as cataract formation or exacerbation, and elevated intraocular pressure, or IOP, which can lead to glaucoma.

XIPERE is being developed for the treatment of macular edema associated with uveitis. Uveitis is a set of ocular inflammatory conditions affecting approximately 350,000 patients in the United States and more than one million worldwide. Approximately one-third of uveitis patients develop uveitic macular edema, a build-up of fluid in the macula, the area of the retina responsible for sharp, straight-ahead vision. Macular edema is the leading cause of vision loss and blindness in uveitis patients and can occur from uveitis affecting any anatomic location—anterior, intermediate, posterior or panuveitis. The uveitis market is expected to grow to nearly $550 million by 2024 in the United States, and over $1 billion globally.

XIPERE regulatory approval pathway

On December 19, 2018, we submitted a New Drug Application, or NDA, to the FDA for XIPERE for the treatment of macular edema associated with uveitis. On February 20, 2019, we announced that we had received notification that the FDA had accepted the NDA and assigned a Prescription Drug User Fee Act, or PDUFA, goal date for completion of its review by October 19, 2019.

On October 18, 2019, we received a complete response letter, or CRL, from the FDA regarding our NDA for XIPERE. The FDA did not identify any efficacy issues, and there were no requests for further clinical efficacy studies. As anticipated, the CRL included the FDA's request for additional stability data, additional clarifying information on components of the manufacturing process, and reinspection of the drug product manufacturer. The CRL included one new request for additional data on clinical use of the final to-be-marketed SCS Microinjector delivery system. In response to that request, we proposed the submission of SCS Microinjector clinical use information in 160 subjects from our TOPAZ study, as described below, for the treatment of macular edema associated with retinal vein occlusion, or RVO. In subsequent correspondence, the FDA agreed that it would be acceptable for us to submit such data in lieu of the requested clinical use evaluation.

In November 2019, we were informed by our commercial contract manufacturer for XIPERE that the FDA requested that the manufacturer complete certain manufacturing activities within its facility. Undertaking these activities, while not specifically related to XIPERE, may delay the production of the drug product stability data needed to resubmit our NDA. Based on current information from the manufacturer, we expect to resubmit the XIPERE NDA by the end of August 2020. We expect the PDUFA goal date for the resubmitted NDA to be six months from the FDA's receipt of the resubmission.

We are also evaluating options for potential submissions to regulatory agencies in additional territories outside of the United States and Canada for XIPERE for the treatment of patients with macular edema associated with uveitis.

License agreement for commercialization of XIPERE in United States and Canada

On October 22, 2019, we entered into an exclusive license agreement with Bausch for the commercialization and development of XIPERE in the United States and Canada, or the License Agreement. Pursuant to the License Agreement, Bausch paid us an upfront payment of $5.0 million, which is subject to a refund if the License Agreement is terminated in specified circumstances. In addition, Bausch has agreed to make additional payments of up to $15.0 million upon the achievement of specified pre-launch development and regulatory milestones and up to an aggregate of $56.0 million in additional milestone payments upon the achievement of specified regulatory approvals for specified additional indications of XIPERE and specified levels of annual net sales. Further, during the applicable royalty term, we will also be entitled to receive tiered royalties at increasing percentages, from the high-teens to twenty percent, based on XIPERE achieving certain annual net sales thresholds in the United States and Canada, as well as a lower royalty on annual net sales of other products, in each case subject to reductions in specified circumstances, although we will not receive any royalties on the first $30.0 million of cumulative net sales of all products.

We are responsible for all development expenses for XIPERE until our NDA for XIPERE is approved by the FDA, subject to specified exceptions, as well as manufacturing costs in connection with the NDA. We are also responsible for all clinical and development expenses conducted to satisfy the FDA's requests in the CRL and any subsequent CRL related to the NDA, or the CRL-related expenses. If XIPERE is approved by the FDA, Bausch will be responsible for all expenses following such approval, although we will be responsible for the CRL-related expenses and for one-half of the costs of any post-approval clinical trials required by the FDA, up to a specified maximum amount.

We intend to continue discussions with potential collaborators for the commercialization and development of XIPERE in other countries around the world.

XIPERE Phase 3 clinical trial data

In PEACHTREE, a pivotal Phase 3 randomized, controlled, multi-center clinical trial, we evaluated the safety and efficacy of XIPERE administered through the SCS in patients with macular edema associated with non-infectious uveitis. PEACHTREE was conducted at 63 investigational sites and enrolled 160 patients with macular edema associated with non-infectious uveitis, randomized either to a treatment arm consisting of 96 patients who received a 4.0 mg dose of XIPERE or to a sham injection procedure arm consisting of 64 patients. We used a sham injection procedure as a comparator for XIPERE, as opposed to an active drug, because there were no approved therapies for macular edema associated with uveitis against which to compare XIPERE, and there were no controlled, randomized trials with data in patients who could be used as an appropriate comparator arm.

PEACHTREE was the first Phase 3 clinical trial of a drug candidate for patients with uveitic macular edema in which improvement in best corrected visual acuity, or BCVA, was the primary efficacy endpoint. It was also the first pivotal trial in which patients were evaluated across all types of uveitis: anterior, posterior, intermediate, and panuveitis. The trial met its primary endpoint with 47% of patients who received XIPERE every 12 weeks gaining at least 15 letters in BCVA as measured using the Early

Treatment of Diabetic Retinopathy Study, or ETDRS, scale, from baseline at week 24, compared to 16% of patients who underwent a sham procedure. This difference was statistically significant, with a p-value of less than 0.001. All key secondary and additional endpoints of the PEACHTREE trial were also achieved.

XIPERE was generally well tolerated, with no treatment-related serious adverse events reported in the trial. Through 24 weeks, corticosteroid-related elevated IOP adverse events were reported for approximately 11.5% of patients in the treatment arm, compared to 15.6% of patients in the control arm, when including patients who received corticosteroid rescue medication. Specifically, 72% of patients in the control arm were administered rescue medication, with 37 of the 46 receiving intravitreal or periocular corticosteroid injections, such as intravitreal OZURDEX and periocular and intravitreal triamcinolone acetonide. Of those 37 control arm patients receiving local corticosteroid rescue medication, 10 patients, or 27%, experienced elevated IOP adverse events. In the PeriOcular and INTravitreal Corticosteroids for Uveitic Macular Edema Trial (POINT) Study, a recent National Eye Institute clinical trial studying the effect of current commercial treatments on macular edema associated with uveitis, over 30% of uveitis patients who received intravitreal steroid injections experienced steroid-related elevated IOP adverse events and received treatments to lower IOP. The reduced number of IOP adverse events in the XIPERE-treated patients in PEACHTREE suggest an IOP-sparing benefit, possibly due to the unique compartmentalization and ocular distribution of the drug inherent to administration via suprachoroidal injection. Preclinical studies investigating suprachoroidal administration support this assertion, with low corticosteroid exposure observed within the anterior chamber and trabecular meshwork.

In PEACHTREE, adverse events involving changes in cataract grading from baseline were similar in each arm, with approximately 7.3% and 6.3% of patients in the treatment arm and control arm showing adverse event changes in cataract grading, respectively. Further, no cataract surgeries resulted from this trial. Three serious adverse events occurred in the trial, all of which were identified in the CLS-TA arm: sialadenitis, posttraumatic compression fracture of the first lumbar vertebral body, and a retinal detachment approximately 8 weeks after the injection procedure. None of these serious adverse events were deemed treatment related by the study investigator or led to study discontinuation.

In January 2020, results of the PEACHTREE trial were published in *Ophthalmology*, the peer-reviewed journal of the American Academy of Ophthalmology.

In MAGNOLIA, our extension trial of PEACHTREE, we followed 28 of the 96 patients who were in the treatment arm of PEACHTREE across 22 clinical sites for six additional months without protocol-directed treatment to better understand XIPERE's long-term clinical profile. In MAGNOLIA, 50% of XIPERE-treated subjects maintained a mean improvement of 12.1 letters in BCVA from baseline through 36 additional weeks after their second suprachoroidal injection of XIPERE without requiring additional treatment.

In AZALEA, a Phase 3 safety trial, an additional 38 patients with non-infectious uveitis were enrolled in order to collect additional safety information required for our NDA submission. These patients were administered XIPERE at baseline and at week 12 and evaluated every 4 weeks after initial treatment, with a final evaluation at week 24. XIPERE was generally well tolerated, with no treatment-related serious adverse events reported in the trial.

In 2018, we were conducting SAPPHIRE, a Phase 3 trial, to assess the efficacy and safety of XIPERE together with intravitreal Eylea (aflibercept) in patients with RVO. We were also conducting TOPAZ, the companion Phase 3 trial to the SAPPHIRE trial assessing the efficacy and safety of suprachoroidal XIPERE together with an intravitreal anti-VEGF agent (either Lucentis, ranibizumab, or Avastin, bevacizumab) in patients with RVO. In November 2018, we announced that the primary endpoint of our Phase 3 clinical trial evaluating XIPERE together with intravitreal Eylea in patients with RVO was not achieved, and we discontinued the SAPPHIRE and TOPAZ trials at that time.

Axitinib for Suprachoroidal Injection (CLS-AX)

Our most advanced internal development program is our proprietary suspension of axitinib for suprachoroidal injection, which we refer to as CLS-AX. CLS-AX is an inhibitor of vascular endothelial growth factor receptor-1, -2 and -3 that we believe may benefit patients who respond suboptimally to current anti-VEGF therapies.

Axitinib is a TKI currently approved to treat renal cell cancer, and with its broad VEGF blockade, we believe it may have efficacy advantages over existing retinal therapies, which predominantly focus on VEGF-A blockade and may upregulate other forms of VEGF. Axitinib achieves pan-VEGF blockade by acting at a different level of the angiogenesis cascade, directly inhibiting VEGF receptors-1, -2, and -3 with high potency and specificity. In multiple preclinical animal studies by independent investigators, axitinib has inhibited corneal, retinal and choroidal angiogenesis. In one of these studies, axitinib more effectively inhibited experimental corneal neovascularization than other TKIs. In another study, axitinib showed better biocompatibility with ocular cells than other TKIs.

We are developing CLS-AX for administration to the SCS as a long-acting therapy for wet AMD. Current wet AMD therapy has a ceiling of efficacy as increased dosage or more intense regimens yield limited or no additional visual benefit, and is associated

with a significant treatment burden. This treatment burden is further highlighted by recent large "real-world" retrospective studies of wet AMD which underscore the difficulty in adhering to regimens. These real world studies demonstrate that patients are undertreated, receiving only 6 to 7 injections per year on average, resulting in mean improvement of only one to three letters in visual acuity after one year of treatment.

Based on preclinical data in multiple species, we believe that suprachoroidal injection of CLS-AX could benefit patients for several reasons. First, axitinib has intrinsic high potency and can achieve pan-VEGF inhibition through receptor blockade, which may benefit patients who respond suboptimally to current anti-VEGF-A therapy. Second, axitinib has been observed to have a pharmacodynamic effect, with reduced growth of experimental neovascularization and decreased fluorescein leakage. Third, suprachoroidal administration of axitinib can potentially achieve prolonged duration and targeted delivery to affected tissue layers. For these reasons, we are advancing CLS-AX as our lead internal development asset and expect to submit an IND for CLS-AX in mid-2020. This would potentially enable us to initiate a Phase 1/2a clinical trial by the end of 2020.

Gene Therapy

We believe our platform offers the potential for safer, targeted ocular gene therapy without some of the risks of surgery and subretinal administration. Suprachoroidal administration of gene therapy could ultimately enhance access to care because it does not require specialized gene therapy surgery treatment centers. The procedure for suprachoroidal injection is conducted in an office setting and is similar in terms of patient preparation and duration to the procedure for intravitreal injection. Therefore, we believe our products could be incorporated into retina specialists' standard medical practice.

During the past several years, gene therapy has demonstrated in preclinical studies and clinical trials conducted by third parties that genetic material can be effectively and tolerably introduced to the retinal tissues, most often using an AAV. Safe and reproducible delivery of gene therapy vector into the subretinal space is essential for successful targeting of the retinal pigment epithelium, or RPE, and photoreceptor rods or cones. Currently, the only approved retinal gene therapy and most investigational retinal gene therapies are delivered via retinal surgery at a limited number of specialized ocular gene therapy treatment centers. During the pars plana vitrectomy surgery, the surgeon creates a small hole in the retina to inject the gene therapy beneath the retina to the subretinal space without tearing or damaging the retina and macula. This process creates a small retinal detachment, which separates and exposes the photoreceptors and RPE to the gene therapy. The retina is in a disease state and already compromised, and the procedure carries iatrogenic risk. However, the success of this surgery is critical for the clinical efficacy of retinal gene therapy. Consequently, the surgery requires extensive training and the limited number of specialized ocular gene therapy centers creates patient access issues. Unlike vitrectomy, suprachoroidal administration does not require detachment of the photoreceptors from the RPE, and consequently, avoids the risk of iatrogenic subretinal injection to an already-compromised retina. Suprachoroidal injection procedure training is minimal and could ultimately enhance access to care because it would not have to be administered at a specialized gene therapy surgery treatment center.

In preclinical studies conducted independently and through collaborations with both an academic center and gene therapy companies, we have observed that SCS injection can administer both viral and non-viral gene therapy. Using marker genes like green fluorescent protein and luciferase in both rabbits and non-human primates, gene therapy was delivered with our SCS injection to achieve expression in the retina and choroid.

Inherited retinal diseases, or IRDs, such as Stargardt disease and Usher syndrome, represent some of the most challenging diseases that ophthalmologists encounter. They cause progressive, relentless vision loss due to changes in genes critical to the survival of photoreceptors and RPE cells, yet delivery of therapeutics to these cells is challenging. In preclinical animal studies from which data was presented at the American Academy of Ophthalmology 2019 Annual Meeting in October 2019, the suprachoroidal injection of luciferase DNA nanoparticles, or DNPs, in rabbits produced activity comparable to that seen from subretinal injections of luciferase DNPs. In these studies, SCS injections of DNPs were generally well tolerated across both rabbits and non-human primates, and no significant abnormalities were observed on ophthalmic exams. DNPs can also transfer large genes at potentially higher doses without the risks of subretinal surgery, which may allow for gene therapy in some of the most common IRDs.

We believe suprachoroidal administration may further enhance the value proposition of ocular gene therapy by potentially improving safety and expanding access. We are dedicating some of our resources toward development of therapeutics using this approach and are exploring non-viral gene therapies in preclinical studies both alone and in collaborations with an academic center and gene therapy companies.

Pipeline expansion through license of SCS Microinjector

In August 2019, we entered into an option and license agreement with REGENXBIO, pursuant to which we granted REGENXBIO an exclusive option, or the Option, to enter into a commercial license agreement granting REGENXBIO an exclusive, worldwide and sublicensable license to our SCS Microinjector for the delivery of AAV-based gene therapies for the treatment of wet

AMD, diabetic retinopathy and other conditions for which anti-VEGF treatment is currently the standard of care. REGENXBIO exercised the Option on October 29, 2019 and paid us an option fee equal to $2.0 million less $0.5 million received under a prior technology access agreement. Under the license agreement, REGENXBIO has agreed to make additional payments to us of up to an aggregate of $34.0 million upon the achievement of specified development milestones and up to $102.0 million in sales-based milestone payments, as well as mid-single digit royalties on net sales of products using the SCS Microinjector during the royalty term.

REGENXBIO will be responsible for all development, regulatory and commercialization activities for their gene therapy product candidates. We will be responsible for supplying the SCS Microinjector in support of REGENXBIO's preclinical studies, clinical studies and commercial use.

On July 9, 2019, we entered into a worldwide licensing agreement with Aura for the use of our SCS Microinjector to deliver Aura's proprietary drug candidates into the SCS for the potential treatment of certain ocular cancers, including choroidal melanoma. If the collaboration proves successful following preclinical and proof-of-concept studies, Aura may utilize the SCS Microinjector for certain future development programs. Pursuant to the licensing agreement, we are eligible to receive payments related to pre-specified development, regulatory and sales milestones, as well as royalties on product sales that utilize the SCS Microinjector.

Manufacturing

We do not own any manufacturing facilities. We utilize contract manufacturers to formulate and produce our drug candidates and to produce our SCS Microinjector used for our clinical trials. We procure active pharmaceutical ingredients for our drugs from third-party suppliers. We expect to utilize third-party manufacturers to produce commercial quantities of our drugs and SCS Microinjector, if approved.

On May 8, 2018, we entered into a supply agreement with Gerresheimer Regensburg GmbH to supply our SCS Microinjector. Unless terminated earlier pursuant to its terms, the Gerresheimer agreement has an initial term of five years, after which it renews in three-year increments unless either party gives notice of non-renewal at least one year in advance. Each party has the right to terminate the agreement for customary reasons such as material breach and bankruptcy. The Gerresheimer agreement contains provisions relating to compliance by Gerresheimer with current Good Manufacturing Practices, confidentiality and other customary matters for an agreement of this nature. We anticipate entering into commercial supply agreements with our other suppliers at a later date.

Commercialization

We have entered into an exclusive license agreement with Bausch for the commercialization and development of XIPERE in the United States and Canada. We may enter into distribution or licensing arrangements for commercialization rights for other regions. If any of our future product candidates, including CLS-AX, are approved by the FDA, we may either commercialize those product candidates ourselves or through license or collaboration agreements with third parties.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidate that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

XIPERE faces competition from other commercially available forms of TA and other topical, injectable and implantable corticosteroids. Bristol-Myers Squibb markets TA under the brand name Kenalog. Kenalog is indicated only for intramuscular or intraarticular injection; however, it is used off-label for intraocular inflammation using intravitreal and periocular administration. There are also a number of generic equivalents of Kenalog. In addition, Alcon's injectable TA, Triesence, is approved in the United States for the treatment of uveitis and other inflammatory conditions unresponsive to topical corticosteroids, although it is not indicated for the treatment of macular edema associated with uveitis or RVO. OZURDEX, marketed by Allergan, is a bioerodable extended release implant that delivers the corticosteroid dexamethasone and is approved for the treatment of non-infectious uveitis affecting the posterior segment of the eye and for macular edema due to RVO in both the United States and in the European Union, and received approval from the FDA to treat diabetic macular edema, or DME.

Additionally, our collaborator Bausch markets Retisert, an intravitreal implant of the corticosteroid fluocinolone acetonide for the treatment of non-infectious uveitis. Eyepoint Pharmaceuticals markets Yutiq, an injectable form of fluocinolone acetonide for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

Our product candidate, CLS-AX, could also compete with anti-VEGF drugs, which are the current standard of care for RVO and wet AMD. Genentech's products Lucentis and Avastin are both anti-VEGF antibodies. Lucentis is currently approved in the United States and European Union for the treatment of wet AMD, macular edema following RVO, and diabetic retinopathy in patients with DME. Avastin is an anti-VEGF drug used off-label by uveitis and retina specialists in both the United States and in certain countries of the European Union for the treatment of numerous retinal diseases, but it is not indicated for ophthalmic use. In the United States, Regeneron's anti-VEGF product, Eylea, is approved for the treatment of wet AMD, macular edema following RVO and diabetic retinopathy. In the European Union, Eylea is approved for the treatment of wet AMD and RVO. Novartis' Beovu was recently approved for the treatment of wet AMD in the United States, and has been recommended for approval in the European Union at a recent meeting of European Medicines Agency's drug evaluation committee.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient recruitment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors may also obtain FDA or other regulatory approval for their drugs before 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 or obtaining FDA market exclusivity, thereby delaying our product approvals. Competitors' patent protection could also potentially delay FDA approval of our product candidates for up to 30 months, and we may still be subject to potential patent litigation that might arise beyond the 30 months. The key competitive factors affecting the success of our product candidates, if approved for marketing, are likely to be their efficacy, safety, method of administration, convenience, price and the availability of coverage and reimbursement from government and other third-party payors.

Intellectual property

Our success depends in part on our ability to obtain and maintain patent and other intellectual property and proprietary protection for our technologies and methods of accessing the SCS, drug candidates and formulations as well as patent and other intellectual property and proprietary protection for novel applications, uses, and technological innovations related to our drug candidates, proprietary delivery devices and core technologies. We also rely on trade secrets, know-how, and continuing technological innovation to develop and maintain our proprietary position.

Patents and patent applications

Our patent estate, on a worldwide basis, includes 19 granted U.S. patents broadly directed to devices and methods of administering drugs into the SCS by injection, including one design patent. In addition, our patent estate includes one allowed U.S. patent application, 14 patent applications pending in the United States, 42 issued foreign patents and five allowed foreign patents, one pending international PCT application and 47 patent applications pending in major international markets, including the European Union, Canada, India, Japan, China and Australia, relating to our SCS delivery technology, as well as the formulations of our current therapeutic drug candidates and delivery device. Of these patents and patent applications, we license five of the 19 issued U.S. patents, the allowed U.S. application, three pending U.S. applications, 14 of the issued foreign patents and one of the allowed foreign patents, and six foreign patent applications in major international markets, each relating to methods of delivering drugs to the eye by microneedle administration, pursuant to a license agreement with Georgia Tech Research Corporation and Emory University that is described below. With respect to in-licensed international PCT applications, according to the terms of the license agreement, we advise Georgia Tech and Emory regarding the countries in which patent applications should be pursued. Subject to payment of required maintenance fees, annuities and other charges, our issued in-licensed U.S. patents are expected to expire between 2027 and 2029, without taking into account possible patent term adjustments or extensions. Applications relating to SCS delivery technology and methods, our current therapeutic drug candidates and formulations, various therapeutic uses, including treatment of specific indications such as macular edema associated with uveitis and RVO, wet AMD as well as DME and improvement of specified clinical parameters, are expected to expire between 2027 and 2039, without taking into account possible patent term adjustments or extensions.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be extended by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and

granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review.

Our product candidates are protected against genericization through numerous patents. In the case of XIPERE injected into the SCS, an applicant who files a paragraph 4 ANDA or 505(b)(2) NDA certifying they may circumvent our patents must also demonstrate comparability of the proposed drug, which we believe may require a clinical trial in macular edema associated with uveitis, against our product, unless a biowaiver is obtained.

Third-party patent filings

Numerous U.S. and foreign issued patents and patent applications owned by third parties exist in the fields in which we are developing products, including patents and applications related to surgical methods of accessing the SCS and certain formulations of TA. Because patent applications can take many years to issue, there may be applications unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe.

Under U.S. law, a person may be able to patent a discovery of a new way to use a previously known compound, even if such compound itself is patented, provided the newly discovered use is novel and nonobvious. Such a method-of-use patent, however, if valid, only protects the use of a claimed compound for the specified methods claimed in the patent. This type of patent does not prevent persons from using the compound for any previously known use of the compound. Further, this type of patent does not prevent persons from making and marketing the compound for an indication that is outside the scope of the patented method.

License agreement with Emory and Georgia Tech

We have entered into a license agreement with Emory University, or Emory, and the Georgia Tech Research Corporation, or GTRC, under which we received a worldwide exclusive license to specified patents relating to methods and devices for drug delivery using a microinjector. The field of the license covers all ophthalmic uses of the microinjector for mammals and birds. Under this license agreement, we have agreed to direct all prosecution of intellectual property to the licensors' patent counsel and have agreed to pay for all intellectual property expenses associated with the licensed patents.

In addition to upfront and milestone payments of $65,000 in the aggregate made to date, the license agreement requires us to make a $75,000 milestone payment upon the occurrence of a specified event relating to the commercialization of a drug developed using the licensed patents. On July 1, 2018 and 2019, we paid Emory and GTRC $75,000 and $50,000, respectively, to extend the date by which we may achieve the commercialization milestone. We are obligated to pay an annual license maintenance fee of $25,000, which will continue until the first commercial sale of a product covered by the licensed patents. Additionally, we will owe a low single-digit royalty on any worldwide net product sales related to the licensed patents, with minimum annual royalties starting at $15,000 per year after commercialization. The minimum annual royalty increases each year after the first commercial sale, up to a maximum amount of $100,000 per year in the sixth calendar year and in subsequent years.

We are solely responsible for the development and commercialization of products related to the licensed patients. We are obligated to provide Emory and GTRC a written report detailing our activities related to the development and commercialization of products twice a year.

Royalties are calculated based on net sales of products covered by a patent licensed under the agreement, and are due on each such product sold as long as the patent covering that particular product is valid and unexpired. Unless otherwise terminated pursuant to its termination provisions, this license agreement will expire upon the expiration of the last to expire of the licensed patents. We have the right to terminate this license agreement at any time upon 60 days' written notice to Emory and GTRC. Emory and GTRC may also terminate this license agreement in the event of a material breach by us. This license agreement will immediately terminate if we challenge the validity or enforceability of any of the licensed patents in a court or other governmental agency of competent jurisdiction.

Trademarks, trade secrets and know-how

Our trademark portfolio currently consists of two registered trademarks in Australia and Korea, two registered and one pending application in Russia, two registered trademarks in Singapore, six registered trademarks in Brazil, three registered trademarks in Canada and two pending applications in Canada, five registered and one pending application in China, four registered trademarks in the European Union, two registered trademarks in each of India and New Zealand, two registered trademarks in each of Israel and Japan, seven registered trademarks in Mexico, four registered and three pending applications in South Africa, four registered

trademarks in the United States and three pending applications in the United States. We also have two international registrations: the first with pending extensions of protection to Australia, Japan, Mexico and registered in the European Union, India, New Zealand, Korea and Singapore, and the second with extensions of protection pending in India and Mexico and registered in Australia, China, European Union, Israel, Japan, Korea, Russia, and Singapore. In addition to patent and trademark protection, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees, and consultants, and employees. These and other agreements, such as invention assignment agreements, grant us ownership of technologies that are developed through a relationship with a third party.

Government regulation

In the United States, the FDA regulates drug and device products under the FDCA and its implementing regulations. While it may be the case that when a drug and a device are used together, which is called a combination product, the FDA typically regulates the dispenser of a drug, such as a syringe co-packaged with a drug, as a drug itself.

In the case of our product candidates, the primary mode of action is attributable to the drug component of the product, which means that the FDA's Center for Drug Evaluation and Research, or CDER, has primary jurisdiction over the premarket development, review and approval of our product candidates. We have been advised that, within CDER, the division responsible for ophthalmology, which will have primary jurisdiction, views our product candidate as a drug. Based on our discussions with the FDA, including our pre-NDA meeting, we do not anticipate that the FDA will require changes to this approach, although the FDA could change its position during the course of its review of any marketing application that we may submit.

Drugs

The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are governed by extensive regulation by governmental authorities in the United States and other countries. The FDA, under the FDCA, regulates pharmaceutical products in the United States. The steps required before a drug may be approved for marketing in the United States generally include:

- preclinical laboratory tests and animal tests conducted under GLP;
- the submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product and conducted in accordance with Good Clinical Practices, or GCP;
- the submission to the FDA of an NDA;
- FDA acceptance, review and approval of the NDA, which might include an Advisory Committee review; and
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with current Good Manufacturing Practices, or cGMPs.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain. The FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Preclinical studies include laboratory evaluations of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. The FDA or an IRB may nevertheless initiate a clinical hold after the 30 days if, for example, significant health risks arise.

In the United States, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at each of the sites at which the trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Clinical trials are typically conducted in three sequential phases prior to approval, but the phases may overlap. These phases generally include the following:

Phase 1. Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects, frequently healthy volunteers. In Phase 1, the product candidate is usually tested for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamics.

Phase 2. Phase 2 clinical trials usually involve studies in a limited patient population to (1) evaluate the efficacy of the product candidate for specific indications, (2) determine dosage tolerance and optimal dosage and (3) identify possible adverse effects and safety risks.

Phase 3. If a product candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 clinical trials, the clinical trial program will be expanded to Phase 3 clinical trials to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites.

Phase 4 clinical trials may be conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA in the form of post-market requirements or commitments. Failure to promptly conduct any required Phase 4 clinical trials could result in enforcement action or withdrawal of approval.

The results of preclinical studies and clinical trials, together with detailed information on the manufacture, composition and quality of the product, are submitted to the FDA in the form of an NDA, requesting approval to market the product. The application must be accompanied by a significant user fee payment, although waivers may be granted and exemptions apply in limited cases. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval and require additional preclinical, clinical or other studies.

Review of application

Once an NDA has been accepted for filing, which occurs, if at all, 60 days after submission, the FDA sets a user fee goal date that informs the applicant of the specific date by which the FDA intends to complete its review. This is typically 10 months from the date of submission for drugs that are not new molecular entities, such as our product candidates. The review process can be expedited if priority review is granted. In such a case, the FDA review period is only 6 months. Alternatively, the FDA review process can be extended by FDA requests for additional information or clarification. The FDA reviews NDAs to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA may inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMPs and may also inspect clinical trial sites for integrity of the data supporting safety and efficacy. The device component of our products will also be subject to review as part of the NDA review process and its manufacturers subject to inspection for compliance with device cGMPs embodied in the Quality System Regulation, or QSR. During the approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS, and the FDA will not approve the application without an approved REMS, if required. A REMS can substantially increase the costs of obtaining approval. The FDA could also require a special warning, known as a black box warning, to be included in the product label in order to highlight a particular safety risk. The FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. The FDA may require post-marketing testing and surveillance to monitor safety or efficacy of a product. FDA will issue either an approval of the NDA or a CRL, detailing the deficiencies and information required for reconsideration of the application.

Post-approval requirements

Approved drugs that are manufactured or distributed in the United States are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims and some manufacturing and supplier changes are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for approved products, as well as new application fees for certain supplemental applications.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. The FDA may also require a REMS, which could involve requirements for, among other things, a medication guide, special training for prescribers and dispensers, and patient registries.

In addition, entities involved in the manufacture and distribution of approved devices or drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. The FDA has promulgated specific requirements for drug cGMPs, device cGMPs embodied in the QSR and combination product cGMPs that, for drug/device combination products, specify the requirements within the drug cGMPs and the QSR with which manufacturers must comply. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, including without limitation the FDCA, the federal civil False Claims Act, other federal and state health care fraud and abuse laws and state consumer protection laws. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

The Hatch-Waxman amendments

Our regulatory strategy is to pursue development of our drugs as Section 505(b)(2) NDAs under the FDCA. As an alternative path to FDA approval for modifications to formulations or uses of drugs previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments. A Section 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This type of application permits reliance for such approvals on literature or on an FDA finding of safety, effectiveness or both for an approved drug product. As such, under Section 505(b)(2), the FDA may rely, for approval of an NDA, on data not developed by the applicant. Therefore, if we can satisfy the conditions required for a Section 505(b)(2) NDA submission, it may eliminate the need for us to conduct some of the preclinical studies or clinical trials for the new product candidate that might otherwise have been required, although the review time is not shortened. As a condition for approval, the FDA may also require us to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug.

Orange Book listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the

drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, known as the Orange Book. Any applicant who files an Abbreviated New Drug Application, or ANDA, seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify, for each patent listed in the Orange Book for the referenced drug, to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA, (2) such patent has expired, (3) the date on which such patent expires or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. The fourth certification described above is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. This section viii statement does not require notice to the patent holder or NDA owner. There might also be no relevant patent certification.

If the reference NDA holder and patent owners file patent litigation directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification, expiration of the patent, settlement of the lawsuit, or a decision in the case that is favorable to the applicant. Even if the 45 days expire, a patent infringement lawsuit can be brought and could delay market entry, but it would not extend the FDA-related 30-month stay of approval.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-patent exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug.

A drug, including one approved under a 505(b)(2) application, may obtain a three-year period of non-patent market exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application until after that three-year exclusivity period has run. However, the FDA can accept an application and begin the review process during the three-year exclusivity period. A 505(b)(2) NDA may also be subject to a five-year exclusivity period for a new chemical entity, whereby the FDA will not accept for filing, with limited exception, a product seeking to rely upon the FDA's findings of safety or effectiveness for such new chemical entity.

Orphan drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States, or in other limited cases. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan drugs are eligible for certain incentives, including tax credits for qualified clinical testing. In addition, an NDA for a product that has received orphan drug designation is not subject to a prescription drug user fee unless the application includes an indication other than the rare disease or condition for which the drug was designated.

If a product 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 active moiety for the same indication for seven years, except in limited circumstances, such as another drug's showing of clinical superiority over the drug with orphan exclusivity. Competitors, however, may receive approval of different active moieties for the same indication or obtain approval for the same active moiety for a different indication. In addition, doctors may prescribe products for off-label uses and undermine our exclusivity. Orphan drug exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same active moiety for the same indication before we do, unless we are able to demonstrate that our product is clinically superior.

We do not plan to pursue orphan drug designation for XIPERE for the treatment of uveitis in the United States. However, we may seek designation for other products in the future. We cannot guarantee that we will obtain orphan drug designation for any products in any jurisdiction. Even if we are able to obtain orphan drug designation for a product, we cannot be sure that such product will be approved, that we will be able to obtain orphan drug exclusivity upon approval, if ever, or that we will be able to maintain any exclusivity that is granted.

Foreign regulation

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

Federal and state fraud and abuse, data privacy and security and transparency laws

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict our business practices. These laws include, without limitation, anti-kickback and false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. Therefore, even if we structure our programs with the intent of compliance with such laws, there can be no certainty that we would not need to defend ourselves against enforcement or litigation due to the fact that there is significant enforcement interest in life sciences companies in the United States and some of the applicable laws are broad in scope.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law 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 civil False Claims Act.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The federal civil False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the federal civil False Claims Act. Pharmaceutical, device and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-covered, uses.

The government may further prosecute conduct constituting a false claim under the federal criminal False Claims Act. The federal criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the federal civil False Claims Act, requires proof of intent to submit a false claim.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal and civil statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare

benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

Under HIPAA, the U.S. Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including certain health care providers, health plans, and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in health care transactions and standardization of identifiers for health plans and providers. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH and their regulations, including the omnibus final rule published on January 25, 2013, also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that are applicable to our business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. Accordingly, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. New laws and regulations governing privacy and security may be adopted in the future as well.

In the EU/EEA, the General Data Protection Regulation (2016/679), or GDPR, went into effect on May 25, 2018 and replaced Directive 95/46/EC (the EU Privacy Directive). The GDPR applies to identified or identifiable personal data processed by automated means (for example, a computer database of customers) and data contained in, or intended to be part of, non-automated filing systems (traditional paper files) as well as transfer of such data to a country outside of the EU/EEA. Under the GDPR, fines of up to €20.0 million or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. The GDPR includes more stringent operational requirements for processors and controllers of personal data and creates additional rights for data subjects.

Additionally, in June 2016, United Kingdom voters approved an exit from the EU, commonly referred to as "Brexit," which could also lead to further legislative and regulatory changes. In March 2017, the United Kingdom began the process to leave the EU by April 2019. While the Data Protection Act of 2018, that "implements" and complements the GDPR has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under GDPR. During the period of "transition" (i.e., until December 31, 2020), EU law will continue to apply in the UK, including GDPR, after which the GDPR will be converted into UK law. Beginning in 2021, the UK will be a "third country" under the GDPR. We may, however, incur liabilities, expenses, costs, and other operational losses under GDPR and applicable EU Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. Effective January 1, 2020, the CCPA requires covered companies to provide new disclosures to California consumers, provides such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches. The CCPA could impact our business activities depending on how it is interpreted and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information.

Additionally, a trend has continued of increased federal and state regulation of payments and transfers of value provided to healthcare professionals and/or entities. On February 8, 2013, the Centers for Medicare & Medicaid Services, or CMS, released its final rule implementing the Physician Payments Sunshine Act that imposes annual reporting requirements on certain manufacturers of drugs, devices, biologicals and medical supplies for payments and other transfers of value provided by them, directly or indirectly, to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. Certain states also mandate implementation of commercial compliance programs, impose restrictions on

pharmaceutical manufacturer and device manufacturer marketing practices, require registration of pharmaceutical sales representatives, require drug manufacturers to report information on the pricing of certain drugs, or require tracking and reporting of gifts, compensation and other remuneration to particular types of healthcare professionals and entities.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such laws. The heightening compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the health care laws or regulations described above that are applicable to us, or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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. To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Coverage and reimbursement

The physicians who use our product candidates, if approved, may be reimbursed by third-party payors for both the suprachoroidal injection using our SCS Microinjector and for the drug itself. On July 1, 2016, the American Medical Association, or AMA, approved a new Category III Current Procedural Terminology, or CPT, code for the suprachoroidal injection of pharmacologic agents. Category III codes are a set of temporary codes maintained by the AMA for emerging technology, services and procedures. Payment for these services or procedures are based on the coverage policies of individual third-party payors, including private insurers and government-funded programs, like Medicare, and Medicare administrative contractors. CPT code 0465T became effective on January 1, 2017, but we believe obtaining a separate CPT code for the use of our products is essential to our commercial success. We intend to seek a Category 1 CPT code and a separate Healthcare Common Procedure Coding System, or HCPCS, code as maintained by CMS for the drug itself should we receive approval from the FDA. We believe that separate CPT and HCPCS codes will help third-party payors differentiate our drug candidates from other drugs currently on the market administered through intravitreal injections, although we can provide no assurance that CMS will approve the creation of a separate CPT code or HCPCS code. Additionally, there is no guarantee that these billing codes or the payment amounts, if any, associated with such codes will not change in the future.

Our strategy will include efforts to engage third-party payors to establish coverage, coding and reimbursement that will facilitate access to our product candidates and the SCS injection procedure as we expand our commercialization efforts in the United States. Our success in these efforts depends in part on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for the procedures during which our product candidates are administered and for the drugs themselves. Failure by physicians, hospitals, ambulatory surgery centers, and other users of our products to obtain sufficient coverage and adequate reimbursement from third-party payors for the procedures to administer our product candidates or for the product candidates themselves, or adverse changes in third-party payors' policies would have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

In the U.S., third-party payors continue to implement initiatives that restrict the use of certain technologies to those that meet certain clinical evidentiary requirements. Failure to obtain favorable coverage policies could have a material adverse effect on our business and operations.

In addition to uncertainties surrounding coverage policies, third-party payors from time to time update reimbursement amounts and also revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to ambulatory surgery centers, hospitals and physicians for the procedures performed administering our products, which could directly impact the demand for any of our product candidates that may be approved. An example of payment updates is the Medicare program updates to physician payments, which is done on an annual basis using a prescribed statutory formula. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. However, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula and established a quality payment program, also referred to as the Quality Payment Program. The quality payment program has two tracks, one known as the merit based incentive payment system for providers in the fee-for service Medicare program, and the advanced alternative payment model for providers in specific care models, such as accountable care organizations. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time it is unclear how the introduction of the Quality Payment Program will impact

overall physician reimbursement under the Medicare program. Any changes in coverage and reimbursement that further restricts coverage of our products or lowers reimbursement for procedures using our products could materially affect our business.

Healthcare reform

Current and future legislative proposals to further reform healthcare or reduce healthcare costs may result in lower reimbursement for our products, or for the procedures associated with the use of our products, or limit coverage of our products. The cost containment measures that third-party payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our revenues from the sale of our products.

For example, implementation of the Affordable Care Act has the potential to substantially change healthcare financing and delivery by both governmental and private insurers, and significantly impact the pharmaceutical and medical device industries.

The Affordable Care Act imposed, among other things, a new federal excise tax on the sale of certain medical devices, established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, and provided incentives to programs that increase the federal government's comparative effectiveness research. There remain judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated medical device tax and "Cadillac" tax on high-cost employer-sponsored health coverage and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, CMS published a new final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to the BBA, will remain in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs

for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

Employees

As of December 31, 2019, we had 33 employees, all of whom were full-time and were located in the United States. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Corporate Information

We were incorporated under the laws of the State of Delaware in May 2011. Our principal executive offices are located at 900 North Point Parkway, Suite 200, Alpharetta, Georgia. Our telephone number is (678) 270-3631.

Available Information

Our internet website address is www.clearsidebio.com. In addition to the information about us and our subsidiaries contained in this Annual Report, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or SEC. Additionally the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Annual Report on Form 10-K. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We incurred net losses of $30.8 million, $82.8 million and $59.0 million for the years ended December 31, 2019, 2018 and 2017, respectively.

We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We have not completed development of, and obtained marketing approval for, any drugs. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- conduct and complete our ongoing and planned clinical trials;
- seek to discover, research and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio; and
- hire additional clinical, manufacturing and scientific personnel.

To become and remain profitable, we must succeed in developing drugs that can generate significant revenue once commercialized. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, manufacturing, obtaining regulatory approval and potentially entering into agreements for the commercialization of any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate sufficient revenue to achieve profitability.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations. A decline in our value could also cause you to lose all or part of your investment.

Our consolidated financial statements have been prepared assuming that we will continue as a going concern.

We have incurred recurring losses from operations since inception which raises substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. In addition, if there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, or at all.

We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce or altogether cease our drug development programs or commercialization efforts.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2021. However, we will need to obtain substantial additional funding in connection with our continuing operation beyond the first quarter of 2021. Our future capital requirements will depend on many factors, including:

- the progress and results of our ongoing, planned and future clinical trial programs;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, whether performed by us or third parties, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license and development agreements. We do not currently have any committed external source of funds other than our credit facility, although as described in this report we have also entered into an at-the-market sales facility that allows us to sell shares of our common stock at prevailing market prices and on specified terms, depending on market conditions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development efforts or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been largely focused on raising capital, identifying potential product candidates, broadening our expertise in the development of our product candidates, including our SCS Microinjector, and undertaking preclinical studies and conducting early clinical trials. We have not yet demonstrated an ability to successfully complete multiple later-stage clinical trials,

obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We may not be successful in our transition from a company with a research and development focus to a company capable of supporting commercial activities.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We may not be able to generate sufficient cash to service our indebtedness.

Our current loan agreement had an outstanding principal balance of $5.0 million as of December 31, 2019. The loan agreement, as amended to date, contains negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions, incurring indebtedness or liens, paying dividends or making investments and other specified business transactions. In addition, our failure to maintain a minimum cash balance at our bank would require us to transfer an amount equal to the outstanding loan balance to a pledged account that would restrict our access to such funds. Our obligations under the loan agreement also are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition. We were in compliance with these covenants as of December 31, 2019 but there can be no assurance that we will remain in compliance. We may also enter into other debt agreements in the future which may contain similar or more restrictive terms.

Our ability to make scheduled monthly payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. Failure to comply with the conditions of the loan agreement could result in an event of default, which could result in an acceleration of amounts due under the loan agreement. We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and our lenders could seek to enforce security interests in the collateral securing such indebtedness, which would harm our business.

Risks Related to the Development of Our Product Candidates

Our efforts are focused on the development of product candidates for treatment of eye disease through suprachoroidal injection and partnering with companies who can leverage our SCS Microinjector to deliver their ophthalmic product candidates to the suprachoroidal space. Suprachoroidal injection is a novel approach and may fail to achieve and sustain market acceptance.

Injecting drugs into the SCS is a novel approach for ophthalmic therapies, and there is no guarantee this approach will provide adequate patient benefit or be accepted by physicians, patients or third-party payors. We have also licensed our SCS Microinjector technology to REGENXBIO for in-office delivery of REGENXBIO's AAV-based therapeutics to the SCS to potentially treat wet AMD, diabetic retinopathy and other conditions for which anti-VEGF treatment is currently the standard of care and to Aura to deliver Aura's proprietary drug candidates into the SCS for the potential treatment of certain ocular cancers, including choroidal melanoma. Although our clinical trial results suggest that suprachoroidal injection of drugs, such as XIPERE, may be effective at treating back of the eye diseases, to date no company has developed a drug delivered via suprachoroidal administration that has received marketing approval.

We cannot guarantee that suprachoroidal injection of drugs will prove in ongoing and future clinical trials to be a safe or effective approach for treating eye diseases in humans, nor can we ensure that such drugs will achieve regulatory approval, even if the clinical trials are successful.

Even if our product candidate, or a product candidate of one of our collaboration partners, delivered via suprachoroidal injection achieves marketing approval, the novelty of suprachoroidal injection may make it difficult to demonstrate to physicians and third-party payors that suprachoroidal injection of drugs is an appropriate approach for treating eye diseases and provides advantages

compared to the current standards of care. Further, if we or our commercialization and collaboration partners are not successful in conveying to physicians, patients and third-party payors that the suprachoroidal administration of drug candidates with our proprietary SCS Microinjector provides useful patient outcomes, we or our commercialization and collaboration partners may experience reluctance, or refusal, on the part of physicians to order and use, and third-party payors to cover and provide adequate reimbursement for, such product candidates. Additionally, in some cases, product candidates delivered using our SCS Microinjector will complement the current standard of care, rather than serve as a replacement for the current standard of care. Therefore, we or our commercialization and collaboration partners may encounter significant difficulty in gaining broad market acceptance by physicians, third-party payors and potential patients.

Our licensing partners may require that we modify our SCS Microinjector to deliver their product candidates, and we may be unable to do so.

We are currently partnering with companies who can leverage our SCS Microinjector to deliver their ophthalmic product candidates to the suprachoroidal space. Our current and future licensing partners may request modifications to the design of our SCS Microinjector to accommodate the delivery of their respective product candidates. If we are unable to make such modifications, we may not receive regulatory and development milestone payments that we otherwise would be eligible to receive, which could significantly harm our financial position and adversely affect our stock price.

All of our product candidates are in clinical or preclinical development. If we are unable to obtain regulatory approval for and commercialize our product candidates, either on our own or with a third party, or if we experience significant delays in doing so, our business may be harmed.

Given our human experience with our clinical programs, the successful development of any of our product candidates is extremely uncertain, and we cannot guarantee that we will be successful in developing any of our product candidates. Further, the FDA may conclude that our clinical trials are not sufficient to support approval of our product candidates.

We have not completed the development of any product candidates, we currently generate no revenues from sales of any products and we may never be able to develop a marketable product. We have invested substantially all of our efforts and financial resources in the development of our proprietary SCS Microinjector for suprachoroidal injection of drugs and the identification of potential drug candidates using that technology. Our ability to generate revenue from our product candidates will depend heavily on their successful development and eventual commercialization, either by us or third parties. The success of those product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and requisite clinical trials;
- performing preclinical studies and clinical trials in compliance with FDA requirements;
- receipt of marketing approvals from applicable regulatory authorities;
- ability to import sufficient quantity of product for trials or potential commercialization;
- obtaining marketing approvals with labeling for sufficiently broad patient populations and indications, without unduly restrictive distribution limitations or safety warnings, such as black box warnings or a risk evaluation and mitigation strategy, or REMS, program;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- launching commercial sales of products, if and when approved, whether alone or in collaboration with others;
- successful training of physicians in the proper use of our SCS Microinjector;
- the ability to market our products for use with our SCS Microinjector without a requirement from the FDA that we obtain a separate medical device authorization;
- acceptance of the therapies and of the concept of suprachoroidal injection of drugs, if and when approved, by physicians, patients and third-party payors;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;

- protecting our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the drugs and our SCS Microinjector following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

Data from our clinical trials that we announce or publish from time to time may change as more patient data become available, and such data are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish data from our clinical studies. Data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our prospects for obtaining regulatory approval of our product candidates.

We may not be successful in our efforts to build a pipeline of product candidates.

A key element of our strategy is to build a pipeline of product candidates for the treatment of a variety of diseases of the back of the eye via suprachoroidal injection and to progress these product candidates through developmental efforts. We may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have significant side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval or achieve market acceptance. If we do not successfully develop product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect our stock price.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of our product candidates.

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. For example, we were previously developing XIPERE in combination with an anti-VEGF therapy for the treatment of macular edema associated with RVO. In November 2018, we announced that the primary endpoint of our Phase 3 clinical trial evaluating XIPERE together with intravitreal Eylea in patients with RVO was not achieved. In light of the 8-week topline data, we discontinued our Phase 3 trials of suprachoroidal XIPERE together with an intravitreal anti-VEGF agent in patients with RVO, as well as the clinical development of XIPERE in combination with anti-VEGF agents for the treatment of RVO.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

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

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials.

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval 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, such as black box warnings or a REMS program;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our drug development costs may also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could 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 and impair our or our potential collaborators' ability to successfully commercialize our product candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. We have relatively limited experience enrolling patients in our clinical trials, and cannot predict how successful we will be at enrolling patients in future clinical trials. In addition, if we are not successful at enrolling patients in one clinical trial, it may affect when we are able to initiate our next clinical trial, which could result in significant delays in our efforts to pursue regulatory approval of and commercialize our product candidates. In addition, some of our competitors have ongoing clinical trials to treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors. Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the availability of drugs approved to treat the diseases under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;

- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which could cause our value to decline and limit our ability to obtain additional financing.

The COVID-19 coronavirus could adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread to multiple countries, including the United States and several European countries. If the COVID-19 coronavirus continues to spread in the United States, we may experience disruptions that could severely impact our business, supply chain, preclinical studies and clinical trials, including:

- delays or inability to obtain raw material or ingredients;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others; and
- limitations in employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which the COVID-19 coronavirus may impact our business, supply chain, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

If serious adverse or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate. In addition, in some cases, the FDA could issue a clinical hold to stop the study.

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

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Risks Related to Our Dependence on Third Parties

We have granted an exclusive license to Bausch for the commercialization and development of XIPERE in the United States and Canada, and we intend to seek one or more partners for the commercialization of XIPERE in other jurisdictions around the world. If we are unable to secure additional commercialization partners, or if our partners fail to successfully commercialize XIPERE in their respective markets, our business and prospects will be materially harmed.

Our business prospects and our ability to generate product revenue related to XIPERE, if any, will be heavily dependent on the efforts of third parties with whom we have entered, or will enter, into arrangements to perform sales, marketing and distribution services for XIPERE in the United States and internationally. For instance, we have granted an exclusive license to Bausch for the commercialization and development of XIPERE in the United States and Canada. Pursuant to our agreement with Bausch, we are entitled to receive payments based on the achievement of specified sales and regulatory milestones and tiered royalties based on annual net sales of XIPERE. The successful or timely achievement of many of these milestones is outside of our control because the relevant activities will be conducted by Bausch. We expect to depend to a large degree on the payments from Bausch and future potential commercialization partners in order to fund our operations, and a failure to receive such payments may cause us to:

- delay, reduce or terminate certain research and development programs;
- reduce headcount;
- pursue the raising of additional funds through equity or convertible debt financings that could be dilutive to our stockholders;
- seek funds by entering into agreements that require us to assign rights to technologies or products that we would have otherwise retained;
- enter into new arrangements that may be less favorable than those we would have obtained under different circumstances; or
- consider strategic transactions or engaging in a joint venture with a third party.

We intend to enter into similar arrangements with third parties for the commercialization of XIPERE in other jurisdictions outside of the United States and Canada. We may be unsuccessful in entering into such commercialization arrangements with third parties or may be unable to do so on terms that are favorable to us. Our product revenue related to XIPERE, if any, or the profitability of such product revenue, may be lower, perhaps substantially lower, than if we directly marketed and sold XIPERE. Such revenue will be heavily dependent on the commercialization efforts of our partners, and we may have little or no control over such third parties. Any disputes with our commercialization partners concerning the adequacy of their efforts will substantially divert the attention of our senior management from other business activities and will require us to incur substantial legal costs to fund litigation or arbitration proceedings. If we are unable to establish licensing or collaboration arrangements with additional partners or if our partners fail to exercise commercially reasonable efforts to market and sell XIPERE in their respective licensed jurisdictions or are otherwise ineffective in doing so, our business will be materially harmed, and we may not be able to adequately remedy the harm through negotiation, litigation, arbitration or termination of the commercialization agreements.

We intend to enter into collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We have entered into, and intend to continue to enter into, agreements with third-party collaborators for the development and commercialization of our product candidates. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and smaller biotechnology companies. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- 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;

- collaborators may refuse to perform clinical trials or other obligations required for approval in a particular jurisdiction outside the United States;
- 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 could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized on 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;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to 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 or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such 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; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

We expect to rely on third parties to conduct our clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.

We have engaged contract research organizations, or CROs, for our ongoing and planned clinical trials. We also expect to engage CROs for any of our other product candidates that may progress to clinical development. We expect to rely on CROs, as well as other third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our drug 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 responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so by us or third parties can result in FDA refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance

with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our or our potential collaborators' efforts to, successfully commercialize our product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent the commercialization of XIPERE or our other current or future product candidates.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure or regulatory noncompliance on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of XIPERE, including our SCS Microinjector, for preclinical and clinical studies and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of XIPERE, including the XIPERE drug product, our SCS Microinjector, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities or personnel. We currently procure the active pharmaceutical ingredient in XIPERE on a purchase order basis from a third-party manufacturer, but we do not have a commercial supply agreement in place with that manufacturer. In addition, we have entered into a supply agreement with Gerresheimer, our SCS Microinjector supplier. Some of our current suppliers are based outside of the United States. In addition, some of the facilities of our third-party manufacturers have only undergone a limited number of FDA inspections or no inspections. We expect to continue to rely on third parties as we proceed with preclinical and clinical studies using our SCS Microinjector, as well as for commercial manufacture, if any of our product candidates receives marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of XIPERE including our SCS Microinjector or such quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts.

We also expect to rely on third-party manufacturers or collaborators for the manufacture of commercial supply of any other product candidates for which we obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or collaborators or to do so on acceptable terms.

Reliance on third-party manufacturers or collaborators entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates, including our proprietary drug formulations packaged together with our SCS Microinjector, are regulated under the drug regulations of the FDCA. Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations, regulations applicable to drug/device combination products, including applicable provisions of the FDA's drug cGMP regulations, device cGMP requirements embodied in the Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. For example, in preparation for our NDA submission for XIPERE for the treatment of patients with macular edema associated with uveitis, we conducted audits of our third-party manufacturers, and identified items that require correction prior to the FDA's pre-approval inspection of those manufacturing facilities. While we are working with these manufacturers to resolve these issues, there can be no assurance that we, or they, will be able to remediate those issues in a timely manner or at all. As a result, we or our suppliers may not pass an FDA pre-approval inspection. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, a refusal to file determination by the FDA, receipt of a CRL, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect our ability to achieve regulatory approval of our product candidates, including XIPERE.

Our product candidates that we may develop may compete with other drugs and devices for access to manufacturing facilities. There are a limited number of manufacturers that operate under the drug and device cGMP regulations applicable to our product candidates and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance or our SCS Microinjector. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our drugs and the components of our SCS Microinjector, we may incur added costs and delays in identifying and qualifying any such replacement. For example, the FDA could require supplemental data if a new supplier is relied upon for the supply of our products. Any interruption or delay in the supply of components and materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders.

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

If we are not able to establish additional collaborations, we may have to alter some of our future development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the future development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration 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. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such 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 increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to the Commercialization of Our Product Candidates

If we are unable to establish sales and distribution capabilities for our product candidates for which we do not out-license commercialization rights, we may not be successful in commercializing those product candidates, if and when they are approved.

We do not have a sales infrastructure. To achieve commercial success for any product candidate for which we may obtain marketing approval in the United States and have not licensed the commercialization rights to a third party, we will need to establish a sales organization. There are risks involved with establishing our own sales and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our drugs on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate an adequate number of physicians as to the benefits of our product candidates;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage compared to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales and distribution capabilities and, instead, enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to sell and distribute any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Suprachoroidal injection of drugs is a novel approach and physicians, patients or third-party payors may be hesitant to deviate from or change the current standard of care. If our product candidates do not achieve an adequate level of market acceptance, we may not generate significant product revenue and we 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 potential advantages compared to alternative treatments;
- our ability to offer our drugs for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the healthcare community and patients to adopt new technologies and our novel approach of SCS injection of drugs;
- the willingness of uveitis and retina specialists to expend the time necessary to receive proper training on injecting drugs into the SCS using our SCS Microinjector;
- the ability to manufacture our product in sufficient quantities and yields;
- the strength of marketing and distribution support provided by us or our collaborators;
- the availability of third-party payor coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our drugs together with other medications.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

With respect to XIPERE, we face competition from other commercially available forms of TA and other injectable and implantable corticosteroids. Bristol-Myers Squibb markets TA under the brand name Kenalog. Kenalog is indicated only for

intramuscular or intraarticular injection; however, it is commonly used off-label for intraocular inflammation. There are also a number of generic equivalents of Kenalog. In addition, Alcon's injectable TA, Triesence, is approved in the United States for the treatment of uveitis and other inflammatory conditions unresponsive to topical corticosteroids, although it is not indicated for the treatment of macular edema associated with uveitis or RVO. OZURDEX, marketed by Allergan, is a bioerodable extended release implant that delivers the corticosteroid dexamethasone and is approved for the treatment of non-infectious uveitis affecting the posterior segment of the eye and for macular edema due to RVO in both the United States and in the European Union.

Additionally, our collaborator Bausch markets Retisert, an intravitreal implant of the corticosteroid fluocinolone acetonide for the treatment of non-infectious uveitis. Eyepoint Pharmaceuticals markets Yutiq, an injectable form of fluocinolone acetonide for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

Our product candidate, CLS-AX, could also compete with anti-VEGF drugs, which are the current standard of care for RVO and wet AMD. Genentech's products Lucentis and Avastin are both anti-VEGF antibodies. Lucentis is currently approved in the United States and European Union for the treatment of wet AMD, macular edema following RVO, and diabetic retinopathy in patients with DME. Avastin is an anti-VEGF drug used off-label by uveitis and retina specialists in both the United States and in certain countries of the European Union for the treatment of numerous retinal diseases, but it is not indicated for ophthalmic use. In the United States, Regeneron's anti-VEGF product, Eylea, is approved for the treatment of wet AMD, macular edema following RVO and diabetic retinopathy. In the European Union, Eylea is approved for the treatment of wet AMD and RVO. Novartis' Beovu was recently approved for the treatment of wet AMD in the United States and has been recommended for approval in the European Union at a recent meeting of European Medicines Agency's drug evaluation committee

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 product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in product approval delays if a competitor obtains market exclusivity from the FDA or our competitors establishing a strong market position before we or our collaborators are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs. For some of the indications that we are pursuing, drugs used off-label, such as Kenalog and Avastin, serve as cheaper alternatives to our product candidates. Their lower prices could result in significant pricing pressure, even if our product candidates are otherwise viewed as a preferable therapy. Additional drugs may become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic drugs.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our product candidates may be subject to unfavorable pricing regulations, third-party coverage and reimbursement policies or healthcare reform initiatives.

Our and our collaborators' ability to commercialize any product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for our product candidates will be available from government payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, managed care plans and other third-party payors. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medical products they will pay for and establish reimbursement levels. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs and products. Coverage and reimbursement may not be available and, even if these are available, the level of reimbursement may not be satisfactory. Inadequate reimbursement levels may adversely affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining coverage and adequate reimbursement for our drugs may be difficult. We or our collaborators may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement compared to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we or our collaborators may not be able to successfully commercialize any product candidates for which marketing approval is obtained.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. By way of example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for outpatient drug purchases by those covered by Medicare under a new Part D program and introduced a new reimbursement methodology based on average sales prices for Medicare Part B physician-administered drugs, including drugs currently on the market used by physicians to treat the clinical indications for which we are currently seeking FDA approval and likely our product candidates, if approved. As a result of this legislation and the expansion of federal coverage of drug products, there is additional pressure to contain and reduce costs. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. These cost reduction initiatives and other provisions of the MMA could decrease the coverage and reimbursement that we receive for any approved products and could seriously harm our business.

Further, from time to time, typically on an annual basis, payment amounts are updated and revised by third-party payors. Because we expect that customers who use our product candidates, if approved, will be separately reimbursed for the procedure administering our products, these updates could directly impact the demand for our products. An example of payment updates is the Medicare program updates to physician payments, which is done on an annual basis using a prescribed statutory formula. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. However, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time it is unclear how the introduction of the quality payment program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. We cannot predict how pending and future healthcare legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our products or lowers reimbursement for procedures using our products could materially affect our business.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the product is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent.

We believe that physicians who use our product candidates, if approved, may be reimbursed by third-party payors for both the suprachoroidal injection using our SCS Microinjector and for the drug itself. On July 1, 2016, the American Medical Association, or AMA, approved a new Category III Current Procedural Terminology, or CPT, code for the suprachoroidal injection of pharmacologic agents. Category III codes are a set of temporary codes maintained by the AMA for emerging technology, services and procedures. Payment for these services or procedures are based on the coverage policies of individual payors, including private insurers and government-funded programs, like Medicare, and Medicare administrative contractors. CPT code 0465T became effective on January 1, 2017. We intend to seek a separate Healthcare Common Procedure Coding System, or HCPCS, code as maintained by CMS for the drug itself. We believe that separate CPT and HCPCS codes will help payors differentiate our drug candidates from other drugs currently on the market administered through intravitreal injections, although we can provide no assurance that CMS will approve the creation of a separate HCPCS code or that the Category III codes will remain in effect. Additionally, there is no guarantee that these billing codes or the payment amounts, if any, associated with such codes will be sufficient to successfully commercialize any approved product and, even if adequate payment amounts are obtained, they could change in the future.

Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all. Our or our collaborators' inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved drugs that we develop could significantly harm our operating results, our ability to raise capital and our overall financial condition.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues able to be generated from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably if they are approved for sale.

Product liability lawsuits against us could cause us to incur substantial liabilities.

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

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- our or our collaborators' inability to commercialize any drugs that we may develop.

We currently hold $10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we or our collaborators commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Employee Matters and Managing Our Growth

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

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers and senior management, as well as the other members of our scientific and clinical development teams. Our executive officers may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop and gain regulatory approval of our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our strategy. Our consultants and advisors may have commitments under

consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2019, we had 33 full-time employees. As our development progresses, we expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our business and operations would suffer in the event of material computer system failures or security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our CROs, contract manufacturing organizations and other third parties on whom we rely, are vulnerable to damage from computer viruses, unauthorized access, security breaches, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents, inadvertent or accidental cyber issues caused by employees or other insiders, or external security breaches could result in a material disruption of our clinical and product development activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. For example, the loss or compromise of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security incident was to result in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur significant unexpected losses, expenses and liabilities, we could face litigation or suffer reputational harm and the further development of our product candidates could be delayed.

Risks Related to Our Intellectual Property

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

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We and our licensors seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technology 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 or that we have published an invention prior to filing a relevant patent application. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. For example, we do not control the prosecution of the patent applications licensed to us under the Emory/GT License described below. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

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 or visa-versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. 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.

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 United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and may also affect patent litigation. The United States Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could significantly harm our business and financial condition. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our owned and licensed patents and patent applications.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. 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 drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs 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 and may not be of sufficient scope or strength to provide us with any commercial advantage. Our competitors may be able to design around our owned or licensed patents by developing similar or alternative technologies or drugs without infringing on our intellectual property rights.

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 drugs, or limit the duration of the patent protection of our technology and drugs. 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 drugs similar or identical to ours, and our business will suffer.

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

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, 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. In addition, in a patent infringement proceeding, a court may decide that a patent of ours 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. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which would undermine our competitive position.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm business.

Our commercial success depends upon our ability, and the ability of any collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. In particular, we are focused on developing product candidates based on widely used therapeutic agents, many of which are protected by proprietary rights of third parties, and we are developing proprietary formulations of these therapeutic agents specifically for suprachoroidal injection using our proprietary SCS Microinjector. Although we seek to develop our proprietary drug formulations that don't infringe the intellectual property rights of others, we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drugs or other aspects of our technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our technology and drugs. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations.

Competing products may be sold in countries in which our patent coverage might not exist or be as strong. If we lose a patent lawsuit alleging our infringement of a competitor's patent, or if FDA approval is stayed pending the outcome of patent litigation, we could be prevented from marketing our products. As a result, our ability to grow our business and compete in the market may be harmed.

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. If securities analysts or investors perceive these results to be negative, it could hurt 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.

If we fail to comply with our obligations under our existing intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a license agreement with Emory University and Georgia Tech Research Corporation, or the Emory/GT License, and may enter into additional license agreements in the future. Our existing license agreement imposes, and we expect that future license agreements would impose, various diligence, milestone payment, royalty, insurance and other obligations on us. For example, under the Emory/GT License, we are required to use commercially reasonable efforts to develop and commercialize licensed products under the agreement and to satisfy other specified obligations, including the payment of license fees and minimum royalty payments. If we fail to comply with our obligations under our license agreements, our licensors may have the right to terminate these license agreements, in which event we might not be able to market any product that is covered by these agreements, or to convert the license to a non-exclusive license, which could impair the value of the product candidate being developed under the license agreement. Termination of these license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. If our licensors under the Emory/GT License were to terminate their license agreement with us for any reason, we would lose access to critical technology related to our SCS Microinjector.

We may need to license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of our product candidates. It may be necessary for us or our collaborators to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to cease development of one or more or our product candidates or accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We may also in the future be subject to

claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, 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. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our or our collaborators' ability to commercialize our product candidates.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. Other than the trade name XIPERE, we have not yet selected trademarks for our product candidates or begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. In addition, third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

Some intellectual property that we have in-licensed may have been discovered through a government funded program and may be subject to certain federal regulations.

Some of the intellectual property rights we have licensed, including such rights licensed from Emory University and Georgia Tech Research Corporation, may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government may have the right to require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention, (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also could take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third

parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

In light of our receipt of a CRL from the FDA regarding our NDA for XIPERE, the U.S. regulatory requirements and timing for XIPERE approval are uncertain, and we may never obtain regulatory approval in the United States.

In December 2018, we submitted an NDA to the FDA for XIPERE for the treatment of macular edema associated with uveitis. The NDA was accepted for review by the FDA in February 2019, and a PDUFA goal date was assigned for October 19, 2019. In August 2019, we announced that the FDA requested certain items related to chemistry, manufacturing and controls and that we expected to receive a CRL from the FDA. On October 18, 2019, the FDA issued a CRL regarding the NDA, indicating that their review was complete and the NDA was not ready for approval in its present form. As a result, the approval of our NDA for XIPERE has been delayed and may never occur.

In its CRL, the FDA requested additional stability data for the triamcinolone acetonide suspension, reinspection of the drug manufacturer and additional data on clinical use of the final to-be-marketed SCS Microinjector delivery system. In response to that request, we proposed the submission of SCS Microinjector clinical use information in 160 subjects from our TOPAZ study for the treatment of macular edema associated with retinal vein occlusion. In subsequent correspondence, the FDA agreed that it would be acceptable for us to submit such data in lieu of the requested clinical use evaluation.

In November 2019, we were informed by our commercial contract manufacturer for XIPERE that the FDA requested that the manufacturer complete certain manufacturing activities within its facility. These activities, while not specifically related to XIPERE, may delay the production of the drug product stability data needed to resubmit our NDA. While we believe, based on information received from the manufacturer, that we will be able resubmit the NDA by the end of August 2020, we cannot predict the outcome of any interactions with the FDA nor can we guarantee when, or if, we will be successful in receiving regulatory approval for XIPERE.

The U.S. regulatory requirements and timing for XIPERE approval are uncertain at this time, and we may never obtain regulatory approval of XIPERE or any of our other product candidates in the United States. If we do not obtain approval for XIPERE or are delayed in obtaining such approval, it would have a material adverse effect on our operations and financial condition.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we and our collaborators will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export, and reporting of safety and other post-market information, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency, or EMA, and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent us, or any collaborator to whom we grant rights, from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or

prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit its approved use, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

If the FDA does not conclude that our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are seeking FDA approval through the Section 505(b)(2) regulatory pathway for XIPERE and may pursue that pathway for our other product candidates. We believe that our product candidates, including our proprietary drug formulations packaged together with our SCS Microinjector, will be regulated under the drug provisions of the FDCA, enabling us to submit NDAs for approval of our product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and complications and risks associated with our product candidates, would likely substantially increase. We may need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all.

Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in competitive products reaching the market before our product candidates, which could impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization, or that a competitor would not obtain approval first, including subsequent market exclusivity from the FDA, thereby delaying potential approval of our product.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Additional time may be required to obtain regulatory approval for our product candidates because of the complexity involved with co-packaging a drug with a dispensing device.

Our product candidates require coordination within the FDA and similar foreign regulatory agencies for review of their drug along with the co-packaged SCS Microinjector. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of co-packaged products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. In addition, to date, the FDA has not requested a separate medical device authorization submission for our SCS Microinjector. However, the FDA may request a separate medical device authorization submission for our SCS Microinjector in the future, which could delay the development and commercialization of our product candidates.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing or requirements. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals in order for us or our collaborators to commercialize our products in any market.

A variety of risks associated with marketing our product candidates internationally could affect our business.

We may seek regulatory approval for our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other 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 taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- 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;
- 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;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union may be a source of instability in international markets, create significant currency fluctuations and pose additional risks to our business, revenue, financial condition and results of operations.

The uncertainty concerning the United Kingdom's legal, political and economic relationship with the European Union may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border cooperation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise).These developments, or the perception that any of them could occur, have had and may continue to have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the United Kingdom financial and banking markets, as well as on the

regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the United Kingdom and the EU are unable to negotiate acceptable trading and customs terms or if other EU Member States pursue withdrawal, barrier-free access between the United Kingdom and other EU Member States or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the United Kingdom and the EU and, in particular, any arrangements for the United Kingdom to retain access to EU markets after the transition period.

Such a withdrawal from the EU is unprecedented, and it is unclear how the United Kingdom's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our operations and partners. There may continue to be economic uncertainty surrounding the consequences of Brexit, which could adversely affect our business, revenue, financial condition, results of operations and could adversely affect the market price of our common stock.

Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could involve requirements for, among other things, a medication guide, special training for prescribers and dispensers, and patient registries. If any of our product candidates receives marketing approval, the accompanying label may limit its approved uses, which could limit sales of the product, or include a black box warning to highlight a specific health risk.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of products to ensure products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our drugs for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, such as the federal civil False Claims Act, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our drugs, including device malfunctions, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have negative consequences, including:

- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a drug;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- recall or withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- clinical holds;
- safety alerts;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;

- refusal to permit the import or export of our drugs;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements regarding safety monitoring, or pharmacovigilance, and with requirements related to the development of drugs for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Even though we have received orphan drug designation in the European Union for the treatment of non-infectious uveitis, we may not be able to obtain orphan drug marketing exclusivity for this product candidate.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. We have received orphan drug designation from the EMA for the treatment of non-infectious uveitis, and we may seek orphan drug designation from the FDA or EMA for our future product candidates. However, we cannot pursue orphan drug designation from the FDA for the treatment of uveitis.

Regulation (EC) No 141/2000 and Regulation (EC) No 847/2000 provide that a product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives the medicinal product is unlikely to be developed. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition. Once authorized, orphan medicinal products are entitled to ten years of market exclusivity in all EU Member States and in addition a range of other benefits during the development and regulatory review process including scientific assistance for study protocols, authorization through the centralized marketing authorization procedure covering all member countries and a reduction or elimination of registration and marketing authorization fees. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten-year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. In addition, the period of market exclusivity may be reduced to six years if it can be demonstrated based on available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity. There is no guarantee that we will be able to obtain or maintain orphan exclusivity even if we receive marketing authorization in Europe.

Our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct or failure to comply with applicable regulatory requirements. Misconduct by employees and independent contractors, such as principal investigators, CROs, consultants, commercial partners and vendors, could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. It is not always possible to identify and deter employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities 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 be in compliance with such laws. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of substantial civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, imprisonment, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or

similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

Our current and future relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal civil False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including, without limitation, the federal civil False Claims Act which permits private individuals, on behalf of the government, to bring civil whistleblower or qui tam actions to enforce the law, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, including federal health care programs, such as, the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- HIPAA, which created additional federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on “covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the Physician Payments Sunshine Act, created under Section 6002 of the Affordable Care Act, imposed annual reporting requirements for certain manufacturers of drugs, devices, biologics and medical supplies for certain payments and “transfers of value” provided to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign 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; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- foreign data privacy regulations, such as the General Data Protection Regulation (2016/679), or GDPR, which went into effect on May 25, 2018 and applies to identified or identifiable personal data in electronic or paper form. Under the GDPR, fines of up to €20.0 million or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. The GDPR includes more stringent operational requirements for processors and controllers of personal data and creates additional rights for data subjects.

Further, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and the healthcare fraud statute. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. In addition, the Affordable Care Act provided 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 civil False Claims Act.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, as well as reputational harm, which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to the same criminal, civil and administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for most branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the federal civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There remain judicial and congressional challenges to certain aspects of the Affordable Care Act, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Act included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the Affordable Care Act mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, CMS published a new final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to the BBA, will stay in effect through 2029 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could negatively impact customers for our product candidates, if approved, and, accordingly, our financial operations.

Further, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs.. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and, at the same, implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to

allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Governments outside the United States tend to impose strict price controls, which may affect our revenue, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

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 harm 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 and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

The 2017 comprehensive tax reform bill and possible future changes in tax laws or regulations could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the Tax Act, which significantly revised the Internal Revenue Code of 1986, as amended. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing

items, as well as any other future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places in which we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

We plan to use potential future operating losses and our federal and state NOL carryforwards to offset future taxable income, if any. However, our ability to use existing NOL carryforwards could be limited as a result of issuances of equity securities.

As of December 31, 2019, we had approximately $219.8 million of federal and $7.6 million of state net operating loss, or NOL, carryforwards. If not utilized, the portion of these federal NOL carryforwards arising in tax years ending before 2018 will begin to expire at various dates beginning in 2031, and these state NOL carryforwards will begin to expire at various dates beginning in 2027. Under the Tax Act, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the changes to the federal NOL rules included in the Tax Act. However, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, as interpreted by the U.S. Internal Revenue Service, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative stock ownership change of more than 50% over a three-year period. The completion of our IPO, follow-on public offerings, private placements and other transactions that have occurred, and future offerings of our securities may trigger, or may have already triggered, such an ownership change. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future. We have not conducted an analysis as to whether such a change of ownership has occurred, but if such a change has occurred or occurs in the future, we will be limited regarding the amount of NOL carryforwards that can be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the value of our NOL carryforwards before they expire, which could result in greater tax liabilities than we would incur in the absence of such a limitation.

Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not be sustained.

We cannot assure you that an active trading market will continue to develop or be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares without depressing the market price for your shares or to sell your shares at all.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has been and may continue to be volatile. Since January 1, 2018, our common stock has traded at prices between $0.56 and $15.06 per share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the structure of healthcare payment systems;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;

- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of us and our business;
- recruitment or departure of key personnel; and
- sales of our common stock, including sales by our directors and officers or specific stockholders.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to initiate or to continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

The issuance of additional stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

Our certificate of incorporation authorizes us to issue up to 100,000,000 shares of common stock and up to 10,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, we may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investment, our stock incentive plans or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

If a significant number of our shares are sold into the market, it could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. All of our outstanding shares of common stock are available for sale in the public market, subject only to the restrictions of Rule 144 under the Securities Act in the case of our affiliates.

In addition, we have filed registration statements on Form S-8 registering the issuance of shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. These registered shares will be available for sale in the public market subject to vesting arrangements and exercise of options and, in the case of our affiliates, the restrictions of Rule 144.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors are elected each year;
- stockholders are not entitled to remove directors other than by a 66 2/3% vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) ending December 31, 2021, which is the end of the fiscal year following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes-Oxley Act and the rules and regulations of The Nasdaq Stock Market. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of

our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in this report and future annual reports on Form 10-K, as required by Section 404 of the Sarbanes-Oxley Act. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by The Nasdaq Stock Market, the Securities and Exchange Commission or other regulatory authorities.

We have broad discretion in the use of our cash and cash equivalents and may invest or spend our cash in ways with which you do not agree.

We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of our cash may not yield any return on your investment. Our failure to apply our resources effectively could compromise our ability to pursue our growth strategy. You will not have the opportunity to influence our decisions on how to use our cash and cash equivalents.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, our current loan agreement prohibits us from paying dividends without the consent of the lenders under the agreement, and the terms of any future debt agreements may likewise preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

We incur significant costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur significant legal, accounting and other costs, which we expect to increase, especially after we cease to be an emerging growth company under SEC rules. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities.

If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal offices occupy approximately 20,000 square feet of office space in Alpharetta, Georgia under a lease with an initial term until September 2023, with a renewal option for one additional five-year term.

We believe that our current leased facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results or financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASE OF EQUITY SECURITIES

Market Information for Common Stock

Our common stock is listed on The Nasdaq Global Market under the symbol "CLSD".

Dividend Policy

We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Additionally, our ability to pay dividends on our common stock is limited by restrictions under the terms of the agreements governing our credit facility.

Stockholders

As of March 11, 2020, we had 44,868,558 shares of common stock outstanding held by 12 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Parties

None.

ITEM 6. SELECTED FINANCIAL DATA

The following selected statement of operations data for the years ended December 31, 2019, 2018 and 2017 and balance sheet data as of December 31, 2019 and 2018 is derived from our audited financial statements included within this Annual Report. The statement of operations data for the year ended December 31, 2016 and 2015 and the balance sheet data as of December 31, 2017, 2016 and 2015 have been derived from our audited financial statements which are not included herein. Our historical results are not

necessarily indicative of the results to be expected in the future. The selected financial data should be read together with Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in conjunction with the financial statements, related notes, and other financial information included elsewhere in this Annual Report.

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands, except share and per share data)				
License and other revenue	$ 2,173	$ 30	$ 345	$ 520	$ —
Operating expenses:					
Research and development	15,658	68,291	49,053	19,455	10,762
General and administrative	16,819	14,684	9,700	6,263	6,555
Total operating expenses	32,477	82,975	58,753	25,718	17,317
Loss from operations	(30,304)	(82,945)	(58,408)	(25,198)	(17,317)
Other (expense) income	(466)	127	(567)	(684)	(322)
Net loss	$ (30,770)	$ (82,818)	$ (58,975)	$ (25,882)	$ (17,639)
Net loss per share of common stock — basic and diluted	$ (0.81)	$ (2.69)	$ (2.33)	$ (1.97)	$ (7.54)
Weighted average shares outstanding — basic and diluted	38,170,830	30,733,600	25,311,614	13,111,067	2,338,950

	December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Balance sheet data:					
Cash and cash equivalents	$ 22,595	$ 8,043	$ 9,224	$ 34,284	$ 20,283
Short-term investments	—	32,835	28,416	48,807	—
Restricted cash	360	360	360	360	—
Total assets	26,776	44,120	40,493	84,813	21,055
Deferred revenue	5,000	—	160	180	700
Debt	5,152	9,975	8,009	7,586	5,976
Total liabilities	15,619	20,500	19,078	13,154	10,400
Total stockholders' equity (deficit)	11,157	23,620	21,415	71,659	(36,659)

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the related notes to those statements included later in this Annual Report. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, beliefs and expectations that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly in Item 1A. "Risk Factors" and "Special Note Regarding Forward-Looking Statements."

Overview

We are a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases. Our proprietary SCS Microinjector targeting the suprachoroidal space, or SCS, offers unique access to the macula, retina and choroid where sight-threatening disease often occurs. Our SCS injection platform is an inherently flexible, in-office, non-surgical procedure intended to provide targeted delivery of established and new formulations of medications, as well as future therapeutic innovations such as gene therapy, to the site of disease.

We are leveraging our SCS injection platform by building an internal research and development pipeline, in areas such as novel small molecules and gene therapy, and by creating external collaborations with other companies. Using our suprachoroidal injection technology that can be used in conjunction with proprietary formulations of existing drugs as well as novel therapies, we believe we have created a broad therapeutic platform for developing product candidates to treat serious eye diseases.

We have incurred net losses since our inception in May 2011. Our operations to date have been limited to organizing and staffing our company, raising capital, conducting preclinical studies and clinical trials and other research and development initiatives. To date, we have not generated any revenue, other than license and other revenue, and we have primarily financed our operations through public offerings and private placements of our equity securities, issuances of convertible promissory notes and loan agreements. As of December 31, 2019, we had an accumulated deficit of $237.7 million. We recorded net losses of $30.8 million, $82.8 million and $59.0 million for the years ended December 31, 2019, 2018 and 2017, respectively. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the necessary development for and obtaining regulatory approval of our product candidates, as well as discovering compounds and developing proprietary solutions to utilize with our SCS Microinjector.

We expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate significant product or license and other revenue unless and until we successfully complete necessary development of, obtain regulatory approval for and successfully commercialize one or more of our product candidates, either on our own or together with a third party. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities. Our clinical trial expenses have decreased significantly following our decision to discontinue late-stage clinical trials of XIPERE for indications other than uveitis. However, we will continue our efforts to seek to discover, research and develop additional product candidates and seek regulatory approvals in additional regions for XIPERE for the treatment of macular edema associated with uveitis.

Components of Operating Results

Revenue

We have not generated any revenue from the sale of any drugs, and we do not expect to generate any product revenue unless or until we obtain regulatory approval of and commercialize our product candidates, either on our own or with a third party. Our revenue in recent years has been generated primarily from our license agreements. We are seeking to enter into additional license and other agreements with third parties to evaluate the potential use of our proprietary SCS Microinjector with the third party's product candidates for the treatment of various eye diseases. These agreements may include payments to us for technology access, upfront license payments, regulatory and commercial milestone payments and royalties.

Research and Development

Since our inception, we have focused on our development programs. Research and development expenses consist primarily of costs incurred for the research and development of our preclinical and clinical product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and share-based compensation expense for research and development personnel;
- expenses incurred under agreements with contract research organizations, or CROs, as well as contract manufacturing organizations and consultants that conduct clinical trials and preclinical studies;
- costs associated with preclinical and development activities;
- costs associated with submitting regulatory approval applications for our product candidates;
- costs associated with training physicians on the suprachoroidal injection procedure and educating and providing them with appropriate product candidate information;
- costs associated with technology and intellectual property licenses;
- costs for our research and development facility; and
- depreciation expense for assets used in research and development activities.

We expense research and development costs to operations as incurred. These costs include preclinical activities, such as manufacturing and stability and toxicology studies, that are supportive of a product candidate itself. In addition, there are expenses related to clinical trials and similar activities for each program, including costs associated with CROs. Clinical costs are recognized based on the terms of underlying agreements, as well as an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations and additional information provided to us by our vendors about their actual costs occurred. Expenses related to activities that support more than one development program or activity, such as salaries, share-based compensation and depreciation, are not classified as direct preclinical costs or clinical costs and are separately classified as unallocated.

The following table shows our research and development expenses by type of activity for the years ended December 31, 2019, 2018 and 2017.

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
XIPERE (uveitis program)	$ 2,947	$ 8,803	$ 12,702
XIPERE (RVO program)	2,323	44,432	23,487
XIPERE (DME program)	(133)	3,062	4,217
Wet AMD program	67	3	252
Total program expense	5,204	56,300	40,658
Unallocated	10,454	11,991	8,395
Total research and development expense	$ 15,658	$ 68,291	$ 49,053

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended under contracts with research institutions, consultants and CROs that conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If future timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we would modify our estimates of accrued expenses accordingly on a prospective basis.

During the year ended December 31, 2019, we recorded all remaining expenses reported by our CRO in connection with the termination of our XIPERE development program for RVO.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when or to what extent we will

generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that include the following:

- the costs associated with process development, scale-up and manufacturing of XIPERE and the SCS Microinjector for clinical trials and for requirements associated with regulatory filings associated with approval;
- the number of trials required for approval and any requirement for extension trials;
- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profiles of the product candidates.

In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

General and Administrative

General and administrative expenses consist primarily of salaries and other related costs, including share-based compensation, for personnel in executive, finance and administrative functions. General and administrative costs historically included commercial pre-launch preparations for XIPERE, and also include facility related costs not otherwise included in research and development expenses, as well as professional fees for legal, patent, consulting, and accounting and audit services.

Other Income (Expense)

Other income consists of interest income earned on our cash, cash equivalents and short-term investments. Interest income is not currently significant to our financial statements.

Other expense consists of interest expense incurred under our loan agreements.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with U.S GAAP, we evaluate our estimates and judgments on an ongoing basis. Significant estimates include assumptions used in the determination of share-based compensation and some of our research and development expenses. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets

and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those accounting principles generally accepted in the United States of America that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this Annual Report, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Revenue recognition

On January 1, 2018, we adopted Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers (Topic 606)*, or ASC 606, as amended by ASU 2016-08, 2016-10, 2016-12 and 2016-20 using the modified retrospective method. Under ASC 606, we recognize revenue in an amount that reflects the consideration to which we expect to be entitled in exchange for the transfer of promised goods or services to customers. To determine revenue recognition for contracts with customers that are within the scope of ASC 606, we perform the following steps: (1) identify the contract with the customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services transferred to the customer.

As part of the accounting for our revenue arrangements, we develop assumptions that require judgment such as the estimate of the stand-alone selling price for each performance obligation identified in the contract.

Licenses of intellectual property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promised goods or services, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, we evaluate whether the achievement of the milestones is considered probable and estimate the amount to be included in the transaction price using the most likely amount method. Performance milestone payments represent a form of variable consideration. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Achievement of milestones that are not within our or our licensee's control, such as regulatory approvals, are not considered probable until the approvals are achieved. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis and we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achieving such 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 revenues and earnings in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the outset of the arrangement.

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

Accrued expenses

As part of the process of preparing our financial statements, we are required to estimate accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with applicable vendor personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include fees paid to CROs and investigative sites in connection with clinical trials.

We accrue our expenses related to clinical trials based on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct research activities or manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the level of effort varies from our estimate, we will adjust the accrual accordingly. If we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. Although we do not currently anticipate the future settlement of existing accruals to differ materially from our estimates, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low for any period.

Fair value measurements

We record some of our financial assets and liabilities at fair value in accordance with the provisions of Accounting Standards Codification, or ASC, Topic 820 on fair value measurements. As defined in the guidance, fair value, defined as an exit price, represents the amount that would be received to sell an asset or pay to transfer a liability in an orderly transaction between market participants. As a result, fair value is a market-based approach that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering these assumptions, the guidance defines a three-tier value hierarchy that prioritizes the inputs used in the valuation methodologies in measuring fair value.

- Level 1—Unadjusted quoted prices in active, accessible markets for identical assets or liabilities.
- Level 2—Other inputs that are directly or indirectly observable in the marketplace.
- Level 3—Unobservable inputs that are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

Our material financial instruments at December 31, 2019 and 2018 consisted primarily of cash and cash equivalents, short-term investments and long-term debt. The fair value of cash and cash equivalents, treasury bills, other current assets and accounts payable approximate their respective carrying values due to the short-term nature of these instruments and are classified as Level 1 in the fair value hierarchy. The fair value of long-term debt approximates the carrying value due to variable interest rates that correspond to market rates. We have determined our short-term investments, comprised of commercial paper, to be Level 2 in the fair value hierarchy. The fair value was determined using a market approach, based on prices and other relevant information generated by market transactions involving similar assets. The short-term investments consist of investments with original maturity dates from date of acquisition of 90 to 365 days and are classified as available-for-sale.

Share-based compensation

Compensation cost related to share-based awards granted to employees is measured based on the estimated fair value of the award at the grant date. We estimate the fair value of stock options using a Black-Scholes option pricing model. Compensation expense for options granted to non-employees is determined as the fair value of consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. Share-based compensation costs are expensed on a straight-line basis over the relevant vesting period. The fair value of restricted stock units, or RSUs, granted is measured based on the market value of our common stock on the date of grant and is recognized ratably over the requisite service period, which is generally the vesting period of

the awards. All share-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations and comprehensive loss based upon the underlying employees' roles.

Significant factors, assumptions and methodologies used in determining fair value

Determining the appropriate fair value measurement of share-based awards requires the use of subjective assumptions. The determination of the fair value measurement of options using the Black-Scholes option pricing model is affected by our estimated common stock fair values as well as assumptions regarding a number of other subjective variables. These other variables include the expected term of the options, our expected stock price volatility over the expected term of the options, stock option exercise and cancellation behaviors, risk-free interest rates and expected dividends.

We estimated the fair value of stock options at the grant date using Black-Scholes option pricing model with the following assumptions:

- *Fair value of our common stock.* For stock options granted after June 1, 2016, the date of our IPO, we estimate the fair value of our common stock by reference to the closing price of our common stock on The Nasdaq Global Market on the date of grant.
- *Volatility.* We calculate expected volatility based on our historical volatility and utilize data from a representative group of publicly traded companies. We selected representative companies from the pharmaceutical industry with similar characteristics to us, including stage of product development and therapeutic focus.
- *Expected term.* We used the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, as we do not have sufficient historical exercise and post-vesting termination data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees.
- *Risk-free rate.* The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected time to liquidity.
- *Forfeitures.* Forfeitures are accounted for as they occur.
- *Dividend yield.* We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future.

We have an employee stock purchase plan that is considered a compensatory plan. The fair value of the discount and the look-back period of the employee stock purchase plan are estimated using the Black-Scholes option pricing model and expense is recognized over the six-month withholding period prior to the purchase date.

Share-based compensation expense related to stock options, the employee stock purchase plan and RSUs aggregated $4.6 million, $4.8 million and $3.4 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Tax valuation allowance

We recorded deferred tax assets of $46.2 million, primarily related to our net operating losses, as of December 31, 2019, which have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. We record a valuation allowance if it is more likely than not that a deferred tax asset will not be realized. We provided a full valuation allowance on our deferred tax assets that primarily consist of cumulative net operating losses, or NOLs for the period from our inception through December 31, 2019. We incurred a net loss for tax purposes of $24.7 million for the year ended December 31, 2019. Due to our three-year cumulative loss position, history of operating losses and losses expected to be incurred in the foreseeable future, we considered it necessary to provide for a full valuation allowance against our net deferred tax assets.

Our deferred tax assets are primarily composed of federal and state tax NOL carryforwards. As of December 31, 2019, we had federal NOL carryforwards of $219.8 million and state NOL carryforwards of $7.6 million available to reduce future taxable income, if any. These federal NOL carryforwards will begin to expire at various dates starting in 2031. The state NOL carryforwards will begin to expire at various dates starting in 2027. In general, if we experience a greater than 50 percentage point aggregate change in ownership of specified significant stockholders over a three-year period, utilization of our pre-change NOL carryforwards will be subject to an annual limitation under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and similar state laws. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization and may be substantial. If we experience a Section 382 ownership change as a result of future offerings or changes in our stock ownership, some of which changes are outside our control, the tax benefits related to the NOL carryforwards may be further limited or lost.

Results of Operations for the Years Ended December 31, 2019 and 2018

The following table sets forth our results of operations for the years ended December 31, 2019 and 2018.

	Year Ended December 31,		Period-to-Period Change
	2019	2018	
	(in thousands)		
License and other revenue	$ 2,173	$ 30	$ 2,143
Operating expenses:			
Research and development	15,658	68,291	(52,633)
General and administrative	16,819	14,684	2,135
Total operating expenses	32,477	82,975	(50,498)
Loss from operations	(30,304)	(82,945)	52,641
Other (expense) income	(466)	127	(593)
Net loss	$ (30,770)	$ (82,818)	$ 52,048

Revenue. In the year ended December 31, 2019 we recognized $2.1 million of revenue associated with our license agreements. In the years ended December 31, 2019 and 2018, we recognized $0.1 million and $30,000, respectively, of revenue associated with other agreements.

Research and development. Research and development expense decreased by $52.6 million, from $68.3 million for the year ended December 31, 2018 to $15.7 million for the year ended December 31, 2019. This was primarily attributable to a $42.1 million decrease due to closing down the SAPPHIRE and TOPAZ trials. Additionally, there was a $4.6 million decrease due to the completion of the PEACHTREE trial during the first quarter of 2018, a $3.2 million decrease in costs related to our DME program, as the TYBEE trial was completed in the second quarter of 2018, a $1.2 million decrease in costs related to device and drug manufacturing, a $0.6 million decrease in costs related to quality assurance as audits related to our NDA filing were completed during 2018 and a $1.4 million decrease in regulatory expenses as the NDA submission for XIPERE was completed in the fourth quarter of 2018. These decreases were partially offset by a $0.4 million increase in employee-related costs and a $0.5 million increase in nonclinical activities.

General and administrative. General and administrative expenses increased by $2.1 million, from $14.7 million for the year ended December 31, 2018 to $16.8 million for the year ended December 31, 2019. The increase was primarily attributable to a $1.9 million increase in employee-related costs, including accrued expenses related to the resignation of our former CEO, and an increase of $0.9 million in professional fees. These increases were partially offset by a $0.4 million decrease that was primarily attributable to marketing-related expenses related to the change of our business strategy to seek partners for XIPERE rather than commercialize it on our own.

Other (expense) income. The decrease from other income of $0.1 million in 2018 to other expense of $0.5 million in 2019 was the result of higher interest income on short-term investment balances in the first quarter of 2018 following our public offering of common stock, which balances decreased over time.

Results of Operations for the Years Ended December 31, 2018 and 2017

The following table sets forth our results of operations for the years ended December 31, 2018 and 2017.

	Year Ended December 31,		Period-to-Period Change
	2018	2017	
	(in thousands)		
License and other revenue	$ 30	$ 345	$ (315)
Operating expenses:			
Research and development	68,291	49,053	19,238
General and administrative	14,684	9,700	4,984
Total operating expenses	82,975	58,753	24,222
Loss from operations	(82,945)	(58,408)	(24,537)
Other income (expense)	127	(567)	694
Net loss	$ (82,818)	$ (58,975)	$ (23,843)

Revenue. In the years ended December 31, 2018 and 2017, we recognized $30,000 and $0.3 million, respectively, of revenue associated with license and other agreements.

R*esearch and development*. Research and development expense increased by $19.2 million, from $49.1 million for the year ended December 31, 2017 to $68.3 million for the year ended December 31, 2018. This was primarily attributable to an increase in costs related to our clinical program in RVO. Costs for our RVO program increased $20.9 million, which included purchases of clinical drug supply for SAPPHIRE, start-up costs and purchases of clinical drug supply for TOPAZ and the accelerated close-out costs in connection with discontinuing both trials due to failing to achieve the primary endpoint of SAPPHIRE. We also incurred a $1.4 million increase in regulatory costs in preparation of the NDA submission for XIPERE for the treatment of macular edema associated with uveitis, a $1.4 million increase in employee-related costs due to an increase in headcount and a $0.8 million increase in costs related to device and drug manufacturing. These increases were partially offset by a $4.3 million decrease in clinical costs for our uveitis program, as PEACHTREE was completed during the first quarter of 2018, and a $0.2 million decrease in costs associated with our wet AMD program, which was discontinued in the first quarter of 2017.

General and administrative. General and administrative expenses increased by $5.0 million, from $9.7 million for the year ended December 31, 2017 to $14.7 million for the year ended December 31, 2018. The increase was primarily attributable to a $2.5 million increase in employee-related costs and an increase of $2.0 million in marketing-related expenses as we prepared for the potential commercialization of XIPERE for the treatment of macular edema associated with uveitis.

Other income (expense). Other income (expense) for each of the years ended December 31, 2018 and 2017 primarily consisted of interest on long-term debt, the amortization of financing costs, the accretion of warrants and the final payment related to our loan agreements, offset by interest income from our short-term investments. The increase in income for 2018 compared to 2017 was the result of higher short-term investment balances from the net proceeds of our public offering of common stock in the first quarter of 2018.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through the proceeds of public offerings of our common stock, sales of convertible preferred stock and the issuance of long-term debt. As of December 31, 2019, we had cash and cash equivalents of $22.6 million. We invest any cash in excess of our immediate requirements primarily with a view to liquidity and capital preservation. As of December 31, 2019, our funds were held in cash and money market funds.

On November 24, 2019, we entered into a securities purchase agreement with accredited investors who were existing stockholders and who purchased 3.2 million shares of our common stock in a private placement transaction at a price of $1.054 per share. We raised net cash proceeds of $3.3 million after deducting offering expenses.

On October 22, 2019, we entered into the License Agreement with Bausch, pursuant to which we received an upfront payment of $5.0 million, which is subject to a refund if the License Agreement is terminated in specified circumstances. On October 29, 2019, REGENXBIO exercised its option under an option and license agreement and paid us an option fee equal to $2.0 million, less a credit of $0.5 million previously received under a technology access agreement.

On May 14, 2018, we entered into a loan and security agreement with Silicon Valley Bank and MidCap Financial Services, or collectively the Lenders, which amended and restated in its entirety a prior loan and security agreement with the Lenders. The loan and security agreement, as amended to date, or the Loan Agreement, originally provided for term loans of up to $20.0 million in the aggregate, with a floating interest rate equal to 6.5% plus the greater of (i) the 30-day U.S. LIBOR, as reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue or (ii) 1.89%.

We borrowed an initial tranche of $10.0 million on May 14, 2018, of which $7.0 million was used to repay all amounts outstanding under the amended and restated loan and security agreement, including the fees payable in connection with the final payment. The prepayment fees were waived. Of the remaining $10.0 million capacity originally contemplated, $5.0 million became available but we elected not to draw it, and the other $5.0 million did not become available for draw. On October 18, 2019, we entered into an amendment to the Loan Agreement and repaid $5.0 million of the outstanding principal balance. We did not pay any final payment or termination fees in connection with the $5.0 million prepayment.

Under the Loan Agreement, we are required to pay accrued interest only on the $5.0 million remaining outstanding balance through April 30, 2020, or if we complete a specified financial milestone, through October 31, 2020, followed by consecutive equal monthly payments of principal and interest in arrears continuing through the maturity date of October 1, 2022. We have the option to prepay the outstanding balance in full, subject to a prepayment fee of 2% of the original principal amount for any prepayment prior to

October 1, 2022. A final payment of 5.50% of the aggregate borrowed amount is due at maturity of the loan on October 1, 2022, or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default. In addition, we agreed that if our cash and cash equivalents balance with Silicon Valley Bank falls below $10.0 million, we will transfer to a pledged account an amount of cash and cash equivalents equal to the sum of the then-outstanding principal balance of the term loan plus a final payment fee of $0.3 million.

The amounts due under the Loan Agreement are secured by substantially all of our assets.

On March 12, 2018, we closed a follow-on public offering in which we sold approximately 6.5 million shares of common stock at a public offering price of $13.00 per share, resulting in net proceeds of $79.6 million after deducting underwriting discounts and commissions and estimated offering expenses.

On June 30, 2017, we entered into an at-the-market sales agreement, or the ATM agreement, with Cowen and Company LLC, or Cowen, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50.0 million through Cowen acting as our sales agent. During the year ended December 31, 2019, we sold 9.0 million shares of our common stock for net proceeds of $10.3 million under the ATM agreement, after the payment of commissions to Cowen. Subsequent to December 31, 2019, we have sold 0.5 million shares of our common stock for net proceeds of $1.2 million under the ATM agreement.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, ongoing costs related to our NDA submission for XIPERE, research and development costs to build our product candidate pipeline, legal and other regulatory expenses and general overhead costs.

The successful development of our product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of XIPERE or any future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from product sales. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; and
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that candidate.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license and development agreements. Other than potential payments we may receive under our license and other agreements, we do not currently have any committed external source of funds, though, as described above, we may also be able to sell our common stock under the ATM agreement with Cowen subject to the terms of that agreement and depending on market conditions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, including any future collaboration or licensing arrangement for XIPERE outside the U.S. and Canada, we may be required to relinquish additional rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We also incur costs as a public company, including costs and expenses for fees to members of our board of directors, accounting and finance personnel costs, directors and officers insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with reporting requirements under the Exchange Act and rules implemented by the SEC and Nasdaq.

Outlook

We have suffered recurring losses and negative cash flows from operations since inception and anticipate incurring additional losses until such time, if ever, that we can obtain FDA approval to market and then generate significant royalties from XIPERE and other licensing arrangements. We will need additional financing to fund our operations. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date of this report. We have plans to mitigate this going concern risk, which primarily consist of raising additional capital, potentially in a combination of equity or debt financings or restructurings, or potentially entering into additional collaborations, partnerships and other strategic arrangements.

Based on our current plans and forecasted expenses, we expect that our cash and cash equivalents as of December 31, 2019 will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2021. This estimate does not give effect to the potential restriction of cash pursuant to the Loan Agreement. The estimate does not give effect to additional development milestone payments we might receive under the agreements with Bausch or REGENXBIO or in connection with any other potential license or collaboration agreement for XIPERE or any future product candidates. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

Our financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result should we be unable to continue as a going concern.

Cash Flows

The following is a summary of the net cash flows provided by (used in) our operating, investing and financing activities:

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (27,068)	$ (79,200)	$ (51,083)
Investing activities	32,925	(3,760)	20,121
Financing activities	8,695	81,779	5,362
Net change in cash and cash equivalents	$ 14,552	$ (1,181)	$ (25,600)

During the years ended December 31, 2019, 2018 and 2017, our operating activities used net cash of $27.1 million, $79.2 million and $51.1 million, respectively. The use of cash in each period primarily resulted from our net losses. The decrease in net loss for the year ended December 31, 2019 as compared to the year ended December 31, 2018 was primarily attributable to lower research and development expenses as a result of the completion of the PEACHTREE and TYBEE trials in the prior year and the discontinuation of the SAPPHIRE and TOPAZ trials. The year ended December 31, 2019 also included a net cash outflow of $5.1 million from a decrease in accounts payable, which was the result of payments we made in connection with winding down the clinical trials.

The increase in net loss for the year ended December 31, 2018 as compared to the year ended December 31, 2017 was primarily attributable to higher research and development expenses related to our Phase 3 clinical trials PEACHTREE, SAPPHIRE and TOPAZ and the related expenses to support them including employee-related costs. In addition, for the year ended December 31, 2018, we incurred regulatory costs in preparation for an NDA submission and costs associated with the planned commercialization of XIPERE.

During the year ended December 31, 2019, our net cash provided by investing activities was $32.9 million compared to net cash used in investing activities of $3.8 million during the year ended December 31, 2018 and compared to net cash provided by investing activities of $20.1 million during the year ended December 31, 2017. In the year ended December 31, 2019, net cash provided by investing activities consisted of maturities of short-term available-for-sale investments. In the year ended December 31, 2018, net cash used in investing activities was primarily for the purchase of $80.1 million of short-term, available-for-sale investments, which included commercial paper and treasury bills, offset by the maturities of $76.5 million of short-term, available-for-sale investments, which included corporate bonds, commercial paper and treasury bills and $88,000 for the purchase of furniture and fixtures. In the year ended December 31, 2017, cash flows provided by investing activities was primarily from $68.5 million for the maturities of short-term, available-for-sale investments, which include certificates of deposit, corporate bonds and government bonds, commercial

paper, treasury bills and agency obligations, partially offset by the purchase of $48.1 million of short-term, available-for-sale investments and $0.3 million for the purchase of furniture and fixtures for our corporate office.

During the years ended December 31, 2019, 2018 and 2017, our net cash provided by financing activities was $8.7 million, $81.8 million and $5.4 million, respectively. The net cash provided by financing activities for the year ended December 31, 2019 was primarily comprised of $10.3 million of net proceeds from sales of common stock pursuant to our ATM agreement and $3.3 million of net proceeds from a private placement of common stock, partially offset by a $5.0 million principal payment made under our Loan Agreement. The net cash provided by financing activities for the year ended December 31, 2018 was primarily comprised of the $79.6 million of net proceeds received from a public follow-on offering of our common stock in March 2018, $1.7 million of net proceeds received from the Loan Agreement and $0.5 million of proceeds received from shares issued from the exercise of stock options and the employee stock purchase plan. The net cash provided by financing activities for the year ended December 31, 2017 was comprised primarily of the $5.1 million of net proceeds received from the underwriters' exercise of their option to purchase additional shares as part of our public offering of common stock that initially closed in December 2016.

Contractual Obligations

The following table summarizes our significant contractual obligations as of December 31, 2019, which consisted of obligations under leases for our corporate headquarters in Alpharetta, Georgia, obligations under the Loan Agreement and our manufacturing supply agreement with Gerresheimer.

	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(in thousands)		
Operating lease obligations	$ 1,493	$ 378	$ 799	$ 316	$ —
Long-term debt obligations [1]	5,996	1,717	4,279	—	—
Manufacturing supply agreement	499	499	—	—	—
Total	$ 7,988	$ 2,594	$ 5,078	$ 316	$ —

(1) Includes estimated interest expense at the minimum rate of 8.39% plus the final payment fee.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Recent Accounting Pronouncements

See Item 8. "Financial Statements and Supplementary Data – Note 2, Significant Accounting Policies" for a discussion of recent accounting pronouncements and their effect on us.

JOBS Act

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of December 31, 2019, we had cash and cash equivalents of $22.6 million. We generally hold our cash in interest-bearing money market accounts. Due to the short-term maturities of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

We do not engage in any hedging activities against changes in interest rates. Our outstanding debt instruments carried a floating interest rate that is 6.5% plus the greater of (i) the 30-day U.S. LIBOR, reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue or (ii) 1.89%. Based on the current outstanding balance under the Loan Agreement, a 100 basis point increase in the LIBOR rate would result in a $50,000 increase in annual interest expense.

We do not have any foreign currency or other material derivative financial instruments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to financial statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Clearside Biomedical, Inc.

Opinion on the Financial Statements
We have audited the accompanying balance sheets of Clearside Biomedical, Inc. (the Company) as of December 31, 2019 and 2018, and the related statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern
The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses, negative cash flows from operations, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of ASU No. 2016-02, *Leases (Topic 842).*

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2014.

Atlanta, Georgia
March 13, 2020

CLEARSIDE BIOMEDICAL, INC.
Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 22,595	$ 8,043
Short-term investments	—	32,835
Prepaid expenses	1,139	2,049
Other current assets	1,485	17
Total current assets	25,219	42,944
Property and equipment, net	541	790
Operating lease right-of-use asset	656	—
Restricted cash	360	360
Other assets	—	26
Total assets	$ 26,776	$ 44,120
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,280	$ 6,869
Accrued liabilities	2,930	2,923
Current portion of long-term debt	1,333	556
Current portion of operating lease liabilities	360	—
Current portion of deferred rent	—	128
Deferred revenue	5,000	—
Total current liabilities	10,903	10,476
Long-term debt	3,819	9,419
Operating lease liabilities	897	—
Deferred rent	—	605
Total liabilities	15,619	20,500
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized and no shares issued at December 31, 2019 and 2018	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2019 and 2018; 44,413,372 and 32,119,227 shares issued and outstanding at December 31, 2019 and 2018, respectively	44	32
Additional paid-in capital	248,770	230,475
Accumulated deficit	(237,657)	(206,887)
Total stockholders' equity	11,157	23,620
Total liabilities and stockholders' equity	$ 26,776	$ 44,120

See accompanying notes to the financial statements

CLEARSIDE BIOMEDICAL, INC.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,		
	2019	2018	2017
License and other revenue	$ 2,173	$ 30	$ 345
Operating expenses:			
Research and development	15,658	68,291	49,053
General and administrative	16,819	14,684	9,700
Total operating expenses	32,477	82,975	58,753
Loss from operations	(30,304)	(82,945)	(58,408)
Other (expense) income	(466)	127	(567)
Net loss	$ (30,770)	$ (82,818)	$ (58,975)
Net loss per share of common stock — basic and diluted	$ (0.81)	$ (2.69)	$ (2.33)
Weighted average shares outstanding — basic and diluted	38,170,830	30,733,600	25,311,614
Net loss	$ (30,770)	$ (82,818)	$ (58,975)
Unrealized gain on available-for-sale investments	—	—	5
Comprehensive loss	$ (30,770)	$ (82,818)	$ (58,970)

See accompanying notes to the financial statements.

CLEARSIDE BIOMEDICAL, INC.
Statement of Stockholders' Equity (Deficit)
(in thousands, except share data)

	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2016	24,573,033	$ 25	$ 136,892	$ (65,245)	$ (13)	$ 71,659
Issuance of common shares in follow-on offering	600,000	—	5,057	—	—	5,057
Issuance of common shares under employee stock purchase plan	9,692	—	66	—	—	66
Exercise of stock options	171,926	—	239	—	—	239
Share-based compensation expense	—	—	3,364	—	—	3,364
Net loss	—	—	—	(58,975)	—	(58,975)
Other comprehensive gain	—	—	—	—	5	5
Balance at December 31, 2017	25,354,651	25	145,618	(124,220)	(8)	21,415
Cumulative effect of accounting change	—	—	—	151	8	159
Issuance of common shares in follow-on offering	6,548,712	7	79,557	—	—	79,564
Issuance of common shares under employee stock purchase plan	12,595	—	50	—	—	50
Exercise of stock options	203,269	—	465		—	465
Share-based compensation expense	—	—	4,785	—	—	4,785
Net loss	—	—	—	(82,818)	—	(82,818)
Balance at December 31, 2018	32,119,227	32	230,475	(206,887)	—	23,620
Issuance of common shares from at-the-market sales agreement	8,976,940	9	10,310	—	—	10,319
Issuance of common shares in private placement	3,178,367	3	3,321	—	—	3,324
Issuance of common shares under employee stock purchase plan	52,476	—	45	—	—	45
Exercise of stock options	16,362	—	7	—	—	7
Vesting and settlement of restricted stock units	70,000	—	—	—	—	—
Share-based compensation expense	—	—	4,612	—	—	4,612
Net loss	—	—	—	(30,770)	—	(30,770)
Balance at December 31, 2019	44,413,372	$ 44	$ 248,770	$ (237,657)	$ —	$ 11,157

See accompanying notes to the financial statements.

CLEARSIDE BIOMEDICAL, INC.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2019	2018	2017
Operating activities			
Net loss	$ (30,770)	$ (82,818)	$ (58,975)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	211	189	182
Share-based compensation expense	4,612	4,785	3,364
Non-cash interest expense	163	154	211
Accretion of debt discount	67	112	212
Loss on disposal of fixed assets	63	—	—
Amortization and accretion on available-for-sale investments, net	(115)	(748)	(31)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(558)	(505)	(833)
Other assets and liabilities	(159)	(55)	92
Accounts payable and accrued liabilities	(5,582)	(314)	4,715
Deferred revenue	5,000	—	(20)
Net cash used in operating activities	(27,068)	(79,200)	(51,083)
Investing activities			
Maturities of available-for-sale-investments	32,950	76,470	68,543
Purchase of available-for-sale investments	—	(80,142)	(48,116)
Acquisition of property and equipment	(25)	(88)	(306)
Net cash provided by (used in) investing activities	32,925	(3,760)	20,121
Financing activities			
Proceeds from at-the-market sales agreement, net of issuance costs	10,319	—	—
Proceeds from private placement, net of issuance costs	3,324	—	—
Proceeds from follow-on offering, net of issuance costs	—	79,564	5,057
Proceeds from exercise of stock options	7	465	239
Proceeds from shares issued under employee stock purchase plan	45	50	66
Proceeds from issuance of long-term debt	—	10,000	—
Principal payments made on long-term debt	(5,000)	(8,300)	—
Net cash provided by financing activities	8,695	81,779	5,362
Net decrease in cash, cash equivalents and restricted cash	14,552	(1,181)	(25,600)
Cash, cash equivalents and restricted cash, beginning of period	8,403	9,584	35,184
Cash, cash equivalents and restricted cash, end of period	$ 22,955	$ 8,403	$ 9,584
Supplemental disclosure			
Interest paid	$ 843	$ 751	$ 653
Supplemental disclosure of noncash investing and financing activities			
Tenant improvements paid by landlord	$ —	$ —	$ 637

Reconciliation of cash, cash equivalents and restricted cash:

	December 31,		
	2019	2018	2017
Cash and cash equivalents	$ 22,595	$ 8,043	$ 9,224
Restricted cash	360	360	360
Cash, cash equivalents and restricted cash at end of period	$ 22,955	$ 8,403	$ 9,584

See accompanying notes to the financial statements.

1. The Company

Clearside Biomedical, Inc. (the "Company") is a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases. The Company's proprietary SCS Microinjector targeting the suprachoroidal space offers unique access to the macula, retina and choroid where sight-threatening disease often occurs. This suprachoroidal space injection platform is an inherently flexible, in-office, non-surgical procedure, intended to provide targeted delivery to the site of disease and to work with both established and new formulations of medications, as well as future therapeutic innovations such as gene therapy. Incorporated in the State of Delaware on May 26, 2011, the Company has its corporate headquarters in Alpharetta, Georgia.

The Company's activities since inception have primarily consisted of developing product and technology rights, raising capital and performing research and development activities. The Company has no current source of revenue to sustain present activities, and does not expect to generate meaningful revenue until and unless the Company receives regulatory approval of and successfully commercializes its product candidates, either on its own or with a third party. The Company has funded its operations primarily through the sale of convertible preferred stock and common stock and the issuance of long-term debt. The Company is subject to a number of risks and uncertainties similar to those of other life science companies at a similar stage of development, including, among others, the need to obtain adequate additional financing, successful development efforts including regulatory approval of products, compliance with government regulations, successful commercialization of potential products, protection of proprietary technology and dependence on key individuals.

Liquidity

The Company had cash and cash equivalents of $22.6 million as of December 31, 2019. The Company has funded its operations primarily through the sale of convertible preferred stock and common stock and the issuance of long-term debt. The Company will continue to need to obtain additional financing to fund future operations, including completing the development, partnering and potential commercialization of its primary product candidates. The Company will need to obtain additional financing to conduct additional trials for the regulatory approval of its product candidates if requested by regulatory bodies, and completing the development of any additional product candidates that might be acquired. If such products were to receive regulatory approval, the Company would need to obtain additional financing to prepare for the potential commercialization of its product candidates, if the Company decides to commercialize the products on its own.

The Company has suffered recurring losses and negative cash flows from operations since inception and anticipates incurring additional losses until such time, if ever, that it can obtain FDA approval to sell, and then generate significant revenue from commercializing its lead product candidate, XIPERE, either on its own or together with a third party. In the absence of product or other revenues, the amount, timing, nature or source of which cannot be predicted, the Company's losses will continue as it conducts its research and development activities.

These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. Until the Company can generate sufficient revenue, the Company will need to finance future cash needs through public or private equity offerings, license agreements, debt financings or restructurings, collaborations, strategic alliances and marketing or distribution arrangements.

The Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result should the Company be unable to continue as a going concern.

2. Significant Accounting Policies

Basis of Presentation

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of income and expenses during the reporting periods. Significant items subject to such estimates and assumptions include the accounting for useful lives to calculate depreciation and amortization, clinical trial accruals, share-based compensation expense and income tax valuation allowance. Actual results could differ from these estimates.

Revenue Recognition

The Company recognizes revenue from its contracts with customers under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"). The Company's primary revenue arrangements are license agreements which typically include upfront payments, regulatory and commercial milestone payments and royalties based on future product sales. The arrangements may also include payments for the Company's SCS Microinjector devices as well as payments for assistance and oversight of the customer's use of the Company's technology. In determining the amount of revenue to be recognized under these agreements, the Company performs the following steps: (i) identifies the promised goods and services to be transferred in the contract, (ii) identifies the performance obligations, (iii) determines the transaction price, (iv) allocates the transaction price to the performance obligations and (v) recognizes revenue as the performance obligations are satisfied.

The Company receives payments from its customers based on billing schedules established in each contract. Up-front and other payments may require deferral of revenue recognition to a future period until the Company performs its obligations under the arrangement. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment.

Property and Equipment, Net

Property and equipment is recorded at historical cost. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets, or for leasehold improvement the lesser of the useful life or remaining lease term. Repairs and maintenance are expensed when incurred. Upon retirement or sale, the cost of the assets disposed of and the related accumulated depreciation are removed from the accounts, and any resulting gain or loss is included in the determination of net income.

Debt Discount

All debt discounts are recorded against the related debt obligation and are amortized using the effective interest rate method over the term of the underlying debt obligation and reflected in interest expense.

Fair Value Measurements

The Company records certain financial assets and liabilities at fair value in accordance with the provisions of ASC Topic 820, *Fair Value Measurements and Disclosures.* As defined in the guidance, fair value, defined as an exit price, represents the amount that would be received to sell an asset or pay to transfer a liability in an orderly transaction between market participants. As a result, fair value is a market-based approach that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering these assumptions, the guidance defines a three-tier value hierarchy that prioritizes the inputs used in the valuation methodologies in measuring fair value.

- Level 1—Unadjusted quoted prices in active, accessible markets for identical assets or liabilities.
- Level 2—Other inputs that are directly or indirectly observable in the marketplace.
- Level 3—Unobservable inputs that are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

Income Taxes

Deferred tax assets or liabilities are recorded for temporary differences between financial statement and tax basis of assets and liabilities, using enacted rates in effect for the year in which the differences are expected to reverse. A valuation allowance is recorded if it is more likely than not that a deferred tax asset will not be realized. The Company has provided a full valuation allowance on its deferred tax assets, which primarily consist of cumulative net operating losses for the period from May 26, 2011 (inception) to December 31, 2019. Due to its history of operating losses since inception and losses expected to be incurred in the foreseeable future, a full valuation allowance was considered necessary.

Research and Development Costs

Research and development costs are charged to expense as incurred and include:

- employee-related expenses, including salaries, benefits, travel and share-based compensation expense for research and development personnel;
- expenses incurred under agreements with contract research organizations, contract manufacturing organizations and consultants that conduct clinical and preclinical studies;
- costs associated with preclinical and development activities;
- costs associated with submitting regulatory approval applications for the Company's product candidates;
- costs associated with training physicians on the suprachoroidal injection procedure and educating and providing them with appropriate product candidate information;
- costs associated with technology and intellectual property licenses;
- costs for the Company's research and development facility; and
- depreciation expense for assets used in research and development activities.

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the financial statements as prepaid or accrued liabilities.

Share-Based Compensation

Compensation cost related to share-based awards granted to employees is measured based on the estimated fair value of the award at the grant date. The Company estimates the fair value of stock options using a Black-Scholes option pricing model. Compensation expense for options granted to non-employees is determined as the fair value of consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of restricted stock units granted is measured based on the market value of the Company's common stock on the date of grant. Share-based compensation costs are expensed on a straight-line basis over the relevant vesting period.

Compensation cost related to shares purchased through the Company's employee stock purchase plan, which is considered compensatory, is based on the estimated fair value of the shares on the offering date, including consideration of the discount and the look back period. The Company estimates the fair value of the shares using a Black-Scholes option pricing model. Compensation expense is recognized over the six-month withholding period prior to the purchase date.

All share-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations and comprehensive loss based upon the underlying employees' roles within the Company.

Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments with an original term of three months or less at the date of purchase.

Short-Term Investments

Short-term investments are investments with original maturities of between 90 and 365 days when purchased and are comprised of certificates of deposit, commercial paper, corporate and government bonds and treasury bills. The Company classifies its short-term

investments as available-for-sale securities. Short-term investments are recorded at fair value and unrealized gains and losses are recorded within interest income. In addition, the Company evaluates the short-investments with unrealized losses to determine whether such losses are other-than-temporary.

Restricted Cash

The Company is required to maintain a stand-by letter of credit as a security deposit for its facility lease in Alpharetta, Georgia. The Company's bank requires the Company to maintain a restricted cash balance to serve as collateral for the letter of credit issued to the landlord by the bank. As of December 31, 2019, the restricted cash balance was invested in a commercial money market account.

Concentration of Credit Risk Arising From Cash Deposits in Excess of Insured Limits

The Company maintains its cash in bank deposits that at times may exceed federally insured limits. The Company has not experienced any loss in such accounts. The Company believes it is not exposed to any significant risks with respect to its cash balances.

Recent Accounting Pronouncements

Accounting Pronouncements Recently Adopted

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, *Leases (ASC 842)*, and subsequently issued updates as part of ASU 2018-11, *Leases, Targeted Improvements*. The new guidance requires organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. The Company adopted ASC 842 effective January 1, 2019 using the optional transition method, did not restate any prior periods and adopted the package of practical expedients. Under the package of practical expedients permitted by the new standard, the Company does not have to reassess whether any expired contracts are or contain leases, the classification of leases or whether initial direct costs should be capitalized. The adoption of the new standard resulted in the recognition of right-of use assets of $1.0 million and lease obligations of $1.7 million on the Company's balance sheet as of January 1, 2019. The adoption did not have a material impact on the Company's statements of operations or cash flows.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation: Improvements to Nonemployee Shared-Based Payment Accounting*. The ASU update expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company adopted ASU 2018-07 effective January 1, 2019, and the adoption did not have a material impact on its financial statements and related disclosures.

Recent Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820-10): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which changes the fair value measurement disclosure requirements of ASC Topic 820, *Fair Value Measurements and Disclosures*. Under this ASU, certain disclosure requirements for fair value measurements are eliminated, amended or added. These changes aim to improve the overall usefulness of disclosures to financial statement users and reduce unnecessary costs to companies when preparing the disclosures. The guidance is effective for the Company beginning on January 1, 2020 and prescribes different transition methods for the various provisions. The Company does not expect the adoption of ASU 2018-13 to have a material impact on its financial statements and disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which simplifies the accounting for income taxes by removing certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new ASU also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates. These changes aim to improve the overall usefulness of disclosures to financial statement users and reduce unnecessary costs to companies when preparing the disclosures. The guidance is effective for the Company beginning on January 1, 2021 and prescribes different transition methods for the various provisions. The Company does not expect the adoption of ASU 2019-12 to have a material impact on its financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost, including trade receivables. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. This guidance is effective for annual reporting periods beginning after December 15, 2019, with early adoption permitted. Entities will apply the amendments using a

modified retrospective approach. The Company does not expect the adoption of ASU 2016-13 to have a material impact on its financial statements and related disclosures.

3. Property and Equipment, Net

Property and equipment, net consisted of the following (dollar amounts in thousands):

	Estimated Useful Lives (Years)	December31, 2019	December31, 2018
Furniture and fixtures	5	$ 337	$ 382
Machinery and equipment	5	121	121
Computer equipment	3	13	19
Leasehold improvements	Lesser of useful life or remaining lease term	667	677
Total property and equipment		1,138	1,199
Less: Accumulated depreciation		(597)	(409)
Property and equipment, net		$ 541	$ 790

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Accrued research and development	$ 359	$ 1,263
Accrued employee costs	1,530	1,191
Accrued severance	751	—
Accrued professional fees	58	63
Accrued interest payable	—	76
Accrued expense	232	330
	$ 2,930	$ 2,923

5. Long-Term Debt

Loan and Security Agreements

In September 2016, the Company entered into an amended and restated loan and security agreement, which was subsequently amended on October 31, 2017 (as amended, the "1st A&R loan agreement") with the Lenders, which amended and restated in its entirety the Company's prior loan agreement. The 1st A&R loan agreement provided for new term loans of up to $15.0 million, with a floating interest rate equal to 7% plus the greater of (i) the 30-day U.S. LIBOR, reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, or (ii) 0.50%.

Under the terms of the 1st A&R loan agreement, an initial tranche of $8.0 million was advanced on September 28, 2016. The draw period of the remaining $7.0 million available under the 1st A&R loan agreement expired on March 31, 2018. The Company was required to pay accrued interest only on the outstanding $8.0 million balance through December 31, 2017, followed by 30 equal payments of principal and accrued interest. The Company had the option to prepay the outstanding balance of the term loans in full, subject to a prepayment fee of 2% of the original principal amount of the aggregate term loans for any prepayment through May 31, 2020. A final payment of $0.5 million was due at the maturity of the loan on June 1, 2020, or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default, and was being accreted in long-term debt over the life of the loan. Of the $8.0 million borrowed, $5.3 million was used to repay all amounts outstanding under the original loan agreement. Closing costs incurred in the refinancing portion of the loan were recorded as expense while the financing costs for the new portion of the loan are recorded in long-term debt and being accreted over the life of the loan. Upon repayment of the original loan agreement, all remaining closing costs associated with the original loan agreement are being accreted to long-term debt over the life of the 1st A&R loan agreement.

On May 14, 2018, the Company entered into the 2nd A&R loan agreement with the Lenders, which amended and restated in its entirety the 1st A&R loan agreement. The 2nd A&R loan agreement provides for new term loans of up to $20.0 million, with a floating interest rate equal to 6.50% plus the greater of (i) the 30-day U.S. LIBOR, as reported in the Wall Street Journal on the last business day of the month the immediately precedes the month in which the interest will accrue, or (ii) 1.89%. The 2nd A&R Loan Agreement includes, among other things, the ability of the Lenders to accelerate the payment of the term loan in the event of a material adverse change and restrictions on the Company's ability to sell, assign, license, transfer or otherwise dispose of its assets, including intellectual property assets, without the prior written consent of the Lenders.

The Company borrowed an initial tranche of $10.0 million on May 14, 2018, of which $7.0 million was used to repay all amounts outstanding under the 1st A&R loan agreement, including fees associated with the final payment. The prepayment fees were waived. Of the remaining $10.0 million available under the 2nd A&R loan agreement, the Company elected not to draw $5.0 million and the other $5.0 million is not available for draw.

On October 18, 2019, the Company entered into the 3rd Amendment with the Lenders. Pursuant to the 3rd Amendment, the Company repaid $5.0 million of the outstanding principal balance of the $10.0 million term loan. The Company did not pay any final payment or termination fees in connection with the $5.0 million prepayment. In addition, the Company and the Lenders agreed to modify the term loan repayment schedule. As amended, the term loan repayment schedule provides for interest only payments through April 30, 2020, or if the Company completes a specified financial milestone, through October 31, 2020, followed by consecutive equal monthly payments of principal and interest in arrears continuing through the maturity date of October 1, 2022. The Company has the option to prepay the outstanding balance in full, subject to a prepayment fee of 2% of the original principal amount for any prepayment prior to October 1, 2022. A final payment of 5.50% of the aggregate borrowed amount is due at maturity of the loan on October 1, 2022, or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default. In addition, the Company agreed that if the Company's cash and cash equivalents balance with SVB falls below $10.0 million, the Company will transfer to a pledged account an amount of cash and cash equivalents equal to the sum of the then-outstanding principal balance of the term loan plus a final payment fee of $340,441. As a result of the 3rd Amendment, as of December 31, 2019, the Company has reflected in current liabilities the amount of principal it expects to pay within the next 12 months.

The term loans under the 2nd A&R loan agreement are secured by substantially all of the Company's assets.

Interest expense on the borrowings under the loan agreements described above was $804,000, $791,000 and $653,000 for the years ended December 31, 2019, 2018 and 2017, respectively. Accretion of the scheduled final payment was $163,000, $154,000 and $211,000 for the years ended December 31, 2019, 2018 and 2017, respectively. Accretion of the deferred closing costs was $67,000, $112,000 and $212,000 for the years ended December 31, 2019, 2018 and 2017, respectively.

As of December 31, 2019, the scheduled payments for the Loan Agreement, including the scheduled final payment in 2022, were as follows (in thousands):

Year Ending December 31,	Principal	Interest and Final Payment	Total
2020	$ 1,333	$ 384	$ 1,717
2021	2,000	219	2,219
2022	1,667	393	2,060
	$ 5,000	$ 996	$ 5,996

6. Preferred and Common Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue 10,000,000 shares of $0.001 par value of preferred stock. As of December 31, 2019 and 2018, there were 10,000,000 shares of preferred stock authorized, none of which were issued and outstanding.

The Company's amended and restated certificate of incorporation authorizes the Company to issue 100,000,000 shares of $0.001 par value common stock. As of December 31, 2019 and 2018, there were 44,413,372 and 32,119,227 shares of common stock outstanding, respectively.

7. Common Stock Warrants

In September 2016, in connection with the 1st A&R loan agreement, the Company issued warrants to the Lenders to purchase up to 29,796 shares of common stock at a price per share of $10.74. The warrants expire in September 2026, or earlier upon the occurrence of specified mergers or acquisitions of the Company, and are immediately exercisable. The warrants were recorded in equity at the time of issuance and had a remaining life of 6.75 years as of December 31, 2019.

8. Share-Based Compensation

Stock Options

In January 2016, the Company's board of directors adopted and approved the Clearside Biomedical, Inc. 2016 Equity Incentive Plan (the "2016 Plan") which became effective on June 1, 2016. The 2016 Plan provides for the grant of share-based awards to employees, directors and consultants of the Company. The 2016 Plan provides for the grant of incentive stock options to employees, and for the grant of nonqualified stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to the Company's employees, directors, and non-employee third parties. The number of shares of common stock reserved for issuance under the 2016 Plan will automatically increase on January 1 each year, for a period of ten years, from January 1, 2017 through January 1, 2026, by 4% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Company's board of directors. At December 31, 2019, under the 2016 Plan, options to purchase 3,391,838 shares of the Company's common stock were outstanding at a weighted average price of $5.05 per share and 394,545 shares remained available for future grant. As of January 1, 2020, the number of shares of common stock that may be issued under the 2016 Plan was automatically increased by 1,776,534 shares, representing 4% of the total number of shares of common stock outstanding on December 31, 2019, increasing the number of shares of common stock available for issuance under the 2016 Plan as of that date to 2,171,079 shares.

As a result of the adoption of the 2016 Plan, no further grants may be made under the Company's 2011 Stock Incentive Plan (the "2011 Plan"). The 2011 Plan provided for the grant of share-based awards to employees, directors and consultants of the Company. At December 31, 2019, options to purchase 695,376 shares of the Company's common stock were outstanding under the 2011 Plan at a weighted average exercise price of $2.53 per share.

The Company has granted stock option awards to employees, directors and consultants. The total share-based compensation expense recognized is reflected in the statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Research and development	$ 1,379	$ 1,766	$ 1,348
General and administrative	2,728	3,004	1,988
Total	$ 4,107	$ 4,770	$ 3,336

Share-based compensation is accounted for in accordance with the provisions of ASC 718, *Compensation-Stock Compensation*. The estimated fair value of options granted is determined as of the date of grant using the Black-Scholes option pricing model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the awards.

The following table sets forth the weighted average assumptions utilized in the Black-Scholes option pricing model to calculate the fair value of the underlying common stock for the years ended December 31, 2019, 2018 and 2017.

	Year Ended December 31,		
	2019	2018	2017
Expected term (years)	7.00	7.00	7.00
Expected stock price volatility	109.49%	93.08%	96.85%
Risk-free interest rate	2.49%	2.87%	2.20%
Expected dividend yield	0.00%	0.00%	0.00%

Expected term (in years): The Company utilized the simplified method as prescribed by ASC 718, as the Company does not have sufficient historical exercise and post-vesting termination data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees.

Risk-free interest rate: The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected time to a possible liquidity event.

Expected dividend yield: The Company has not paid and does not anticipate paying any dividends in the foreseeable future.

Expected stock price volatility: For the years ended December 31, 2019 and 2018, the expected volatility is based on the Company's historical volatility. For the year ended December 31, 2017, the volatility assumption is based on the historical volatilities of the stock of several public entities that are similar to the Company, as the Company did not have sufficient historical transactions in its own shares on which to base expected volatility. The Company selected representative companies from the pharmaceutical industry with similar characteristics, including stage of product development and therapeutic focus.

Forfeitures: As of January 1, 2017, upon adopting ASU 2016-09, the Company began recording forfeitures as they occurred. In prior years, the Company had estimated its forfeiture rate to be zero for the periods presented and any expense true-ups for terminated employees have been immaterial.

The following table summarizes the activity related to stock options during the year ended December 31, 2019:

	Number of Shares	Weighted Average Exercise Price
Options outstanding at December 31, 2018	3,463,096	$ 6.62
Granted	1,920,100	1.23
Exercised	(16,362)	0.40
Cancelled/Forfeited	(1,262,384)	5.01
Options outstanding at December 31, 2019	4,104,450	4.63
Options exercisable at December 31, 2018	1,583,749	5.63
Options exercisable at December 31, 2019	2,452,764	5.44

The following table provides additional information about the Company's stock options that were outstanding and exercisable at December 31, 2019 (aggregate intrinsic values in thousands):

Exercise Price	Options Outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (Years)	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (Years)
$0.00 - $2.99	1,759,903			7.40	716,893			4.87
$3.00 - $6.99	1,465,336			5.41	1,012,211			4.06
$7.00 - $8.99	677,433			5.05	568,759			4.61
$9.00 - $20.84	201,778			7.76	154,901			7.76
	4,104,450	$ 4.63	$ 3,191	6.32	2,452,764	$ 5.44	$ 1,472	4.66

As of December 31, 2019, the Company had $4.0 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.2 years. The weighted average fair values of all stock options granted for the years ended December 31, 2019, 2018 and 2017 was $1.09 per share, $5.98 per share and $5.25 per share, respectively. The intrinsic value is calculated as the difference between the fair market value and the exercise price per share of the stock options. The fair market value per share of common stock as of December 31, 2019 was $2.90, which was the closing sale price of the Company's common stock on the Nasdaq Global Market on that date.

Restricted Stock Units

The Company has granted restricted stock units ("RSUs") to employees under the 2016 Plan. The shares underlying the RSU awards have vesting terms of eight months to two years from the date of grant, subject to the employees' continuous service and subject to accelerated vesting in specified circumstances. The fair value of the RSUs granted is measured based on the market value of the Company's common stock on the date of grant and is recognized ratably over the requisite service period, which is generally the vesting period of the awards.

The following table summarizes the activity related to RSUs during the year ended December 31, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested RSUs outstanding at December 31, 2018	—	$ —
Granted	1,339,300	0.88
Vested	(70,000)	1.09
Non-vested RSUs outstanding at December 31, 2019	1,269,300	0.87

The Company recorded $0.2 million of share-based compensation expense in research and development and $0.3 million of share-based compensation expense in general and administrative for the year ended December 31, 2019 for the RSUs. As of December 31, 2019, the Company had $0.7 million of unrecognized compensation expense related to the RSUs, which amount is expected to be recognized over a weighted average period of 1.3 years.

Employee Stock Purchase Plan

In January 2016, the Company's board of directors adopted and approved the Clearside Biomedical, Inc. 2016 Employee Stock Purchase Plan (the "2016 ESPP") which became effective on June 1, 2016. The 2016 ESPP permits employees to purchase shares of the Company's common stock through payroll deductions up to 15% of their earnings. The number of shares reserved for issuance under the 2016 ESPP will automatically increase for a period of ten years, from January 1, 2017 through January 1, 2026, by the lesser of (i) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (ii) 454,545 shares of common stock or (iii) a lesser number of shares as may be determined by the Company's board of directors. The Company's board of directors elected not to increase the shares reserved for issuance on January 1, 2020. The number of shares of common stock available for issuance under the 2016 ESPP as of December 31, 2019 was 658,807 shares.

The first offering period for the 2016 ESPP commenced on January 1, 2017. The 2016 ESPP is considered a compensatory plan and the fair value of the discount and the look-back period are estimated using the Black-Scholes option pricing model and expense is recognized over the six-month withholding period prior to the purchase date. During the years ended December 31, 2019, 2018 and 2017, the Company issued 52,476, 12,595 and 9,692 shares, respectively, of common stock purchased under the 2016 ESPP.

The share-based compensation expense recognized for the 2016 ESPP is reflected in the statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Research and development	$ 11	$ 5	$ 7
General and administrative	9	10	21
Total	$ 20	$ 15	$ 28

9. Income Taxes

No provision for U.S. federal or state income taxes has been recorded as the Company has incurred net operating losses since inception. Significant components of the Company's net deferred income tax assets consist of the following (in thousands):

	December 31,		
	2019	2018	2017
Deferred tax asset (liability)			
Net operating loss carryforwards	$ 46,305	$ 41,152	$ 27,999
Non-deductible accrued expenses	422	245	248
Right of use asset	(138)	—	—
Lease liability	264	—	—
Deferred rent	—	148	49
Deferred revenue	—	—	38
Stock compensation expense	1,472	899	387
Depreciation differences	(94)	(125)	(18)
Federal tax credits	7,249	6,481	3,437
State tax credits	623	757	524
Disallowed interest expense	99	—	—
Charitable contributions	4	6	6
Valuation allowance	(56,206)	(49,563)	(32,670)
Net deferred tax asset	$ —	$ —	$ —

A reconciliation of the statutory tax rates and the effective tax rates is as follows:

	Year Ended December 31,		
	2019	2018	2017
U.S. federal tax rate	21.00%	21.00%	34.00%
State tax rate	—	(0.73)	2.42
Permanent difference and other	(1.33)	(0.33)	(2.84)
Tax credit	2.06	3.96	3.97
Valuation allowance	(21.73)	(20.39)	(12.42)
ASC 740-10	—	(3.51)	—
Impact of federal rate change	—	—	(25.13)
	0.00%	0.00%	0.00%

In December 2017, the 2017 Tax Cuts and Jobs Act (the "2017 Tax Act") was signed into law. The 2017 Tax Act significantly revises the U.S. corporate income tax by, among other things, lowering the statutory corporate tax rate from 34% to 21%, eliminating certain deductions, imposing a mandatory one-time tax on accumulated earnings of foreign subsidiaries, introducing new tax regimes, and changing how foreign earnings are subject to U.S. tax. The 2017 Tax Act also enhanced and extended through 2026 the option to claim accelerated depreciation deductions on qualified property. As of December 31, 2017, the Company recorded a provisional tax expense of the impact of the 2017 Tax Act of approximately $14.9 million. This amount was primarily comprised of the re-measurement of federal deferred tax liabilities resulting from the permanent reduction in the U.S. statutory corporate tax rate to 21% from 34%. As of December 31, 2018, the Company had completed the accounting for the effects of the 2017 Tax Act and recorded an insignificant adjustment to the provisional estimate recognized as of December 31, 2017.

Certain items of income and expense are not reported in tax returns and financial statements in the same year. The tax effect of such temporary differences is reported as deferred income taxes. The measurement of deferred tax assets is reduced, if necessary, by the amount of any tax benefit that, based on available evidence, is not expected to be realized. The Company establishes a valuation allowance for deferred tax assets for which realization is not likely. As of each reporting date, management considers new evidence, both positive and negative, that could affect its view of the future realization of deferred tax assets.

At December 31, 2019, the Company had a valuation allowance of $56.2 million recorded against the benefit of certain deferred tax assets. The valuation allowance was primarily related to federal and state net operating loss ("NOL") carryforwards that, in the judgment of management, are not more likely than not to be realized. In assessing the recoverability of the Company's deferred tax assets, management considered, among other things, its deferred tax liabilities, its historical earnings and losses, projections of future

income, and tax-planning strategies available to the Company in the relevant jurisdiction. The Company will release this valuation allowance when management determines that it is more likely than not that its deferred tax asset will be realized.

At December 31, 2019, the Company had income tax NOL carryforwards for federal and state purposes of $219.8 million and $7.6 million, respectively. The Company has recorded a deferred tax asset for both federal and state carryforwards of $46.2 million and $150,000, respectively. If not utilized, the federal NOL carryforwards will begin to expire beginning in 2031, and the state NOL carryforwards will begin to expire at various dates beginning in 2027. Additionally, under the 2017 Tax Act, federal net operating losses incurred in 2018 and beyond may be carried forward indefinitely. However, the deductibility of such federal net operating losses is limited. Certain states have also adopted the indefinite carryforward period beginning with the 2018 tax year, but state conformity varies state by state.

Ownership changes, as defined by Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), may limit the amount of net operating losses that a company may utilize to offset future taxable income and taxes payable. Pursuant to Section 382 of the Code, an ownership change occurs when the stock ownership of 5% stockholders increases by more than 50% over a testing period of three years. It is possible that the Company has undergone an ownership change as defined by Section 382 of the Code or that the Company may undergo such a change in the future. Any such ownership change may limit the Company’s ability to utilize net operating losses.

The Company is subject to taxation in the United States and certain state jurisdictions. The U.S. federal statute of limitations remains open for the periods from inception and forward. The Company has not been the subject of examination by the taxing authorities.

Liabilities for uncertain tax positions are recognized based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. Once it is determined that the position meets the recognition threshold, the second step requires the Company to estimate and measure the largest amount of tax benefit that is more likely than not to be realized upon ultimate settlement. The difference between the amount of recognizable tax benefit and the total amount of tax benefit from positions filed or to be filed with the tax authorities is recorded as a liability for uncertain tax benefits.

During 2019, the Company analyzed its uncertain tax positions and recorded an ASC 740-10 reserve in the amount of $2.9 million against its prior year Georgia NOLs. There are no other ASC 740-10 reserves as of December 31, 2019.

10. Commitments and Contingencies

Lease Commitment Summary

The Company leases its facilities and some of its equipment under noncancelable operating lease arrangements that expire at various dates through 2023. In November 2016, the Company signed an office lease agreement to lease approximately 20,000 square feet of office space in Alpharetta, Georgia for its corporate headquarters. The lease agreement is for a six and one-half year term with a renewal option for one additional five-year term. Rental payments are $35,145 per month subject to an increase of 3% per year. Operating lease cost under this lease is recognized on a straight-line basis over the term of the lease. In addition, the lease agreement requires payment of the pro-rata share of the annual operating expenses associated with the premises. The Company relocated to this space in March 2017.

In August 2018, the Company signed an office lease agreement to lease approximately 3,500 square feet of office space in Berkeley, California for its commercial operations. The lease agreement was for a two-year term with a renewal option for an additional one-year term. The Company did not exercise the renewal option for the Berkeley lease and terminated the lease on December 15, 2019, with no further payments due. The termination of the lease did not have a material impact on the Company’s statements of operations. Operating lease cost under this lease was recognized on a straight-line basis over the term of the lease. The Company also paid a pro-rata share of the annual operating expenses associated with the premises.

The Company’s operating leases included on the balance sheet are as follows (in thousands):

	December 31, 2019
Operating lease right-of-use asset	$ 656
Liabilities	
Current portion of operating lease liabilities	$ 360
Operating lease liabilities	897
Total operating lease liabilities	$ 1,257

The Company recognizes a right-of-use asset for the right to use the underlying asset for the lease term, and a lease liability, which represents the present value of the Company's obligation to make payments over the lease term. The renewal option is not included in the calculation of the right-of-use asset and the lease liabilities as the Company has not yet determined if the Alpharetta, Georgia lease will be renewed. The present value of the lease payments is calculated using an incremental borrowing rate as the Company's leases do not provide an implicit interest rate. At December 31, 2019, the Company's incremental borrowing rate was 11.0% and the remaining lease term was 3.75 years.

Minimum lease payments were as follows at December 31, 2019 (in thousands):

Year ending December 31,	
2020	$ 378
2021	392
2022	407
2023	316
Total minimum lease payments	1,493
Less imputed interest	(236)
Total operating lease liabilities	$ 1,257

Operating lease cost, variable lease cost and short-term lease cost were $393,000, $83,000 and $20,000, respectively, for the year ended December 31, 2019.

Contract Service Providers

In the course of the Company's normal business operations, it has agreements with contract service providers to assist in the performance of its research and development, clinical research and manufacturing. Substantially all of these contracts are on an as needed basis.

In May 2018, the Company entered into a manufacturing supply agreement (the "Supply Agreement"), with Gerresheimer Regensburg GmbH, a company incorporated under the laws of Germany ("Gerresheimer"). Gerresheimer will manufacture and supply the Company's proprietary SCS Microinjector. The Company will provide Gerresheimer with a rolling forecast schedule of its projected purchase orders for at least the next four calendar quarters. The Supply Agreement contains an initial five-year term that will automatically renew for successive periods of three years, unless terminated by either party at least 12 months prior to the end of the applicable term.

11. License and Other Agreements

Bausch + Lomb

On October 22, 2019, the Company entered into a License Agreement with Bausch + Lomb, a division of Bausch Health Companies, Inc. ("Bausch"). Pursuant to the License Agreement, the Company has granted an exclusive license to Bausch to develop, manufacture, distribute, promote, market and commercialize XIPERE using the Company's proprietary microneedle (the "Device"), as well as specified other steroids, corticosteroids and NSAIDs in combination with the Device ("Other Products"), subject to specified exceptions, in the United States and Canada for the treatment of ophthalmology indications, including non-infectious uveitis.

Pursuant to the License Agreement, Bausch made an upfront payment of $5.0 million, which is subject to a refund if the License Agreement is terminated in specified circumstances. In addition, Bausch has agreed to make additional payments of up to $15.0 million upon the achievement of specified pre-launch development and regulatory milestones and up to an aggregate of $56.0 million in additional milestone payments upon the achievement of (i) specified regulatory approvals for specified additional

indications of XIPERE and (ii) specified levels of annual net sales (as defined in the License Agreement). Further, during the applicable royalty term, the Company will also be entitled to receive tiered royalties at increasing percentages, from the high-teens to twenty percent, based on the achievement of certain annual net sales thresholds in the United States and Canada, as well as a lower royalty on annual net sales of Other Products, in each case subject to reductions in specified circumstances; provided that the Company will not receive any royalties on the first $30.0 million of cumulative net sales of all products.

The Company is responsible for all development expenses for XIPERE until the Company's New Drug Application ("NDA") for XIPERE is approved by the FDA, subject to specified exceptions, as well as manufacturing costs in connection with the NDA. The Company is also responsible for all clinical and development expenses conducted to satisfy the FDA's requests in the complete response letter issued on October 18, 2019 related to the NDA and any subsequent complete response letter related to the NDA (the "CRL-related expenses"). If XIPERE is approved by the FDA, Bausch will be responsible for all expenses following such approval; provided that the Company will be responsible for the CRL-related expenses and for one-half of the costs of any post-approval clinical trials required by the FDA, up to a specified maximum amount.

Due to the refund provisions in the License Agreement, the upfront payment of $5.0 million received from Bausch is included on the balance sheet as deferred revenue as of December 31, 2019 and will remain in deferred revenue until the refund provisions lapse.

REGENXBIO, Inc.

On August 29, 2019, the Company entered into an option and license agreement with REGENXBIO, Inc. ("REGENXBIO") pursuant to which the Company granted REGENXBIO an exclusive option to enter into a commercial license agreement (the "Option"), which grants REGENXBIO an exclusive, worldwide and sublicensable license to the Company's SCS Microinjector for the delivery of adeno-associated virus-based gene therapies for the treatment of wet age-related macular degeneration, diabetic retinopathy and other conditions for which anti-vascular endothelial growth factor treatment is currently the standard of care. REGENXBIO exercised the Option on October 29, 2019 and paid the Company an option fee equal to $2.0 million, less a credit of $0.5 million previously received under a technology access agreement. In addition, REGENXBIO has agreed to pay the Company up to an aggregate of $34.0 million in milestone payments upon the achievement of specified development milestones and up to an aggregate of $102.0 million in sales-based milestone payments, as well as mid-single digit royalties on net sales of products using the SCS Microinjector during the royalty term.

As of December 31, 2019, it was determined the Company had completed its performance obligation under the license agreement and recognized license revenue of $2.0 million.

Other

The Company periodically enters into short-term agreements with other customers to evaluate the potential use of its proprietary SCS Microinjector with third-party product candidates for the treatment of various diseases. Funds received from these agreements are recognized as revenue over the term of the agreement. The Company recorded $105,000, $30,000 and $325,000 of revenue from these agreements during the years ended December 31, 2019, 2018 and 2017, respectively.

12. Fair Value Measurements

The Company's material financial instruments at December 31, 2019 and 2018 consisted primarily of cash and cash equivalents, short-term investments and long-term debt. The fair value of cash and cash equivalents, treasury bills, other current assets and accounts payable approximate their respective carrying values due to the short-term nature of these instruments and are classified as Level 1 in the fair value hierarchy. The fair value of long-term debt approximates the carrying value due to variable interest rates that correspond to market rates. The Company has determined its short-term investments, comprised of commercial paper, to be Level 2 in the fair value hierarchy. The fair value was determined using a market approach, based on prices and other relevant information generated by market transactions involving similar assets. The short-term investments consist of investments with original maturity dates from date of acquisition of 90 to 365 days and are classified as available-for-sale.

There were no significant transfers between Levels 1, 2 and 3 during the years ended December 31, 2019 and 2018.

The following tables summarize the fair value of financial assets and liabilities that are measured at fair value and the classification by level of input within the fair value hierarchy (in thousands):

	December 31, 2019			
	Level 1	Level 2	Level 3	Recorded Value
Financial Assets:				
Cash and money markets	$ 22,595	$ —	$ —	$ 22,595
Restricted cash money market	360	—	—	360
Total financial assets	$ 22,955	$ —	$ —	$ 22,955

	December 31, 2018			
	Level 1	Level 2	Level 3	Recorded Value
Financial Assets:				
Cash and money markets	$ 8,042	$ —	$ —	$ 8,042
Restricted cash money market	360	—	—	360
Treasury bills	7,490	—	—	7,490
Commercial paper	—	25,346	—	25,346
Total financial assets	$ 15,892	$ 25,346	$ —	$ 41,238

13. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period, without consideration of the dilutive effect of potential common stock equivalents. Diluted net loss per share gives effect to all dilutive potential shares of common stock outstanding during this period.

For all periods presented, the Company's potential common stock equivalents, which included convertible preferred stock, stock options, unvested restricted stock and stock purchase warrants, have been excluded from the computation of diluted net loss per share as their inclusion would have the effect of reducing the net loss per share. Therefore, the denominator used to calculate both basic and diluted net loss per share is the same in all periods presented.

The Company's potential common stock equivalents that have been excluded from the computation of diluted net loss per share for all periods presented because of their antidilutive effect consisted of the following:

	Year Ended December 31,		
	2019	2018	2017
Outstanding stock options	4,104,450	3,075,349	2,243,575
Non-vested restricted stock units	1,269,300	—	—
Stock purchase warrants	29,796	29,796	29,796
	5,403,546	3,105,145	2,273,371

14. Related Party Transactions

On November 22, 2019, the Company issued shares of common stock in a private placement offering at an offering price of $1.054 per share. Two of the purchasers, Hatteras Venture Partners IV SBIC, LP and Hatteras Venture Partners IV, LP, are affiliated with certain of the Company's directors and purchased 1,347,629 and 170,397 shares, respectively.

15. Quarterly Financial Information (unaudited)

Summarized quarterly financial information for each of the years ended December 31, 2019 and 2018 are as follows (in thousands except per share data):

	Quarter Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Operating expenses [1]	$ (15,351)	$ (5,662)	$ (6,509)	$ (4,955)
Net loss	$ (15,404)	$ (5,734)	$ (6,536)	$ (3,096)
Net loss per share of common stock — basic and diluted	$ (0.45)	$ (0.15)	$ (0.17)	$ (0.07)

(1) Based upon final reconciliations from the CRO for SAPPHIRE and TOPAZ, the operating expenses include credits related to previously recorded expenses of $2.6 million and $2.0 million in the three months ended June 30, 2019 and December 31, 2019, respectively.

	Quarter Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Operating expenses	$ (16,453)	$ (20,904)	$ (23,956)	$ (21,662)
Net loss	$ (16,607)	$ (20,701)	$ (23,872)	$ (21,638)
Net loss per share of common stock — basic and diluted	$ (0.62)	$ (0.65)	$ (0.75)	$ (0.68)

16. Subsequent Event

On March 10, 2020, the Company entered into a License Agreement (the "License Agreement") with Arctic Vision (Hong Kong) Limited ("Arctic Vision"). Pursuant to the License Agreement, the Company has granted an exclusive license to Artic Vision to develop, distribute, promote, market and commercialize XIPERE, the Company's proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye using the Company's proprietary SCS Microinjector, subject to specified exceptions, in China, Hong Kong, Macau, Taiwan and South Korea (the "Territory"). Under the terms of the License Agreement, neither party may commercialize XIPERE in the other party's territory and Arctic Vision may pursue development and commercialization of XIPERE for indications associated with uveitis or, upon receipt of the Company's consent, additional indications.

Pursuant to the License Agreement, Arctic Vision has agreed to pay the Company up to a total of $35.5 million. This amount includes an upfront payment of $4.0 million as well as an aggregate of up to $31.5 million in development milestone payments for specified events prior to and including receipt of approval of XIPERE in the United States and sales milestone payments for achievement of specified levels of net sales. Further, during the applicable royalty term, the Company will also be entitled to receive tiered royalties of ten to twelve percent of net sales based on achieving certain annual net sales thresholds in the Territory, subject to customary reductions in specified circumstances.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report at the reasonable assurance level.

Changes in Internal Controls over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting and Attestation Report of the Registered Public Accounting Firm

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, as defined in the Exchange Act Rule 13a-15(f). Management conducted an assessment of our internal control over financial reporting based on the framework established in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework. Based on the assessment, management concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting as required by Section 404(c) of the Sarbanes Oxley Act of 2002. Because we qualify as an emerging growth company under the JOBS Act, management's report was not subject to attestation by our independent registered public accounting firm.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

We will file a definitive Proxy Statement for our 2020 Annual Meeting of Stockholders (the "2020 Proxy Statement") with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2020 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Item 10 is hereby incorporated by reference to the sections of the 2020 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors," and "Information About Our Executive Officers."

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference to the sections of the 2020 Proxy Statement under the captions "Executive Compensation" and "Non-Employee Director Compensation."

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

The information required by Item 12 is hereby incorporated by reference to the sections of the 2020 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans."

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

The information required by Item 13 is hereby incorporated by reference to the sections of the 2020 Proxy Statement under the captions "Transactions with Related Persons" and "Independence of the Board of Directors."

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by Item 14 is hereby incorporated by reference to the sections of the 2020 Proxy Statement under the caption "Ratification of Selection of Independent Auditors."

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

We have filed the following documents as part of this Annual Report:

1. Financial Statements

The financial statements are included in Item 8. "Financial Statements and Supplementary Data."

2. Financial Statement Schedules

All schedules are omitted as information required is inapplicable or the information is presented in the financial statements and the related notes.

3. Exhibits

Exhibit number	Description of document
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37783) filed with the SEC on June 7, 2016).
3.2	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-37783) filed with the SEC on June 7, 2016).

4.1		Specimen stock certificate evidencing shares of Common Stock (incorporated herein by reference to Exhibit 4.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-208916) filed with the SEC on March 18, 2016).
4.2		Third Amended and Restated Investor Rights Agreement, dated as of November 23, 2015, by and among the Registrant and certain of its stockholders (incorporated herein by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-208916), filed with the Commission on January 8, 2016).
4.3		Form of Warrant to Purchase Common Stock issued to lenders in September 2016 in connection with Amended and Restated Loan and Security Agreement (incorporated herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-37783), filed with the Commission on October 4, 2016).
4.4	*	Description of Common Stock of Clearside Biomedical, Inc.
4.5		Registration Rights Agreement, by and among the Registrant and the Investors named therein, dated as of November 22, 2019 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-37783), filed with the Commission on November 25, 2019).
10.1	#	License Agreement, by and among the Registrant, Emory University and The Georgia Tech Research Corporation, dated as of July 4, 2012, as amended by the First Amendment to License Agreement, dated April 2, 2014 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-208916), filed with the Commission on January 8, 2016).
10.2	+	2011 Stock Incentive Plan, as amended to date (incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-208916), filed with the Commission on January 8, 2016).
10.3	+	Form of Incentive Stock Option Grant Notice and Incentive Stock Option Agreement under 2011 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-208916), filed with the Commission on January 8, 2016).
10.4	+	Form of Nonqualified Stock Option Grant Notice and Nonqualified Stock Option Agreement under 2011 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-208916), filed with the Commission on January 8, 2016).
10.5	+	2016 Equity Incentive Plan (incorporated herein by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-8 (File No. 333-212014), file with the Commission on June 14, 2016).
10.6	+	Form of Stock Option Grant Notice and Stock Option Agreement under 2016 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.7 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-208916), filed with the Commission on March 18, 2016).
10.7	+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under 2016 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.8 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-208916), filed with the Commission on March 18, 2016).
10.8	+	Form of Indemnification Agreement with non-employee directors (incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-208916), filed with the Commission on January 8, 2016).
10.9	+	Form of 2016 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.12 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-208916), filed with the Commission on March 18, 2016).
10.11		Office Lease Agreement, dated November 21, 2016, by and between the Registrant and BRE/COH GA LLC (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37783), filed with the Commission on November 23, 2016).
10.12		Second Amendment to License Agreement, by and among the Registrant, Emory University and The Georgia Tech Research Corporation, dated December 12, 2016 (incorporated herein by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K (File No. 001-37783), filed with the Commission on March 16, 2017).
10.13		Sales Agreement, dated June 30, 2017, by and between the Registrant and Cowen and Company, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37783), filed with the SEC on July 3, 2017).
10.14	+	Amended and Restated Executive Employment Agreement, by and between Clearside Biomedical, Inc. and Daniel H. White, dated as of August 3, 2017 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37783), filed with the Commission on November 9, 2017).
10.15	+	Amended and Restated Executive Employment Agreement, by and between Clearside Biomedical, Inc. and Charles A. Deignan, dated as of August 3, 2017 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37783), filed with the Commission on November 9, 2017).

10.16	+	Amended and Restated Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37783), filed with the Commission on November 9, 2017).
10.17		Second Amended and Restated Loan and Security Agreement, by and among the Registrant, Silicon Valley Bank, MidCap Funding III Trust and Midcap Financial Trust, dated as of May 14, 2018 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37783), filed with the Commission on May 15, 2018).
10.18		Supply Agreement, by and among the Registrant and Gerresheimer Regensburg GmbH, dated as of May 8, 2018 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37783), filed with the Commission on August 8, 2018).
10.19	+	Change in Control Equity Acceleration Plan, amending the Registrant's 2016 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37783), filed with the Commission on August 8, 2018.)
10.20	+	Executive Employment Agreement, by and between the Company and Brion S. Raymond, dated as of February 20, 2018. 2018 (incorporated herein by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K (File No. 001-37783), filed with the Commission on March 15, 2019).
10.21		Consent and First Amendment to Second Amended and Restated Loan and Security Agreement, by and between the Registrant and Silicon Valley Bank, dated as of July 3, 2019 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37783), filed with the Commission on August 8, 2019).
10.22		Consent and Second Amendment to Second Amended and Restated Loan and Security Agreement, by and between the Registrant and Silicon Valley Bank, dated as of August 29, 2019 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37783), filed with the Commission on November 8, 2019).
10.23	*	Third Amendment to Second Amended and Restated Loan and Security Agreement, by and between the Registrant and Silicon Valley Bank, dated as of October 18, 2019.
10.24	*	Consent and Fourth Amendment to Second Amended and Restated Loan and Security Agreement, by and between the Registrant and Silicon Valley Bank, dated as of October 22, 2019.
10.25		Third Amendment to License Agreement, by and among the Registrant, Emory University and The Georgia Tech Research Corporation, dated April 1, 2018 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37783), filed with the Commission on August 8, 2019).
10.26	*##	License Agreement, by and between the Registrant and Bausch Health Ireland Limited, dated as of October 22, 2019.
10.27	+	Letter Agreement, by and between the Registrant and George Lasezkay, dated April 16, 2019 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37783), filed with the Commission on April 17, 2019).
10.28	+	Amendment to Offer Letter Agreement, by and between the Registrant and George Lasezkay, dated as of August 6, 2019 (incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37783), filed with the Commission on August 8, 2019).
10.29	*+	Separation Agreement, by and between the Registrant and Daniel White, dated as of April 7, 2019.
10.30	*##	Option and License Agreement by and between the Registrant and REGENXBIO Inc., dated as of August 29, 2019.
10.31	*+	Separation Agreement, by and between the Registrant and Brion Raymond, dated as of January 3, 2020.
10.32	*	Consulting and Independent Contractor Agreement, by and between the Registrant and Brion Raymond, dated as of January 3, 2020.
23.1	*	Consent of Ernst & Young LLP, independent registered public accounting firm.
24.1	*	Power of Attorney (included on signature page).
31.1	*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under 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 Rules 13a-14(b) and 15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to section 906 of The Sarbanes-Oxley Act of 2002.
101.INS		XBRL Instance Document

101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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*	Filed herewith.
+	Indicates management contract or compensatory plan.
#	Confidential treatment has been granted with respect to portions of this exhibit (indicated by asterisks) and those portions have been separately filed with the Securities and Exchange Commission.
^	These certifications are being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
##	Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the Securities and Exchange Commission, certain portions of this exhibit have been redacted. The Registrant hereby agrees to furnish supplementally to the Securities and Exchange Commission, upon its request, an unredacted copy of this exhibit.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

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

CLEARSIDE BIOMEDICAL, INC.

By: /s/ *George Lasezkay, Pharm.D., J.D.*
George Lasezkay, Pharm.D., J.D.
President and Chief Executive Officer

March 13, 2020

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints George Lasezkay, Charles A. Deignan and Leslie Zacks, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Clearside Biomedical, Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ George Lasezkay, Pharm.D., J.D. George Lasezkay, Pharm.D., J.D.	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 13, 2020
/s/ Charles A. Deignan Charles A. Deignan	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 13, 2020
/s/ William D. Humphries William D. Humphries	Director	March 13, 2020
/s/ Richard Croarkin Richard Croarkin	Director	March 13, 2020
/s/ Jeffrey L. Edwards Jeffrey L. Edwards	Director	March 13, 2020
/s/ Christy L. Shaffer, Ph.D. Christy L. Shaffer, Ph.D.	Director	March 13, 2020
/s/Clay B. Thorp Clay B. Thorp	Director	March 13, 2020

DESCRIPTION OF CLEARSIDE BIOMEDICAL, INC. COMMON STOCK

The following description of the common stock of Clearside Biomedical, Inc., or the Company, and certain provisions of the Company's amended and restated certificate of incorporation, or the restated certificate, and amended and restated bylaws, or restated bylaws, are summaries. These summaries are qualified in the entirety by reference to the provisions of the Delaware General Corporation Law, or the DGCL, and the complete text of the restated certificate and restated bylaws, which are incorporated by reference as Exhibits 3.1 and 3.2, respectively, of the Company's Annual Report on Form 10-K to which this description is also an exhibit.

Authorized Capital Stock

The restated certificate authorizes the issuance of up to 100,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share, all of which shares of preferred stock are undesignated. The Company's board of directors may establish the rights and preferences of the preferred stock from time to time.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under the restated certificate and restated bylaws, stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of a liquidation, dissolution or winding up of the Company, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of the Company's debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that the Company's board of directors may designate in the future.

Anti-Takeover Provisions

Section 203 of the DGCL

The Company is subject to Section 203 of the DGCL, or Section 203, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2⁄3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Restated Certificate and Restated Bylaws

The restated certificate provides for the Company's board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of the Company's stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because the Company's stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding will be able to elect all of the directors. The restated certificate and restated bylaws also provide that directors may be removed by the stockholders only for cause upon the vote of 66 2⁄3% or more of the Company's outstanding common stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

The restated certificate and restated bylaws also provide that all stockholder actions must be effected at a duly called meeting of stockholders and eliminate the right of stockholders to act by written consent without a meeting. The restated bylaws also provides that only the chairman of the board, chief executive officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

The restated bylaws also provides that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and specify requirements as to the form and content of a stockholder's notice.

The restated certificate and restated bylaws provide that the stockholders cannot amend many of the provisions described above except by a vote of 66 2⁄3% or more of the Company's outstanding common stock.

The combination of these provisions will make it more difficult for the Company's existing stockholders to replace the board of directors as well as for another party to obtain control of the Company by replacing the board of directors. Since the board of directors has the power to retain and discharge the Company's officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for the board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of the Company.

These provisions are intended to enhance the likelihood of continued stability in the composition of the board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce the Company's vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for the Company's shares and may have the effect of delaying changes in control or management of the Company. As a consequence, these provisions may also inhibit fluctuations in the market price of the Company's stock that could result from actual or rumored takeover attempts. The Company believes that the benefits of these provisions, including increased protection of the the potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure the Company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Transfer Agent and Registrar

The transfer agent and registrar for the common stock is American Stock Transfer & Trust Company. The transfer agent's address is 6201 15th Avenue, Brooklyn, NY 11219.

NASDAQ Global Market Listing

The common stock is listed on The Nasdaq Global Market under the trading symbol "CLSD."

THIRD AMENDMENT TO
SECOND AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT

THIS **THIRD AMENDMENT** to Second Amended and Restated Loan and Security Agreement (this "Amendment") is entered into as of October 18, 2019, by and among **SILICON VALLEY BANK**, a California corporation ("Bank"), as collateral agent (in such capacity, "Collateral Agent"), Bank in its capacity as a Lender, and the other Lenders party to that certain Second Amended and Restated Loan and Security Agreement dated as of May 14, 2018 (as the same may from time to time be amended, modified, supplemented or restated, including by that certain Consent and First Amendment to Second Amended and Restated Loan and Security Agreement dated as of July 3, 2019 and that certain Consent and Second Amendment to Second Amended and Restated Loan and Security Agreement dated as of August 29, 2019, collectively, the "Loan Agreement") (together with Bank, each a "Lender" and collectively, the "Lenders"), and **CLEARSIDE BIOMEDICAL, INC.**, a Delaware corporation ("Borrower").

RECITALS

A. Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

B. Borrower has requested that Lenders amend the Loan Agreement to (i) modify the repayment schedule, (ii) modify certain fees, and (iii) make certain other revisions to the Loan Agreement as more fully set forth herein.

C. Lenders have agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. **Definitions.** Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. **Amendments to Loan Agreement**.

2.1 **Section 2.1.1 (Term Loans)**. Sections 2.1.1(a) and 2.1.1(b) of the Loan Agreement hereby are amended and restated in their entirety to read as follows:

"**2.1.1** **Term Loans**.

(a) Availability. Subject to the terms and conditions of this Agreement, prior to the Third Amendment Effective Date, the Lenders have, severally and not jointly, made term loans to Borrower in an aggregate principal amount of Ten Million Dollars ($10,000,000) according to each Lender's Term Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "Term Loan", and collectively as the "Term Loans"). As of the Third Amendment Effective Date, the outstanding principal balance of the Term Loans is Ten Million Dollars ($10,000,000) before the repayment discussed in subsection (b) below.

(b) Repayment. On the Third Amendment Effective Date, Borrower shall repay Five Million Dollars ($5,000,000) of the outstanding principal balance of the Term Loans and for the avoidance of doubt, no portion of the Final Payment or Termination Fee or any other fees shall be required to be paid by Borrower to Lenders in connection with such prepayment. Any amount of the Term Loans that remain outstanding shall be "interest only" through the Amortization Start Date and shall be payable in accordance with Section 2.3(c) below. Borrower shall repay the Term Loans in equal monthly installments of principal, together with accrued interest, in arrears, to each Lender in accordance with its respective Pro Rata Share, as calculated by such Lender (which calculations shall be deemed correct absent manifest error) (each, a "Term Loan Payment"). Beginning on the Amortization Start Date, each Term Loan Payment shall be payable on the Payment Date of each month. Borrower's final Term Loan Payment, due on the Term Loan Maturity Date, shall include all outstanding principal and accrued and unpaid interest under the Term Loans and the Final Payment. Once repaid, no Term Loan may be reborrowed. Each Term Loan may only be prepaid in accordance with Sections 2.1.1(c)(i) and 2.1.1(c)(ii)."

2.2 **Section 5.2 (Collateral)**. The first paragraph of Section 5.2 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"**5.2** **Collateral**. Borrower has good title to, rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien hereunder, free and clear of any and all Liens except Permitted Liens. Borrower has no Collateral Accounts at or with any bank or financial institution other than Bank or Bank's Affiliates except for the Collateral Accounts described in the Perfection Certificate delivered to Collateral Agent in connection herewith and which Borrower has taken such actions as are necessary to give Collateral Agent a perfected security interest therein, pursuant to the terms of Section 6.6. The Accounts are bona fide, existing obligations of the Account Debtors."

2.3 **Section 6.2 (Financial Statements, Reports, Certificates)**. Section 6.2 of the Loan Agreement hereby is amended by (i) deleting the word "and" at the end of Section 6.2(h), (ii) amending and restating Section 6.2(i) in its entirety to read as follows, and (iii) adding new subsection 6.2(j) thereto to read in their entirety as follows:

"(i) Beneficial Ownership. Prompt written notice of any changes to the beneficial ownership information set out in Addendum 1 to the Perfection Certificate. Borrower understands and acknowledges that Lenders rely on such true, accurate and up-to-date beneficial ownership information to meet Lenders' regulatory obligations to obtain, verify and record information about the beneficial owners of its legal entity customers; and

(j) Other Financial Information. Promptly after Collateral Agent or any Lender's reasonable request therefor, such other information regarding Borrower's or any of its Subsidiaries' operations, business affairs, financial condition and/or compliance with this Agreement."

2.4 **Section 6.6 (Operating Accounts)**. New subsection (d) is hereby added to Section 6.6 of the Loan Agreement as follows:

"(d) Maintain at all times the Pledged Account in accordance with the terms hereof and of the Pledge Agreement."

2.5 Section 6.11 (Formation or Acquisition of Subsidiaries). Section 6.11 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"**6.11 Formation or Acquisition of Subsidiaries**. Notwithstanding and without limiting the negative covenants contained in Sections 7.3 and 7.7 hereof, at the time that Borrower forms any direct or indirect Subsidiary or acquires any direct or indirect Subsidiary after the Effective Date (including, without limitation, pursuant to a Division), Borrower shall (a) with respect to Domestic Subsidiaries only, cause such new Domestic Subsidiary to provide to Collateral Agent and the Lenders a joinder to the Loan Agreement to cause such Domestic Subsidiary to become a co-borrower hereunder, together with such appropriate financing statements and/or Control Agreements, all in form and substance satisfactory to Collateral Agent and the Lenders (including being sufficient to grant Collateral Agent, for the ratable benefit of the Lenders, a first priority Lien (subject to Permitted Liens) in and to the assets of such newly formed or acquired Domestic Subsidiary), (b) provide to Collateral Agent and the Lenders appropriate certificates and powers and financing statements, pledging all of the direct or beneficial ownership interest in such new Subsidiary to Collateral Agent, for the ratable benefit of the Lenders, in form and substance satisfactory to Collateral Agent and the Lenders, and (c) provide to Collateral Agent or the Lenders all other documentation in form and substance reasonably satisfactory to Collateral Agent and the Lenders, which in its opinion is appropriate with respect to the execution and delivery of the applicable documentation referred to above. Any document, agreement, or instrument executed or issued pursuant to this Section 6.11 shall be a Loan Document."

2.6 Section 6.13 (Cash Collateralization Trigger). New Section 6.13 hereby is added to the Loan Agreement in its entirety to read as follows:

"**6.13 Cash Collateralization Trigger**. If, at any time after the Third Amendment Effective Date but prior to repayment in full of all Obligations, the sum of Borrower's unrestricted cash and Cash Equivalents maintained in depository and/or operating accounts at Bank is less than Ten Million Dollars ($10,000,000) (the "**Collateralization Trigger**"), Borrower hereby authorizes and directs Collateral Agent to immediately transfer to the Pledged Account (from any one or a combination of Borrower's accounts at Bank) an amount of cash and/or Cash Equivalents equal to the sum of (i) the then-outstanding principal balance of the Term Loans, plus (ii) an amount equal to the Final Payment, in order to cash collateralize all amounts owing from Borrower to Lenders in connection with the Term Loans and the Final Payment (a "**Cash Collateralization**"), it being understood that the foregoing authorization shall constitute an immediate Cash Collateralization of the Obligations, irrespective of any delay by Collateral Agent in effecting such transfer."

2.7 Section 7.1 (Dispositions). Section 7.1 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"**7.1 Dispositions**. Convey, sell, lease, transfer, assign, or otherwise dispose of (including, without limitation, pursuant to a Division) (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business;

(b) of surplus, worn-out or obsolete Equipment that is, in the reasonable judgment of Borrower, no longer economically practicable to maintain or useful in the ordinary course of business of Borrower; (c) consisting of Permitted Liens and Permitted Investments; (d) consisting of the sale or issuance of any stock of Borrower permitted under Section 7.2 of this Agreement; (e) consisting of Borrower's use or transfer of money or Cash Equivalents in a manner that is not prohibited by the terms of this Agreement or the other Loan Documents; (f) Permitted Licenses, and (g) not to exceed Two Hundred Fifty Thousand Dollars ($250,000) in the aggregate in any fiscal year."

2.8 **Section 7.3 (Mergers or Acquisitions)**. Section 7.3 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"**7.3** **Mergers or Acquisitions**. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock or property of another Person (including, without limitation, by the formation of any Subsidiary or pursuant to a Division). A Subsidiary may merge or consolidate into a Domestic Subsidiary (so long as the surviving entity is a Domestic Subsidiary) or into Borrower (so long as the surviving entity is the Borrower)."

2.9 **Section 7.6 (Maintenance of Collateral Accounts)**. Section 7.6 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"**7.6** **Maintenance of Collateral Accounts**. Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof."

2.10 **Section 8.2 (Covenant Default)**. Section 8.2(a) of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"(a) Borrower fails or neglects to perform any obligation in Sections 6.2, 6.4, 6.5, 6.6, 6.8(b), 6.10, 6.11, or 6.13 or violates any covenant in Section 7; or"

2.11 **Section 14.1 (Definitions)**. The following defined terms and their respective definitions hereby are added or amended and restated in their entirety, as appropriate, in Section 14.1 of the Loan Agreement to read in their entirety to read as follows:

"**Amortization Start Date**" is May 1, 2020; provided however, if Borrower achieves the New Capital Event, the Amortization Start Date shall automatically, with no further action required by the parties hereto, be extended to November 1, 2020.

"**Division**" means, in reference to any Person which is an entity, the division of such Person into two (2) or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, or any analogous action taken pursuant to any other applicable law with respect to any corporation, limited liability company, partnership or other entity.

"**Final Payment**" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Term Loan Maturity Date, (b) the acceleration of any Term Loan, or (c) the

prepayment of a Term Loan pursuant to Section 2.1.1(c)(i) or (ii), equal to Three Hundred Forty Thousand Four Hundred Forty One Dollars and Thirty Six Cents ($340,441.36), payable to Lenders in accordance with their respective Pro Rata Shares

"**Loan Documents**" are, collectively, this Agreement, the Warrants, the Intellectual Property Security Agreement, the Perfection Certificate, the Pledge Agreement, each Compliance Certificate, each Disbursement Letter, each Loan Payment/Advance Request Form, each Guaranty, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

"**New Capital Event**" means Borrower's delivery to Lenders of evidence, in form and substance satisfactory to Lenders in their sole discretion, that Borrower has received, after September 1, 2019, but on or prior to April 23, 2020, net cash proceeds in an aggregate amount not less than Ten Million Dollars ($10,000,000) from (i) the sale of Borrower's equity securities to investors and on terms and conditions acceptable to Lenders in their reasonable discretion, and/or (ii) milestone payments made to Borrower pursuant to a new License Agreement entered into on or after the Third Amendment Effective Date on terms and conditions acceptable to Lenders in their sole discretion.

"**Pledge Agreement**" means that certain Cash Pledge Agreement and Annex I attached thereto executed by Borrower in favor of Collateral Agent for the ratable benefit of Lenders and dated as of the Third Amendment Effective Date.

"**Pledged Account**" means restricted account number xxx-xxx-0991 established and maintained by Borrower at Bank.

"**Third Amendment Effective Date**" means October 18, 2019.

2.12 **Section 14 (Definitions)**. The following defined term and its definition hereby is deleted from Section 14.1 and the balance of the Loan Agreement in its entirety:

"**Final Payment Percentage**".

2.13 New Addendum 1 is hereby added to the Perfection Certificate in the form attached hereto.

3. Limitation of Amendments.

3.1 The amendments set forth in **Section 2**, above, are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, (b) otherwise prejudice any right or remedy which Lenders may now have or may have in the future under or in connection with any Loan Document or (c) constitute a novation of any Indebtedness (or any Liens granted) under the Loan Documents.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in

the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. **Representations and Warranties.** To induce Lenders to enter into this Amendment, Borrower hereby represents and warrants to Lenders as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Lenders on the Effective Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower ;

4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on either Borrower, except as already has been obtained or made; and

4.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Release by Borrower.

5.1 **FOR GOOD AND VALUABLE CONSIDERATION**, Borrower hereby forever relieves, releases, and discharges Collateral Agent and Lenders and their present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Agreement (collectively "Released Claims"). Without limiting the foregoing, the Released Claims shall include any and all

liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

5.2 In furtherance of this release, Borrower expressly acknowledges and waives any and all rights under Section 1542 of the California Civil Code, which provides as follows:

> "**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." (Emphasis added.)

5.3 By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Collateral Agent or any Lender with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

5.4 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Collateral Agent and Lenders to enter into this Agreement, and that Collateral Agent and Lenders would not have done so but for Collateral Agent's and Lenders' expectation that such release is valid and enforceable in all events.

5.5 Borrower hereby represents and warrants to Collateral Agent and Lenders, and Collateral Agent and Lenders are relying thereon, as follows:

(a) Except as expressly stated in this Agreement, none of Collateral Agent, any Lender nor any agent, employee or representative of Collateral Agent or any Lender has made any statement or representation to Borrower regarding any fact relied upon by Borrower in entering into this Agreement.

(b) Borrower has made such investigation of the facts pertaining to this Agreement and all of the matters appertaining thereto, as it deems necessary.

(c) The terms of this Agreement are contractual and not a mere recital.

(d) This Agreement has been carefully read by Borrower, the contents hereof are known and understood by Borrower, and this Agreement is signed freely, and without duress, by Borrower.

(e) Borrower represents and warrants that it is the sole and lawful owner of all right, title and interest in and to every claim and every other matter which it releases herein, and that it has not heretofore assigned or transferred, or purported to assign or transfer, to any person, firm or entity any

claims or other matters herein released. Borrower shall indemnify Collateral Agent and Lenders, defend and hold them harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

6. **Integration**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. 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.

7. **Ratification of Intellectual Property Security Agreement**. Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and conditions of a certain Intellectual Property Security Agreement dated as of August 29, 2019 between Collateral Agent and Borrower, and acknowledges, confirms and agrees that said Intellectual Property Security Agreement (a) contains an accurate and complete listing of all Intellectual Property Collateral (as defined therein) and (b) shall remain in full force and effect.

8. **Ratification of Perfection Certificate**. Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and disclosures contained in a certain Perfection Certificate dated on or prior to the Effective Date and acknowledges, confirms and agrees that the disclosures and information Borrower provided to Lenders in such Perfection Certificate have not changed, as of the date hereof, with the exception of inclusion of Addendum 1 to the Perfection Certificate attached hereto.

9. **Counterparts.** This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

10. **Effectiveness**. This Amendment shall be deemed effective upon (a) the due execution and delivery to Lenders of (i) this Amendment by each party hereto, (ii) Addendum 1 to Perfection Certificate in the form attached hereto, and (iii) the Pledge Agreement together with evidence of Borrower's establishment of the Pledged Account, and (b) Borrower's payment to Lenders of (i) Five Million Dollars ($5,000,000) of the outstanding principal balance owing from Borrower to Lenders in connection with the Term Loans on or prior to the earlier of (A) the date on which Borrower enters into a License Agreement with respect to Xipere or (B) October 1, 2019, and (ii) all Lenders' Expenses due and owing as of the date hereof, which may be debited from any of Borrower's accounts at Bank.

11. **Governing Law**. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of California.

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In Witness Whereof, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BORROWER:

CLEARSIDE BIOMEDICAL, INC.

By /s/ Charles A. Deignan
Name: Charles A. Deignan
Title: CFO

COLLATERAL AGENT AND LENDER:

SILICON VALLEY BANK

By /s/ Michael McMahon
Name: Michael McMahon
Title: Director

LENDERS:

ELM 2016-1 TRUST

By: MidCap Financial Services Capital Management, LLC, as Servicer

By /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

ELM 2018-2 TRUST, as Assignee

By: MidCap Financial Services Capital Management, LLC, as Servicer

By /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

Addendum 1 to Perfection Certificate

1. Is the Company any of the following:

   a. a public company or an issuer of securities that are registered with the Securities and Exchange Commission under Section 12 of the Securities Exchange Act of 1934 or that is required to file reports under Section 15(d) of that Act;

   b. an investment company registered with the Securities and Exchange Commission under the Investment Company Act of 1940;

   c. an investment adviser registered with the Securities and Exchange Commission under the Investment Advisers Act of 1940; or

   d. a pooled investment vehicle operated or advised by a regulated financial institution (including an SEC-registered investment adviser)?

   Yes ☐ No☐

   If yes, skip to the signature page below. If no, continue to question 2:

2. Is the Company a pooled investment vehicle that is ***not*** operated or advised by a regulated financial institution?

   Yes ☐ No☐

   If yes, skip to question 4 below. If no, continue to question 3:

3. Does any **individual**, *directly or indirectly* (for example, if applicable, through such individual's equity interests in the Company's parent entity), through any contract, arrangement, understanding, relationship or otherwise, **own 25% or more** of the equity interests of the Company:

   Yes ☐ No☐

   If yes, complete the following information. If no, continue to question 4 below.

	Name	Date of birth	Residential address	For US Persons, Social Security Number: (non-US persons should provide SSN if available)	For Non-US Persons: Type of ID, ID number, country of issuance, expiration date	Percentage of ownership (if indirect ownership explain structure)
1						
2						
3						
4						

4. Identify one individual with significant responsibility for managing the Company, i.e., an executive officer or senior manager (e.g., Chief Executive Officer, President, Vice President, Chief Financial Officer, Treasurer, Chief Operating Officer, Managing Member or General Partner) or any other individual who regularly performs similar functions. If appropriate, an individual listed in the Perfection Certificate above may also be listed here.

	Name	Date of birth	Residential address	For US Persons, Social Security Number: (non-US persons should provide SSN if available)	For Non-US Persons: Type of ID, ID number, country of issuance, expiration date
1					

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The undersigned hereby certifies, to the best of his or her knowledge, that the information set out in this Addendum 1 to Perfection Certificate and the Perfection Certificate is true, complete and correct.

Date: September __, 2019

By:

Name:

Title:

Email:

Phone:

[*Signature Page to Addendum 1 to Perfection Certificate*]

CONSENT AND FOURTH AMENDMENT TO SECOND AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT

THIS **CONSENT AND FOURTH AMENDMENT** to Second Amended and Restated Loan and Security Agreement (this "Amendment") is entered into as of October 22, 2019, by and among **SILICON VALLEY BANK**, a California corporation ("Bank"), as collateral agent (in such capacity, "Collateral Agent"), Bank in its capacity as a Lender, and the other Lenders party to that certain Second Amended and Restated Loan and Security Agreement dated as of May 14, 2018 (as the same may from time to time be amended, modified, supplemented or restated, including without limitation by that certain Consent and First Amendment to Second Amended and Restated Loan and Security Agreement dated as of July 3, 2019, that certain Consent and Second Amendment to Second Amended and Restated Loan and Security Agreement dated as of August 29, 2019, and that certain Third Amendment to Second Amended and Restated Loan and Security Agreement dated as of October 18, 2019, collectively, the "Loan Agreement") (together with Bank, each a "Lender" and collectively, the "Lenders"), and **CLEARSIDE BIOMEDICAL, INC.**, a Delaware corporation ("Borrower").

RECITALS

A. Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

B. Borrower has informed Lenders that it desires to grant an exclusive license to Bausch Health Ireland Limited, an Irish company having an office at 3013 Lake Drive, Citywest Business Campus, Dublin, Ireland ("Bausch Health"), to develop, manufacture, have manufactured, distribute, promote, market, and otherwise commercialize Products (as such term is defined in the License Agreement) in the United States and Canada, pursuant to the terms of that certain License Agreement by and between Bausch Health and Borrower dated as of October 22, 2019 and attached hereto as Annex I (the "License Agreement"). In connection therewith, Bausch Health has agreed, among other things, to pay to Borrower an upfront payment in the amount of Five Million Dollars ($5,000,000) plus various conditional payments and royalties.

C. Section 7.1 of the Loan Agreement provides that Borrower shall not convey, sell, lease, transfer, assign, or otherwise dispose of all or any part of its business or property without Lenders' prior written consent. Section 7.5 of the Loan Agreement provides that Borrower shall not create, incur allow or suffer any Lien on its property or agree with any Person not to encumber its Intellectual Property except to the extent permitted under Section 7.1 of the Loan Agreement or in the definition of "Permitted Liens" contained therein.

D. Borrower has requested that Lenders consent to Borrower's entry into and performance of the License Agreement and agree that entry into and performance under the License Agreement will not violate sections 7.1 or 7.5 of the Loan Agreement.

E. Lenders have agreed to so consent to Borrower's entry into the License Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. **Definitions**. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. **Consent**. Subject to the terms of Section 8 below, Lenders hereby consent to Borrower's entry into and performance of the License Agreement attached as Annex I to this Amendment (without giving effect to any subsequent amendments or changes thereto).

3. **Amendments to Loan Agreement**.

3.1 **Section 14.1 (Definitions)**. The following defined terms and their respective definitions hereby are added or amended and restated in their entirety, as appropriate, in Section 14.1 of the Loan Agreement to read in their entirety to read as follows:

"**Bausch Health License**" means that certain License Agreement by and between Bausch Health Ireland Limited, an Irish company having an office at 3013 Lake Drive, Citywest Business Campus, Dublin, Ireland ("Bausch Health") and Borrower dated as of October 22, 2019 as attached as Annex I to the Fourth Amendment (without giving effect to any subsequent amendments or changes thereto), pursuant to which Borrower has granted Bausch Health an exclusive license to develop, manufacture, have manufactured, distribute, promote, market, and otherwise commercialize Products (as such term is defined therein) in the United States and Canada.

"**Fourth Amendment**" means that certain Consent and Fourth Amendment to Second Amended and Restated Loan and Security Agreement by and among Collateral Agent, Lenders, and Borrower dated as of the Fourth Amendment Effective Date.

"**Fourth Amendment Effective Date**" is October 22, 2019.

"**Permitted License**" is (a) any non-exclusive license of patent rights of Borrower or its Subsidiaries so long as all such Permitted Licenses are granted to third parties in the ordinary course of business, do not result in a legal transfer of title to the licensed property, and have been granted in exchange for fair consideration, (b) any exclusive license of patent rights of Borrower or its Subsidiaries so long as such Permitted Licenses do not result in a legal transfer of title to the licensed property, are exclusive solely as to discrete geographical areas outside of the United States, and have been granted in exchange for fair consideration, (c) the Aura License, (d) the Regenxbio License, and (e) the Bausch Health License.

4. **Representations and Warranties**. To induce Lenders to enter into this Amendment, Borrower hereby represents and warrants to Lenders as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Lenders on the Effective Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect.

5. **Integration**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. 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.

6. **Ratification of Perfection Certificate**. Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and disclosures contained in a certain Perfection Certificate dated on or prior to the Effective Date and acknowledges, confirms and agrees that the disclosures and information Borrower provided to Lenders in such Perfection Certificate have not changed, as of the date hereof.

7. **Counterparts**. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

8. **Effectiveness**. This Amendment shall be deemed effective upon (a) the due execution and delivery to Lenders of (i) this Amendment by each party hereto, and (ii) a fully-executed copy the License Agreement together with all other documents entered into in connection therewith, and (b) Borrower's payment to Lenders of all Lenders' Expenses due and owing as of the date hereof, which may be debited from any of Borrower's accounts at Bank.

9. **Governing Law**. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of California.

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In Witness Whereof, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BORROWER:

CLEARSIDE BIOMEDICAL, INC.

By: /s/ Charles Deignan
Name: Charles Deignan
Title: CFO

COLLATERAL AGENT AND LENDER:

SILICON VALLEY BANK

By: /s/ Myron O. Jensen
Name: Myron O. Jensen
Title: Vice President

LENDERS:

ELM 2016-1 TRUST

By: MidCap Financial Services Capital Management, LLC, as Servicer

By /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

ELM 2018-2 TRUST, as Assignee

By: MidCap Financial Services Capital Management, LLC, as Servicer

By /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

ANNEX 1

LICENSE AGREEMENT

[*See attached*]

LICENSE AGREEMENT

This **License Agreement** (this "**Agreement**") is made as of October 22, 2019 (the "**Effective Date**"), by and between **Clearside Biomedical, Inc.**, a Delaware corporation having a place of business at 900 North Point Parkway, Suite 200, Alpharetta, GA 30005, United States of America ("**Clearside**"), and **Bausch Health Ireland Limited**, an Irish company having an office at 3013 Lake Drive, Citywest Business Campus, Dublin, Ireland ("**Bausch Health**"). Clearside and Bausch Health are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

Recitals

Whereas, Clearside is a biopharmaceutical company and owns or controls rights to certain suprachoroidal injection technology;

Whereas, Bausch Health wishes to obtain an exclusive license from Clearside to develop, manufacture, have manufactured, distribute, promote, market, and otherwise commercialize Products in the Field in the Territory (each as defined herein), and Clearside is willing to grant such a license to Bausch Health for the Territory, all in accordance with the terms and conditions set forth herein.

Agreement

Now, Therefore, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, have the respective meanings set forth below:

1.1 "**Additional Clearside Development Work**" has the meaning set forth in Section 4.1(a).

1.2 "**Additional Clearside Regulatory Matters**" has the meaning set forth in Section 5.1.

1.3 "**Adverse Event**" means any unwanted or harmful medical occurrence in a patient or subject who is administered treatment using a Product, whether or not considered related to Products, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of Products.

1.4 "**Affiliate**" means, with respect to a Party, any entity that directly or indirectly controls, is controlled by, or is under common control with such Party. As used in this Section 1.4, "control" (and, with correlative meanings, the terms "controlled by" and "under common control

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

with") means, in the case of a corporation, the ownership of fifty percent (50%) or more of the outstanding voting securities thereof or, in the case of any other type of entity, an interest that results in the ability to direct or cause the direction of the management and policies of such party or the power to appoint fifty percent (50%) or more of the members of the governing body of the party or, where ownership of fifty percent (50%) or more of such securities or interest is prohibited by law, ownership of the maximum amount legally permitted.

1.5 "**Agreement**" has the meaning set forth in the preamble.

1.6 "**Alliance Manager**" has the meaning set forth in Section 3.3.

1.7 "**Anti-Corruption Laws**" means local and other anti-corruption laws (including the provisions of the U.S. Foreign Corrupt Practices Act).

1.8 "**Applicable Laws**" means all laws, statutes, ordinances, regulations, rules, or orders of any Governmental Authority of any federal, national, multinational, state, provincial, county, city, or other political subdivision, that may be in effect from time to time and applicable to the activities contemplated by this Agreement.

1.9 "**Approval Payment**" has the meaning set forth in Section 8.1(b).

1.10 "**Assigned Improvements**" has the meaning set forth in Section 12.1(b).

1.11 "**Bankruptcy Code**" has the meaning set forth in Section 2.4.

1.12 "**Bausch Health**" has the meaning set forth in the preamble.

1.13 "**Bausch Health IP**" means the Know-How and Patents that (a) are created by or on behalf of Bausch Health or its Affiliates or Sublicensees in the course of performing Development, Manufacturing or Commercialization activities under the Agreement during the Term of the Agreement and are Controlled by Bausch Health or its Affiliates, and (b) are necessary or useful to research, develop, make, use, sell, offer for sale, import or otherwise exploit the Device or a Product. Bausch Health IP includes Bausch Health's interest in any Joint Patent or Joint Inventions.

1.14 "**Bausch Health Indemnitees**" has the meaning set forth in Section 11.2.

1.15 "**BH Parent**" means Bausch Health Companies Inc., a British Columbia corporation having an office at 2150 St. Elzear Blvd. West, Laval, Quebec H7L 4A8, Canada.

1.16 "**Business Day**" means a day other than Saturday, Sunday or any day on which banks located in Atlanta, Georgia, United States or Dublin, Ireland are authorized or obligated by Applicable Law to close. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified.

1.17 "**Calendar Quarter**" means any respective period of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31 of any Calendar Year,

except that the first Calendar Quarter will commence on the Effective Date and the last Calendar Quarter will end upon the end of the Term.

1.18 "**Calendar Year**" means each successive period of twelve (12) months commencing on January 1 and ending on December 31, except that the first Calendar Year will commence on the Effective Date and the last Calendar Year will end upon the end of the Term.

1.19 "**Change of Control**" means, with respect to Clearside: (a) the sale of all or substantially all of its assets or all of its assets relating to the Device or the XIPERE Product; (b) a merger, reorganization or consolidation involving Clearside in which the holders of the voting securities of Clearside outstanding immediately prior thereto cease to beneficially own at least fifty percent (50%) of the combined voting power of the surviving entity, directly or indirectly, immediately after such merger, reorganization or consolidation; or (c) a transaction in which an entity or individual, group of entities, or individuals acting in concert acquire, directly or indirectly, more than fifty percent (50%) of the voting equity securities of Clearside.

1.20 "**Clearside**" has the meaning set forth in the preamble.

1.21 "**Clearside Indemnitees**" has the meaning set forth in Section 11.1.

1.22 "**Clinical Trial**" shall mean a study in which human subjects or patients are dosed with a drug, whether approved or investigational, including any phase I clinical trial, phase II clinical trial, phase III clinical trial, or any study required to be conducted following Regulatory Approval as a condition to maintaining such approval.

1.23 "**CMO Agreements**" has the meaning set forth in Section 6.1(a).

1.24 "**Commercialization**" or "**Commercialize**" means any activities directed to obtaining pricing or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, selling, or using a product (including establishing the price for and booking sales for such product). When used as a verb, "Commercialize" means to engage in Commercialization.

1.25 "**Commercial Readiness**" means the date on which [***].

1.26 "**Commercial Readiness Payment**" has the meaning set forth in Section 8.1(b).

1.27 "**Commercially Reasonable Efforts**" [***].

1.28 "**Competing Program**" has the meaning set forth in Section 2.6.

1.29 "**Confidential Information**" means all information of the Disclosing Party or its Affiliates, regardless of its form or medium as provided to the Receiving Party or its Affiliates in connection with this Agreement; provided that, Confidential Information excludes any information that the Receiving Party can show by competent evidence: (a) is already known to the Receiving Party at the time it is disclosed to the Receiving Party by the Disclosing Party without an obligation of confidentiality and not through a prior disclosure by the Disclosing Party, (b) is or becomes generally known to the public through no act or omission of the Receiving Party in violation of

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the terms of this Agreement, (c) has been lawfully received by the Receiving Party from a Third Party without restriction on its disclosure and without, to the knowledge of the Receiving Party, a breach by such Third Party of an obligation of confidentiality to the Disclosing Party, or (d) has been independently developed by the Receiving Party without use of or reference to the Confidential Information of the Disclosing Party.

1.30 "**Controlled**" means, with respect to any Know-How, Patents or other intellectual property rights, that a Party has the legal authority or right (whether by ownership, license or otherwise) to grant to the other Party a license, sublicense, access, or right to use (as applicable) under such Know-How, Patents, or other intellectual property rights, on the terms and conditions set forth herein, in each case without breaching the terms of any agreement with a Third Party.

1.31 "**Cover**", "**Covering**", or "**Covered**" with respect to a product, technology, process, or method, means that, but for a license granted to a person under a Valid Claim of a Patent under which such license is granted, the Development, Manufacture, Commercialization and/or other use of such product or the practice of such technology, process, or method, by such person would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).

1.32 "**Development**" or "**Develop**" means, with respect to a product, preclinical and clinical drug or device development activities, including the conduct of Clinical Trials, test method development and stability testing, toxicology, formulation and delivery system development, process development, Manufacturing scale-up, development-stage Manufacturing, quality assurance or quality control procedure development and performance with respect to preclinical or clinical materials, statistical analysis and report writing, regulatory affairs, and all other pre-Regulatory Approval activities. When used as a verb, "Develop" means to engage in Development.

1.33 "**Development Plan**" has the meaning set forth in Section 4.5.

1.34 "**Device**" means Clearside's proprietary medical device containing a microinjection needle for the administration of one or more active pharmaceutical ingredients to the suprachoroidal space having the specifications set forth on Exhibit 1.34 and any and all improvements and enhancements thereof made by or on behalf of, or otherwise Controlled by, Clearside or its Affiliates.

1.35 "**Device Master File**" means Clearside's device master file number [***].

1.36 "**Disclosing Party**" has the meaning set forth in Section 9.1(a).

1.37 "**Dispute**" has the meaning set forth in Section 14.1.

1.38 "**Dollars**" means U.S. dollars, and "**$**" will be interpreted accordingly.

1.39 "**Effective Date**" has the meaning set forth in the preamble.

1.40 "**Emory Agreement**" means that certain License Agreement between Emory University and The Georgia Tech Research Corporation, on the one hand ("**Emory**"), and

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Clearside on the other hand, effective as of July 4, 2012, as amended April 2, 2014, December 2, 2016 and April 1, 2018, and as further amended from time to time in accordance with Section 10.4.

1.41 "**Excess Amount**" has the meaning set forth in Section 8.7.

1.42 "**Executive Officers**" has the meaning set forth in Section 14.3.

1.43 "**FD&C Act**" means that federal statute entitled the Federal Food, Drug, and Cosmetic Act and enacted in 1938 as Public Law 75-717, as such may have been amended, and which is contained in Title 21 of the C.F.R. Section 301 et seq.

1.44 "**FDA**" means the U.S. Food and Drug Administration and successor agency or authority thereto having substantially the same function.

1.45 "**Field**" means the cure, treatment, prophylaxis, palliation, diagnosis, and prevention of conditions, disorders and diseases in the field of ophthalmology in humans and animals, including, but not limited to, non-infectious uveitis.

1.46 "**First Commercial Sale**" means, with respect to a Product, the first arm's length sale of such Product to a Third Party in a region of the Territory by Bausch Health, its Affiliates or Sublicensees for use or consumption in such region following Regulatory Approval. Sales or transfers of reasonable quantities of Product for indigent or similar public support or compassionate use programs are not considered a First Commercial Sale.

1.47 "**GAAP**" means U.S. generally accepted accounting principles, consistently applied.

1.48 "**Generic Product**" means, with respect to a Product in a particular regulatory jurisdiction, on a Product-by-Product and country-by-country basis, any pharmaceutical product (other than the Product itself) that (a) is approved by the Regulatory Authority in such country for at least one indication for which such Product obtained Regulatory Approval from the applicable Regulatory Authority in such jurisdiction (i) through an abbreviated new drug application as defined in 21 U.S.C. 355(j) (or equivalent outside the United States) or (ii) as an A-rated therapeutically equivalent product (or the foreign equivalent thereof), including pursuant to an application under 21 U.S.C. 355(b)(2) (or the foreign equivalent thereof); and (b) is sold in such jurisdiction by a Third Party that is not a Sublicensee and did not purchase such product in a chain of distribution that included any of Bausch Health or its Affiliates or Sublicensees).

1.49 "**Global Brand Elements**" has the meaning set forth in Section 7.4.

1.50 "**Governmental Authority**" means any court, commission, authority, department, ministry, official or other instrumentality of, or being vested with public authority under any law of, any country, region, state or local authority, or any political subdivision thereof, or any association of countries.

1.51 "**Health Canada**" means the department of the government of Canada with responsibility for national public health and any successor agency thereto.

1.52 "**Incremental Withholding Taxes**" has the meaning set forth in Section 8.7.

1.53 "**Indemnifying Party**" has the meaning set forth in Section 11.3(a).

1.54 "**Indemnitee**" has the meaning set forth in Section 11.3(a).

1.55 "**Interim Supply**" means [***] units of XIPERE Product or such other amount as mutually agreed to by the Parties pursuant to the terms of the Supply Agreement.

1.56 "**Invention**" means any inventions, process, method, data, composition of matter, article of manufacture, discovery or finding, patentable or otherwise, that is invented or generated as a result of a Party exercising its rights or carrying out its obligations under this Agreement, whether directly or via its Affiliates, Sublicensees, agents or contractors, including all rights, title and interest in and to the intellectual property rights therein. Clearside's Inventions include any Assigned Improvements.

1.57 "**Joint Inventions**" has the meaning set forth in Section 12.1(a).

1.58 "**Joint Patents**" has the meaning set forth in Section 12.1(a).

1.59 "**Know-How**" means any proprietary scientific or technical information, results, and data of any type, in any tangible or intangible form, including databases, safety information, practices, methods, techniques, specifications, formulations, formulae, knowledge, trade secrets, know-how, skill, experience, test data (including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data), analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data.

1.60 "**Knowledge of Clearside**" means the actual knowledge of the individuals listed on Exhibit 1.60, in each case, after reasonable investigation or inquiry.

1.61 "**Licensed IP**" means the Licensed Know-How, Licensed Marks, and Licensed Patents.

1.62 "**Licensed Know-How**" means any and all Know-How (including Inventions) that is Controlled by Clearside or its Affiliates as of the Effective Date or during the Term that is necessary or useful for the Development, Manufacture or Commercialization of Products in the Field in the Territory, including any such Know-How in the Microneedle Technology and the Assigned Improvements. Licensed Know-How includes Clearside's interest in any Know-How in any Joint Inventions.

1.63 "**Licensed Marks**" means the Trademarks identified on Exhibit 1.63 and the Non-Exclusive Licensed Marks.

1.64 "**Licensed Patents**" means Patents that are Controlled by Clearside or its Affiliates as of the Effective Date or during the Term that claim or are otherwise necessary or useful to the Development, Manufacture or Commercialization of Products in the Field in the Territory,

including any such Patents in the Microneedle Technology and the Assigned Improvements. Licensed Patents existing as of the Effective Date are set forth in Exhibit 1.64. Licensed Patents includes Clearside's interest in any Joint Patent.

1.65 "**Losses**" has the meaning set forth in Section 11.1.

1.66 "**Manufacture**", "**Manufactured**" or "**Manufacturing**" means all activities related to the synthesis, making, production, processing, purifying, formulating, filling, finishing, packaging, labeling, shipping, and holding of Products, or any intermediate thereof, including process and formulation development, process qualification and validation, scale-up, pre-clinical, clinical and commercial production and analytic development, product characterization, stability testing, quality assurance and quality control.

1.67 "**Microneedle Technology**" means any [***].

1.68 "**NDA**" means a new drug application (as defined in the U.S. Federal Food, Drug, and Cosmetic Act of 1938, as amended (21 U.S.C. §§ 301 *et seq*.) (the "**Act**") and applicable regulations promulgated thereunder by the FDA, as amended from time to time), including a new drug application submitted pursuant to the requirements of 21 U.S.C. § 355(b)(2) of the Act (a "**505(b)(2) NDA**"), with all additions, deletion or supplements thereto.

1.69 "**Net Sales**" means, with respect to a Product for a particular period in a particular country in the Territory, the gross amount invoiced by Bausch Health, its Affiliates, or any Sublicensees to Third Parties (excluding any Third Party that is a Sublicensee) for sale of such Product in such country in the Territory, less the following deductions actually taken or accrued:

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***];

(f) [***];

(g) [***];

(h) [***]; and

(i) [***].

[***].

The transfer of Products to a Third Party (i) in connection with the research, development or testing of Products (including the conduct of clinical studies), (ii) for purposes of distribution

as promotional samples, or (iii) for indigent or similar public support or compassionate use programs, where Product is supplied without charge or at the actual Manufacturing cost thereof (without allocation of indirect costs or any mark-up), shall not, in any case, be considered Net Sales of a Product under this Agreement.

To the extent any such deductions apply to the Product as well as any other products of Bausch Health or any of its Affiliates or Sublicensees, such deductions shall be fairly and equitably allocated to the Product and such other products of Bausch Health or any of its Affiliates or Sublicensees, such that the Product does not bear a disproportionate portion of such deductions. Any of the deductions listed above that involves payment by Bausch Health or any of its Affiliates or Sublicensees shall be taken as a deduction in the Calendar Quarter in which the payment is accrued by such entity. To the extent accrued deductions are subsequently reduced or increased, adjustments will be made to that Calendar Quarter.

1.70 "**Non-Exclusive Licensed Marks**" means the Trademarks identified on Exhibit 1.70.

1.71 "**Other Device**" has the meaning set forth in Section 2.6.

1.72 "**Other Drugs**" means each of the steroids, corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDS) identified on Exhibit 1.72 hereto; provided that, as further described in Section 2.7, for each of the steroids, corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDS) identified on Exhibit 1.72 hereto that [***], then such steroids, corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDS) will cease to be Other Drugs for the purpose of this definition of "Other Drugs".

1.73 "**Other Product**" means the Device used in combination with one or more of the Other Drugs; provided that, as further described in Section 2.7, for each Other Product that [***], then such Other Products will cease to be Other Products for the purpose of this definition of "Other Product".

1.74 "**Party**" and "**Parties**" have the meaning set forth in the preamble.

1.75 "**Patent Term Extension**" means any patent term extension, adjustment, or restoration or supplemental protection certificates.

1.76 "**Patents**" means all national, regional and international patents and patent applications, including divisions, continuations, continuations-in-part, additions, re-issues, renewals, extensions, substitutions, re-examinations or restorations, registrations and revalidations, and supplementary protection certificates and equivalents to any of the foregoing.

1.77 "**Payments**" has the meaning set forth in Section 8.7.

1.78 "**Product**" means (i) each XIPERE Product or (ii) each Other Product, if any.

1.79 "**Product Infringement**" has the meaning set forth in Section 12.3(a).

1.80 "**Product-Specific Patents**" has the meaning set forth in Section 12.2(b).

1.81 "**Receiving Party**" has the meaning set forth in Section 9.1(a).

1.82 "**Regulatory Approval**" means, with respect to a Product in a country in the Territory, all approvals from the applicable Regulatory Authorities necessary to market and sell such Product in such country in the Territory (excluding pricing and reimbursement approvals). Notwithstanding the foregoing, Regulatory Approvals exclude the Device Master File.

1.83 "**Regulatory Authority**" means any applicable Governmental Authority responsible for granting Regulatory Approvals for Product, including the FDA and Health Canada.

1.84 "**Regulatory Exclusivity**" means, with respect to a Product in a country, the ability for Bausch Health or any of its Affiliates or Sublicensees to exclude Third Parties from Commercializing such Product in such country, either through data exclusivity rights, orphan drug designation or such other rights conferred by Applicable Laws or a Regulatory Authority in such country, in each case, other than through Patents.

1.85 "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including Regulatory Approvals, and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences or discussions with the relevant Regulatory Authority, in each case, with respect to Products. Notwithstanding the foregoing, Regulatory Submissions exclude the Device Master File.

1.86 "**Remedial Action**" has the meaning set forth in Section 5.9.

1.87 "**Required Post-Approval Commitments**" has the meaning set forth in Section 4.3.

1.88 "**Required Post-Approval Commitments for Other Products**" has the meaning set forth in Section 4.3.

1.89 "**Retained Field**" means all fields and uses other than the Field.

1.90 "**Right of Reference or Use**" means a "Right of Reference or Use" as that term is defined in 21 C.F.R. § 314.3(b), and any non-United States equivalents.

1.91 "**Royalty Term**" has the meaning set forth in Section 8.2(b).

1.92 "**Safety Agreement**" has the meaning set forth in Section 5.6(a).

1.93 "**Sole Inventions**" has the meaning set forth in Section 12.1(a).

1.94 "**Sublicensee**" means any Third Party that is granted a sublicense by Bausch Health under the license grants in Section 2.1.

1.95 "**Supply Agreement**" has the meaning set forth in Section 6.1(a).

1.96 "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon). For the avoidance of doubt, Taxes includes VAT.

1.97 "**Term**" has the meaning set forth in Section 13.1.

1.98 "**Territory**" means Canada and the U.S.

1.99 "**Third Party**" means an entity other than (a) Bausch Health and its Affiliates or (b) Clearside and its Affiliates.

1.100 "**Third Party IP**" has the meaning set forth in Section 8.8(a).

1.101 "**Trademark**" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.102 "**U.S.**" means United States of America, including all possession and territories thereof.

1.103 "**Valid Claim**" means (a) a claim of an issued Licensed Patent that has not expired or been abandoned, or been revoked, held invalid or unenforceable by a patent office, court, or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and (b) a claim of any patent application within a Licensed Patent that has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application and that has been pending for no more than [***] from its earliest priority date.

1.104 "**VAT**" means value-added taxes or other similar taxes.

1.105 "**XIPERE**" means XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension), as is further defined in the XIPERE NDA.

1.106 "**XIPERE NDA**" means NDA number [***] submitted by or on behalf of Clearside to the FDA.

1.107 "**XIPERE NDA Approval Date**" means the date on which the FDA approves the XIPERE NDA.

1.108 "**XIPERE Product**" means the Device used in combination with XIPERE.

ARTICLE 2
LICENSES; EXCLUSIVITY

2.1 **License Grant to Bausch Health**. Subject to the terms and conditions of this Agreement, Clearside hereby grants to Bausch Health (i) an exclusive (even as to Clearside, subject to Clearside's retained rights as set forth in Section 2.3), royalty-bearing license, with the right to grant sublicenses in accordance with Section 2.2, under the Licensed IP (other than the Non-Exclusive Licensed Marks) to Develop (solely in accordance with Section 4.3), Manufacture and have Manufactured (solely in accordance with Section 6.2), Commercialize and otherwise use and exploit Products in the Field in the Territory and (ii) a non-exclusive, royalty-bearing license, with the right to grant sublicenses in accordance with Section 2.2, under the Non-Exclusive Licensed Marks to Develop (solely in accordance with Section 4.3), Manufacture and have Manufactured (solely in accordance with Section 6.2), Commercialize and otherwise use and exploit Products in the Field in the Territory. Bausch Health acknowledges and agrees that the licenses granted in this Section 2.1 contains certain sublicenses under the Emory Agreement and the licenses granted hereunder are subject to the terms and conditions of the Emory Agreement. Bausch Health shall comply with the Emory Agreement in all material respects as such Emory Agreement applies to the sublicenses granted to Bausch Health hereunder.

2.2 **Right to Sublicense**. Subject to the terms and conditions of this Agreement, Bausch Health may grant sublicenses of the licenses granted to it under Section 2.1 (a) to its Affiliates, provided that such sublicense automatically terminates if such Sublicensee ceases to be an Affiliate of Bausch Health, and (b) to a Third Party solely with the prior written consent of Clearside, such consent not to be unreasonably withheld, conditioned, or delayed. Bausch Health shall ensure that any such permitted sublicense is consistent with the terms and conditions of this Agreement, including that (i) each Sublicensee shall comply with Applicable Law, (ii) each Sublicensee shall protect and keep confidential any Confidential Information of Clearside in accordance with Article 9; (iii) each Sublicensee shall comply with Invention assignment obligations under Section 12.1, and (iv) the applicable sublicense will automatically terminate if the Sublicensee challenges, directly or indirectly, the validity, enforceability, or scope of any claim with the Licensed Patents in a court or other governmental agency of competent jurisdiction, including in a reexamination or opposition proceeding. Within [***] after execution, Bausch Health shall provide Clearside with a full and complete copy of each agreement granting a sublicense to a Third Party; provided that Bausch Health may redact any confidential or sensitive information contained therein that is not necessary to confirm compliance with this Agreement. Bausch Health shall remain directly responsible for all of its obligations under this Agreement that have been delegated or sublicensed to any permitted Sublicensee, and any such Sublicensee conduct that would have constituted a breach of this Agreement shall be deemed a breach of this Agreement as if it had been engaged in by Bausch Health.

2.3 **Retained Rights**. Notwithstanding the exclusive license granted to Bausch Health under Section 2.1, Clearside hereby expressly retains the rights to use the Licensed IP in the Field in the Territory (a) to perform its obligations under this Agreement, whether directly or through its Affiliates, Bausch Health or contractors and (b) to Develop and Manufacture the Products for use outside the Territory. For clarity, Clearside retains the exclusive right to practice, license, and otherwise exploit the Licensed IP outside the scope of the license granted to Bausch Health under Section 2.1. Bausch Health acknowledges and agrees that Emory retains, on behalf of itself, its employees, and Emory research collaborators, the right to make, have made, use, import, and transfer Licensed Products (as defined in the Emory Agreement) and practice Technology (as

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defined in the Emory Agreement) for research, educational, and non-commercial and humanitarian clinical purposes.

2.4 Section 365(n) of The Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, including the licenses granted under this Article 2, are and will otherwise be deemed to be for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, U.S. Code) (the "**Bankruptcy Code**"), licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. Each Party agrees that the other Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable Law outside the United States that provide similar protection for "intellectual property." Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code.

2.5 No Implied Licenses; Negative Covenant. Except as set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any trademarks, patents or patent applications of the other Party. Bausch Health shall not, and shall not permit any of its Affiliates or Sublicensees to, practice any Licensed IP outside the scope of the licenses granted by Clearside to Bausch Health under Section 2.1.

2.6 Competing Program. [***], Clearside shall not, and shall ensure that its Affiliates will not, directly or indirectly (independently or for or with any Third Party), including through the grant or receipt of any license to or from any Third Party, engage in [***]. Each Party acknowledges and agrees that: (i) if, at the time of enforcement of any covenant or agreement set forth in this Section 2.6, a court shall hold that the duration or scope stated herein is unreasonable under circumstances then existing, the maximum duration or scope under such circumstances shall be substituted for the stated duration or scope and the court shall be allowed to revise the restrictions contained herein to cover the maximum period and scope permitted by Applicable Law; and (ii) if the courts of any one (1) or more of such jurisdictions hold any covenant or agreement set forth in this Section 2.6 unenforceable in whole or in part, such determination shall not bar or in any way adversely affect the rights of any Party hereto to equitable relief and remedies hereunder in courts of any other jurisdiction as to breaches or violations of any covenant or agreement set forth in this Section 2.6, such covenants and agreements being, for this purpose, severable into diverse and independent covenants and agreements.

2.7 Other Products. For a period of [***], Bausch Health shall have the right, but not the obligation, to Develop the Other Drugs in combination with the Device. For those Other Drugs for which [***], (i) Bausch Health shall cease to have the right to Develop such Other Drugs in combination with the Device and to Develop, Manufacture, have Manufactured or Commercialize any Other Products that may result therefrom, (ii) the rights and licenses granted under Section 2.1 and elsewhere in this Agreement shall terminate with respect to such Other Drugs and any Other Products that may result therefrom and (iii) the obligations in Section 2.6(c) will terminate with respect to such Other Drugs. For those Other Drugs for which [***], Bausch Health may continue to Develop such Other Drugs in combination with the Device and to Develop, Manufacture, have Manufactured or Commercialize any Other Products that may result therefrom and the rights and

licenses granted under Section 2.1 shall continue to apply to such Other Drugs and any Other Products that result therefrom.

ARTICLE 3
INFORMATION EXCHANGE

3.1 Information Transfer.

(a) *Initial Information Transfer to Bausch Health*. Within a reasonable period not to exceed [***] after the Effective Date, Clearside shall provide to Bausch Health, in a format reasonably requested by Bausch Health and without further financial consideration, the clinical data and other Know-How included in the Licensed Know-How, excluding, for clarity, the data and information contained in the Device Master File.

(b) *Continuing Information Transfer to Bausch Health; Assistance*. On an ongoing basis, from time to time during the Term, as reasonably requested by Bausch Health, Clearside shall provide to Bausch Health, in a format reasonably requested by Bausch Health, the Know-How included in the Licensed Know-How, excluding, for clarity, the data and information contained in the Device Master File. Clearside shall make its relevant personnel reasonably available to Bausch Health, at reasonable times during Clearside's normal business hours and upon reasonable prior notice, to answer any questions or provide instruction or assistance as reasonably requested by Bausch Health concerning the information delivered pursuant to this Section 3.1 or otherwise in connection with the Development, Manufacture or Commercialization of Products.

(c) Notwithstanding the above, if Bausch Health requires information from the Device Master File, in whole or in part, to obtain or maintain any Regulatory Approval in the Field in the Territory, then Clearside shall provide to Bausch Health, promptly upon request of Bausch Health, the portion of the Device Master File required to obtain or maintain such Regulatory Approval.

3.2 Transition Services. Promptly after the Effective Date, the Parties shall negotiate in good faith for a definitive agreement for the provision of certain training services respecting the XIPERE Product by Clearside's medical science liaisons to Bausch Health's sales representatives. The duration of the provision of such training services shall be determined by Bausch Health, in its sole discretion, but shall not exceed a period of [***] from the date of receipt of Regulatory Approval by the FDA of the XIPERE NDA, or such longer period as agreed by the Parties in writing. Such training services shall be at Bausch Health's expense, at an hourly rate of [***] per hour. In addition, Clearside shall provide to Bausch Health, at no cost, reasonable access to Clearside personnel involved in the Development of the Device and the XIPERE Product, either in-person at Clearside's facility or by teleconference, but such access shall not include an obligation for Clearside personnel to travel or a level of access or assistance that would unreasonably interfere with the duties of such personnel. Bausch Health shall reimburse all reasonable documented out-of-pocket costs and expenses reasonably incurred by Clearside in connection with this Section 3.3, including travel expenses for any agreed travel by Clearside personnel.

3.3 **Alliance Managers**. Promptly after the Effective Date, each Party shall appoint (and notify the other Party of the identity of) a representative having the appropriate qualifications to act as its alliance manager under this Agreement ("**Alliance Manager**"). The Alliance Managers will serve as the primary contact points between the Parties regarding the activities contemplated by this Agreement. The Alliance Managers will facilitate the flow of information and otherwise promote communication, coordination, and collaboration between the Parties. Each Party may replace its Alliance Manager by written notice to the other Party.

ARTICLE 4
DEVELOPMENT

4.1 **Pre-Approval Development**.

(a) From the Effective Date until the XIPERE NDA Approval Date, Clearside shall be responsible for any and all conduct of the Development of the XIPERE Product in the Territory and shall bear all costs and expenses relating thereto. In addition, Clearside shall be required to conduct (or have conducted), at its costs and expenses, the Development and regulatory work described in Exhibit 4.1 (the "**Additional Clearside Development Work**"), and, to the extent such Additional Clearside Development Work is not completed prior to the XIPERE NDA Approval Date, Clearside shall continue to be required to complete (or have completed) such Additional Clearside Development Work following such date and shall bear all costs and expenses relating thereto; provided that, with respect to the Additional Clearside Development Work described in [***], Clearside's obligations shall be to use Commercially Reasonable Efforts to conduct such Additional Clearside Development Work. Clearside shall use Commercially Reasonable Efforts to: (i) complete the ongoing Development of the XIPERE Product in the Field in the Territory (including the Additional Clearside Development Work); and (ii) obtain Regulatory Approval for the XIPERE Product in the United States, provided that in no event will Clearside be obligated to conduct a Clinical Trial of the XIPERE Product (other than the Additional Clearside Development Work). If the FDA requires an additional Clinical Trial to be conducted prior to Regulatory Approval of the XIPERE NDA (other than the Additional Clearside Development Work), and (A) if Clearside initially notifies Bausch in writing that it will not conduct such Clinical Trial at its cost or (B) if Clearside notifies Bausch in writing that Clearside intends to conduct such Clinical Trial at its cost and subsequently notifies Bausch in writing that Clearside will not conduct such Clinical Trial at its cost, then, in each case of (A) and (B), [***], Bausch Health shall be responsible for the conduct of such required Clinical Trial and Bausch Health shall be responsible for all costs and expenses in connection with the conduct of such Clinical Trial; [***].

(b) In connection with its obligations under Section 4.1(a), Clearside shall be responsible, at its costs, for (i) Manufacturing (or having Manufactured) the validation batches for the XIPERE Product in connection with the XIPERE NDA, (ii) the performance of any and all stability activities that are required in connection with such validation batches (including to the extent such stability activities occur after the approval of the XIPERE NDA) and (iii) the Additional Clearside Development Work (including to the extent such Development work occurs after the approval of the XIPERE NDA).

(c) Clearside shall promptly (and in any event within [***]) inform Bausch Health of any material Development results with respect to the XIPERE Product in the Territory that may negatively affect the timeline for the First Commercial Sale of the XIPERE Product in the Territory and shall promptly respond to Bausch Health's reasonable questions or requests for information relating thereto. In addition, within [***] following the end of each calendar quarter until the XIPERE NDA Approval Date, Clearside shall provide a written report to Bausch Health setting forth in reasonable detail the status of its then-current Development activities in relation to the XIPERE Product in the Territory. Clearside shall promptly respond to Bausch Health's reasonable questions or requests for information relating to any such written report.

4.2 Expanded Indication Development Work. During the [***] period following the XIPERE NDA Approval Date, Clearside shall have the sole right, but not the obligation, at its own cost and expense, to conduct additional Development work on the XIPERE Product in support of obtaining FDA approval of the XIPERE Product for the expanded indication and/or expanded label of non-infectious uveitis. Following such [***] period, either Party may conduct such Development work.

4.3 Post-Approval Development. Subject to Section 4.2, following the XIPERE NDA Approval Date, Bausch Health shall be responsible and have sole decision-making authority, at its expense, itself or with or through its Sublicensees or other Third Parties, for the conduct of any Development of the XIPERE Product and any Other Products in the Field in the Territory, subject to and in accordance with the terms and conditions of this Agreement. Notwithstanding the above, if the FDA grants a conditional Regulatory Approval of the XIPERE NDA or requires any post-Regulatory Approval Development work to maintain the Regulatory Approval of the XIPERE NDA ("**Required Post-Approval Commitments**"), Bausch Health shall use Commercially Reasonable Efforts to conduct such Required Post-Approval Commitments, at its cost and expense, *provided*, that Bausch Health shall be able to deduct [***] of its reasonable documented out-of-pocket costs reasonably incurred by Bausch Health (or its Affiliates) in connection with such Required Post-Approval Commitments from the royalty payments made to Clearside under Section 8.2 below, including the ability to carry forward unused portions of such costs to the following Calendar Quarters, up to a maximum deduction of [***]. For greater certainty, if a Regulatory Authority grants a conditional Regulatory Approval of an Other Product or requires any post-Regulatory Approval Development work to maintain the Regulatory Approval of an Other Product ("**Required Post-Approval Commitments for Other Products**"), Bausch Health shall conduct any such Required Post-Approval Commitments for Other Products, at its own cost and expense, without any deduction from the royalty payments payable hereunder; provided that, Bausch Health shall have no obligation to conduct such Required Post-Approval Commitments for Other Products.

4.4 Diligence. Bausch Health shall use Commercially Reasonable Efforts to Develop and to obtain Regulatory Approval for at least [***] XIPERE Product in the Field in Canada.

4.5 Development Plan. Prior to commencement of any Development of a Product as authorized or otherwise permitted by Section 4.3, Bausch Health shall provide Clearside with a written development plan that contains, in reasonable detail, all major Development activities anticipated for at least the subsequent [***] period (including all Clinical Trials) and proposed

timelines for achieving such activities (the "**Development Plan**"). From time to time, but at least every [***] after the Effective Date, Bausch Health shall provide Clearside with any updates or amendments to the Development Plan.

4.6 Development Records. Bausch Health shall maintain complete, current and accurate records in either tangible or electronic form of (a) all Development activities conducted by or on behalf of Bausch Health, its Affiliates and Sublicensees related to Products; and (b) all material information generated by or on behalf of Bausch Health, its Affiliates and Sublicensees in connection with Development of Products. Bausch Health shall maintain such records in sufficient detail to properly reflect, in a good scientific manner, all significant Development work. Upon Clearside's request, Bausch Health shall, and shall cause its Affiliates and Sublicensees to provide to Clearside copies of any such records to the extent relating to the XIPERE Products or the Device. [***].

4.7 Development Reports. Bausch Health shall keep Clearside reasonably informed of its, its Affiliates' and Sublicensees' Development activities, and results thereof, with respect to Products in the Field in the Territory. Without limiting the generality of the foregoing, from time to time, but at least every [***], Bausch Health shall provide reasonably detailed written updates to Clearside on any Development activities conducted by on behalf of Bausch Health in the preceding [***] period.

4.8 Changes to the Device.

(a) Bausch Health shall not make any modifications, changes, improvements or inventions related to the Device without the prior written consent of Clearside, except as set forth in this Section 4.8. In the event that (a) a Regulatory Authority in the Territory requires a change to the Device in connection with the Regulatory Approval of a Product in the Field in the Territory, (b) a Regulatory Authority in the Territory requires a change to the Device in order for Bausch Health to continue to Develop, Manufacture or Commercialize a Product, or (c) Bausch Health reasonably believes that a change to the Device is necessary for safety purposes, then the Parties shall meet to discuss any such necessary changes to the Device and Clearside shall not unreasonably withhold its consent to such a required change for the Product. If Clearside consents to any such required change to the Device, Clearside shall use Commercially Reasonable Efforts to promptly implement such change. Clearside will be solely responsible for all costs and expenses it incurs to implement any such change to the Device required by a Regulatory Authority prior to Regulatory Approval of the XIPERE Product. For any such change to the Device required by a Regulatory Authority to be conducted after Regulatory Approval of the XIPERE Product, Clearside will bear [***], and Bausch Health will bear [***], of the reasonable documented out-of-pocket costs and expenses incurred by Clearside to implement such change. Bausch Health will be solely responsible for all reasonable documented out-of-pocket costs and expenses incurred by Clearside to implement any other change conducted under this Section 4.8(a).

(b) Other than as set forth in Section 4.8(a), Clearside shall be responsible for the costs and expenses to implement any change to the Device, including any change required by a Regulatory Authority other than in connection with the Regulatory Approval of a Product in the

Field in the Territory or any change required by a Regulatory Authority other than in order for Bausch Health to continue to Develop, Manufacture or Commercialize a Product.

(c) In addition, Clearside shall not make or authorize or otherwise permit a change to the Device that would require a change to any Regulatory Approval granted for the XIPERE Product in the Field in the Territory without the prior written consent of Bausch Health, not to be unreasonably withheld. Clearside, as the holder of the Device Master File, will promptly inform Bausch Health of any manufacturing changes to the Device or of any inspection by a Regulatory Authority of the Device that may reasonably be expected to have an adverse impact on the Regulatory Approvals for a Product.

ARTICLE 5
REGULATORY

5.1 Regulatory Responsibilities of Clearside. Prior to the XIPERE NDA Approval Date, Clearside shall be solely responsible for all regulatory activities and all interactions with Regulatory Authorities necessary to obtain Regulatory Approval of the XIPERE Product in the United States and shall bear all costs and expenses relating thereto, including in connection with the items set out in Exhibit 5.1 ("**Additional Clearside Regulatory Matters**"). Clearside shall use Commercially Reasonable Efforts to obtain Regulatory Approval for the XIPERE Product in the United States. Clearside shall (a) promptly provide Bausch Health with copies of any communications which Clearside receives from the applicable Regulatory Authority concerning the XIPERE Product, (b) provide Bausch Health with draft copies of all proposed communications from Clearside to the applicable Regulatory Authority with respect to the XIPERE Product (including any Additional Clearside Regulatory Matters) prior to Clearside's submission thereof, and (c) permit Bausch Health with a reasonable period of time to review and comment on such communications and Clearside shall consider in good faith any such reasonable comments, provided that Clearside shall not submit any such communications to the Regulatory Authority without the prior consent of Bausch Health, such consent not to be unreasonably withheld (for greater certainty, if Clearside incorporates any and all comments received from Bausch Health into such communications, then Bausch Health shall be deemed to have provided such prior written consent). Clearside shall promptly (and in any event within [***]) inform Bausch Health of any material regulatory developments with respect to the XIPERE Product in the Territory that may negatively affect the timeline for the First Commercial Sale of the XIPERE Product in the Territory and shall promptly respond to Bausch Health's reasonable questions or requests for information relating thereto. In addition, within [***] following the end of each calendar quarter until the XIPERE NDA Approval Date, Clearside shall provide a written report to Bausch Health setting forth in reasonable detail the status of its then-current regulatory activities in relation to the XIPERE Product in the Territory. Clearside shall promptly respond to Bausch Health's reasonable questions or requests for information relating to any such written report.

5.2 Regulatory Responsibility for Expanded Indication. During the [***] period following the XIPERE NDA Approval Date, Clearside shall have the sole right, but not the obligation, at its own cost and expense, to conduct additional regulatory activities on the XIPERE Product in support of preparing and submitting an application for, and obtaining, FDA approval of the XIPERE Product for the expanded indication and/or expanded label of [***]. Following such

[***] period, either Party may conduct such Development work and related regulatory activities. Any such application shall be filed in the name of Bausch Health (or its Affiliate) and, if prepared by Clearside, Bausch Health shall have the right to review and comment on any such application (and any such comments shall be incorporated by Clearside and no such application will be filed without Bausch Health consent).

5.3 Regulatory Responsibilities of Bausch Health.

(a) *General*. Subject to Section 5.2, after the XIPERE NDA Approval Date, (i) Bausch Health shall assume responsibility for any regulatory activities in the Territory, including interactions with Regulatory Authorities and preparation and filing of Regulatory Submissions, at Bausch Health's sole cost and expense; (ii) Bausch Health shall determine the regulatory plans and strategies for Products in the Field in the Territory; (iii) Bausch Health shall own and hold all Regulatory Approvals for Products in the Territory; and (iii) Bausch Health shall use Commercially Reasonable Efforts to seek Regulatory Approval for the XIPERE Product in the Field in Canada.

(b) *Transfer from Clearside*. Within [***] after receipt by Clearside of the Approval Payment, Clearside shall assign and transfer to Bausch Health all Regulatory Submissions in the Territory and Regulatory Approvals in the Territory, including the XIPERE NDA, in each case that are Controlled by Clearside or its Affiliates and that are, in the case of Regulatory Approvals, for the XIPERE Product in the Field, and that are, in the case of Regulatory Submissions, solely related to the XIPERE Product in the Field; provided that Clearside may retain one copy of all such transferred Regulatory Submissions and Regulatory Approvals. In connection therewith, at such time, each Party shall submit to the FDA letters (in a form reasonably agreed to by the Parties) and any other documentation necessary to effect the transfer of such Regulatory Submissions and Regulatory Approvals, including the XIPERE NDA. Bausch Health and Clearside each agree to use all Commercially Reasonable Efforts to take all actions required by the FDA and cooperate with each other to effect the transfer of such Regulatory Submissions and Regulatory Approvals, including the XIPERE NDA, from Clearside to Bausch Health (or Bausch Health's designated Affiliate). For clarity, Clearside will not assign or transfer to Bausch Health the Device Master File. In addition, Clearside shall provide Bausch Health with copies of (but not assign) any Regulatory Submissions that are primarily (but not solely) related to the XIPERE Product.

5.4 Assistance. Subject to Applicable Law and any necessary Third Party consents, Clearside shall reasonably cooperate with Bausch Health in any regulatory activity related to Products in the Field in the Territory, including product label expansions, by providing, to the extent Controlled by Clearside or its Affiliates, access to Regulatory Approvals, Regulatory Submissions, clinical data, and other data, information, and documentation for Products outside of the Territory. For clarity, Clearside is not required to provide Bausch Health with any support, data, information, or documentation that is unrelated to a Product. Bausch Health shall provide Clearside with access to Regulatory Approvals, Regulatory Submissions, clinical data, and other data, information, and documentation for the XIPERE Products, to the extent Controlled by Bausch Health or its Affiliates, solely for use by Clearside and its licensees in connection with the

Development, regulatory approval and Commercialization of XIPERE Products (i) in the Retained Field in the Territory and (ii) outside the Territory.

5.5 Rights of Reference.

(a) Clearside hereby grants to Bausch Health and its permitted Sublicensees for use in connection with any activities under this Agreement, (i) a Right of Reference or Use to any and all Regulatory Submissions Controlled by Clearside or its Affiliates outside the Territory during the Term relating to Products, and (ii) a letter of authorization to the Device Master File. Clearside shall sign, and shall cause its Affiliates to sign, any instruments reasonably requested by Bausch Health in order to effect such grant. Bausch Health may use such right of reference to Clearside's Regulatory Submissions in the Field solely for the purpose of seeking, obtaining, and maintaining Regulatory Approval of Products in Field in the Territory.

(b) Bausch Health hereby grants to Clearside and its licensees a Right of Reference or Use to any and all Regulatory Approvals, Regulatory Submissions, and data referenced or contained therein, in each case that is related to the XIPERE Product and is Controlled by Bausch Health or its Affiliates in the Territory during the Term. Bausch Health shall sign, and cause its Affiliates to sign, any instruments reasonably requested by Clearside or its licensees in order to effect such grant. Clearside and its licensees may use the right of reference to such of Bausch Health's Regulatory Approvals and Regulatory Submissions solely for the purpose of seeking, obtaining, and maintaining regulatory approval of XIPERE Products (i) outside the Territory and (ii) in the Retained Field in the Territory.

5.6 Adverse Events Reporting.

(a) *Safety Agreement*. Within [***] of the Effective Date and in any event prior to the XIPERE NDA Approval Date, Bausch Health and Clearside shall develop and agree to the worldwide safety and pharmacovigilance procedures for the Parties with respect to the Products, such as safety data sharing and exchange, and Adverse Events reporting, in a written agreement (the "**Safety Agreement**"). Such agreement shall describe the coordination of collection, investigation, reporting, and exchange of information concerning Adverse Events or any other important safety information, and Product quality and Product complaints involving Adverse Events, sufficient to permit each Party, its Affiliates, or Sublicensees to comply with its legal obligations. The Parties shall promptly update the Safety Agreement if required by changes in Applicable Law. Each Party shall comply with its respective obligations under the Safety Agreement and shall cause its Affiliates and Sublicensees to comply with such obligations.

(b) *Bausch Responsibilities*. Bausch Health shall comply with all Applicable Law governing Adverse Events in the Territory. After Regulatory Approval, Bausch Health shall maintain an Adverse Event database for Products in the Territory, at its sole cost and expense, and shall report quality complaints associated with Adverse Events and Product safety data to the applicable Regulatory Authorities in the Territory, and shall respond to safety issues and to all requests of Regulatory Authorities related to Products in the Territory. Per timelines stated in the Safety Agreement, Bausch Health shall provide to Clearside accumulated Product safety information (e.g., Adverse Event listings and tabulations) occurring in the Territory from Bausch

Health's Adverse Event database for the Territory. Clearside will not have access to Bausch Health's Adverse Event database. Bausch Health shall notify Clearside on a timely basis of any Adverse Events occurring in the Territory and of other important safety information, as further described in the Safety Agreement.

(c) *Clearside Responsibilities*. Clearside shall provide Bausch Health with all information necessary for Bausch Health to comply with its pharmacovigilance responsibilities in the Territory, including, as applicable, any Adverse Events or other important Product safety information, in each case, in the form and within the timelines outlined in the Safety Agreement.

(d) *Patient Safety*. Each Party shall notify the other in a timely manner and in any event within [***] of receiving any notice from a Regulatory Authority, independent review committee, data safety monitoring board, or another similar Clinical Trial or post-marketing monitoring body alleging significant concern regarding a patient safety issue or other material information relevant to Product safety or efficacy.

5.7 Regulatory Audits and Inspection. The Safety Agreement shall set out the rights and obligations of the Parties respecting, and the applicable procedures for, safety audits and inspection notifications.

5.8 No Harmful Actions. If Clearside believes that Bausch Health is taking or intends to take any action with respect to Products that could have a material adverse effect on Products outside the Territory or in the Territory outside the Field, Clearside may bring the matter to the attention of Bausch Health, and the Parties shall discuss in good faith to resolve such concern. Without limiting the foregoing, unless the Parties otherwise agree: (a) Bausch Health shall not communicate with any Regulatory Authority having jurisdiction outside the Territory unless so ordered by such Regulatory Authority, in which case Bausch Health shall immediately notify Clearside of such order; and (b) Bausch Health shall not submit any Regulatory Submissions or seek Regulatory Approvals for Products outside the Territory. If Bausch Health believes that Clearside is taking or intends to take any action with respect to Products that could have a material adverse effect on Products inside the Field in the Territory, Bausch Health may bring the matter to the attention of Clearside, and the Parties shall discuss in good faith to resolve such concern. Without limiting the foregoing, unless the Parties otherwise agree, unless expressly permitted or required hereunder: (a) Clearside shall not communicate with any Regulatory Authority having jurisdiction inside the Territory respecting the Product in the Field unless so ordered by such Regulatory Authority, in which case Clearside shall immediately notify Bausch Health of such order; and (b) Clearside shall not submit any Regulatory Submissions or seek Regulatory Approvals for Products inside the Field in the Territory.

5.9 Remedial Actions. Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Product may be subject to any recall, corrective action or other regulatory action by any Governmental Authority or Regulatory Authority (a "**Remedial Action**"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. The Parties shall, in good faith, acting reasonably, cooperate and coordinate on the process for such Remedial Action. Bausch Health has sole discretion with respect to any matters relating

to any Remedial Action in the Field in the Territory, including the decision to commence such Remedial Action and the control over such Remedial Action; *provided* that Bausch Health shall not commit any action or omission with the intention to adversely affect the Product. The cost and expenses of any Remedial Action in the Field in the Territory shall be borne solely by Bausch Health. Bausch Health shall, and shall ensure that its Affiliates and Sublicensees will, maintain adequate records to permit the Parties to trace the distribution, sale, and use of Products in the Territory.

ARTICLE 6
MANUFACTURE AND SUPPLY

6.1 Supply.

(a) *Supply Agreement*. Clearside shall, either by itself or through its Affiliates or Third Party contractors, Manufacture and supply to Bausch Health, and Bausch Health shall purchase from Clearside, the Interim Supply, in accordance with the terms of the Supply Agreement. Within [***] after the Effective Date, the Parties shall enter into a written supply agreement, containing the terms set forth on Exhibit 6.1 and such other commercially reasonable terms and conditions as are customary for supply agreements of such kind (the "**Supply Agreement**"), governing the supply of the Interim Supply to Bausch Health and, if agreed by the Parties, additional XIPERE Product to be supplied by Clearside to Bausch Health. The terms of the Supply Agreement will be consistent with the terms of Clearside's agreements with its Third Party manufacturers (the "**CMO Agreements**"). In connection with the Supply Agreement, the Parties shall enter into a written quality agreement on reasonable terms and conditions.

(b) *Third Party Agreements*. Upon Bausch Health's request, Clearside shall reasonably assist Bausch Health in negotiating supply agreements with any of Clearside's Third Party contract manufacturers for the Manufacture and supply of Product.

6.2 Manufacture. Except as provided in the Supply Agreement and related quality agreement, Bausch Health shall be solely responsible for the Manufacture and supply of Products for Development and Commercialization of such Products in the Field in the Territory, including all Product-related quality affairs. Notwithstanding the foregoing or anything else to the contrary in this Agreement, Bausch Health shall not have the right to, and shall not, Manufacture the Device itself or through an Affiliate, and shall only have the right to have the Device Manufactured through a Third Party manufacturer that is approved in advance in writing by Clearside (such approval not to be unreasonably withheld, delayed or conditioned), which shall include Clearside's then-current manufacturer of the Device. Clearside shall provide, at Bausch Health's expense, all assistance reasonably required by Bausch Health in connection with the Manufacture of the Device by an approved Third Party manufacturer, which may include providing an authorization to or conducting a technology transfer to such approved Third Party manufacturer and facilitating the negotiation of any supply agreement with such approved Third Party manufacturer.

ARTICLE 7
COMMERCIALIZATION

7.1 **General**. Bausch Health shall be responsible, in its sole discretion (except as set forth in Section 7.2) and at its expense, itself or with or through its Affiliates or Sublicensees, or other Third Parties, for the Commercialization of Products in the Territory in the Field. All decisions regarding Commercialization of Products in the Field in the Territory shall be made in the sole discretion of Bausch Health, including with respect to (a) the sale and distribution of the Product in the Field in the Territory, (b) all marketing and promotion activities with respect to the Product in the Field in the Territory, (c) establishing the price of the Product in the Territory and negotiating with payors, (d) arranging for and obtaining the Manufacture and supply of the Product for use in the Field in the Territory, as further described in Article 6, and (e) other related Commercialization activities.

7.2 **Diligence**. Bausch Health shall use Commercially Reasonable Efforts to Commercialize (i) [***] and (ii) [***]. Without limiting the generality of the foregoing, Bausch Health shall achieve a First Commercial Sale of the XIPERE Product [***] within [***] after the later of (a) [***] and (b) [***].

7.3 **Commercialization Reports**. Bausch Health shall keep Clearside reasonably informed of its, its Affiliates' and Sublicensees' Commercialization activities with respect to Products in the Field in the Territory. Without limiting the generality of the foregoing, from time to time, but at least every [***] after the Effective Date, Bausch Health shall provide written updates to Clearside on any Commercialization activities conducted by or on behalf of Bausch Health in the preceding [***] period, covering subject matter at a level of detail reasonably required to enable Clearside to determine Bausch Health's compliance with its diligence obligations in Section 7.2. Bausch Health shall make available to Clearside such additional information about its Commercialization activities as may be reasonably requested by Clearside from time to time, including pursuant to one or more telephone calls as reasonably requested by Clearside.

7.4 **Coordination of Commercialization Activities**. The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of XIPERE Products in and outside the Territory. As such, the Parties shall, from time to time, meet to discuss the potential coordination of Commercialization activities where appropriate, which may include scientific and medical communication and product positioning. Each Party shall keep the other Party timely informed on the progress and results of its Commercialization of XIPERE Products in its territory. Notwithstanding the above, the Parties shall retain sole discretion of the Commercialization and related activities of the Products in their respective territories, including that each Party shall determine the price of Products sold in its territory, and neither Party may direct, control, or approve the pricing of Products in the other Party's territory. If the Parties mutually agree, the Parties shall coordinate, develop, and adopt the key distinctive colors, logos, images, symbols, and/or trademarks to be used in connection with the Commercialization of XIPERE Products both in and outside the Territory (such branding elements, collectively, the "**Global Brand Elements**"). Clearside shall own all rights in such Global Brand Elements and shall and hereby does grant Bausch Health the exclusive, royalty-free, fully paid-up, sublicensable right and license to use such Global Brand Elements in connection with the Development, Manufacture and Commercialization of XIPERE Products in the Field in the Territory. Unless

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

mutually agreed, neither Party shall be required to use the Global Brand Elements in their Commercialization of the XIPERE Products in their respective territories.

7.5 Diversion. Each Party hereby covenants and agrees that it shall not, and shall ensure that its Affiliates and Sublicensees shall not, either directly or indirectly, distribute, import, sell, or have sold any Product, including via the Internet or mail order, to any Third Party or to any address in the other Party's territory. Neither Party shall engage, nor permit its Affiliates and Sublicensees to engage, in any advertising or promotional activities relating to any Product for use directed primarily to customers or other buyers or users of Products located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or Sublicensees receive any order for Products for use from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates and Sublicensees to, deliver or tender (or cause to be delivered or tendered) any Product for use in the other Party's territory.

7.6 Product Trademarks. Subject to Sections 4.2 and 7.4, Bausch Health shall have the right, but not the obligation, to use the Licensed Marks in connection with the Development and Commercialization of Products in the Field in the Territory; provided that, in its sole discretion, Bausch Health may also use other Trademarks of its selection and/or its own corporate Trademarks in connection with such Development and Commercialization of Products in the Field in the Territory. Clearside shall own all rights in and to all Licensed Marks in the Territory and shall register and maintain the Licensed Marks in the Territory, at Clearside's cost and expense. Bausch Health shall own all rights in and to all other Trademarks (other than the Licensed Marks) used in the Development and Commercialization of the Products in the Field in the Territory and shall register and maintain such Trademarks in the Territory, at Bausch Health's cost and expense. During the Term, Bausch Health agrees (i) to not do anything inconsistent with Clearside's ownership of the Licensed Marks, (ii) to comply with any terms of use for such Licensed Marks mutually agreed to by the Parties, and (iii) that any goodwill associated with the use of Licensed Marks by Bausch Health shall inure solely to the benefit of Clearside.

7.7 Patent Marking. Bausch Health shall mark all Products in accordance with the applicable patent marking laws and shall require all of its Affiliates and Sublicensees to do the same.

ARTICLE 8
PAYMENTS AND MILESTONES

8.1 Up-Front Payment; Regulatory and Commercial Milestone Payments.

(a) In partial consideration of the rights granted herein, within [***] following the Effective Date, Bausch Health shall pay to Clearside a one-time, non-refundable (except pursuant to Section 13.5), non-creditable up-front payment of Five Million U.S. Dollars (US$5,000,000).

(b) In partial consideration of the rights granted herein, and subject to the remainder of this Section 8.1, Bausch Health shall pay to Clearside the following non-refundable, non-creditable (provided that specified costs incurred by Bausch Health pursuant to Section 4.1(a) may be credited against such payments, as described in Section 4.1(a)), one (1)-time milestone payments within (i) [***] after the first achievement (whether by Clearside, Bausch Health, its/their Affiliates or Sublicensees) of [***] milestone events listed below [***] and (ii) [***] after the first achievement (whether by Clearside, Bausch Health, its/their Affiliates or Sublicensees) of all other milestone events set forth below.

Milestone Event	Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Each milestone payment in this Section 8.1(b) shall be payable only once upon first achievement of the milestone event, [***].

(c) In partial consideration of the rights granted herein, and subject to the remainder of this Section 8.1, Bausch Health shall pay to Clearside the following non-refundable, non-creditable (provided that specified costs incurred by Bausch Health pursuant to Section 4.1(a) may be credited against such payments, as described in Section 4.1(a)) one (1)-time milestone payments as set forth below upon the first achievement of aggregate annual Net Sales of the Products in the Field in the Territory in a Calendar Year that meet or exceed the thresholds set forth below, within [***] after the end of the Calendar Quarter in which the corresponding milestone event(s) is achieved.

Product Annual Net Sales Threshold	**Milestone Payment**
A.Annual Net Sales equal to or greater than [***] in any one Calendar Year	[***]
B.Annual Net Sales equal to or greater than [***] in any one Calendar Year	[***]

Achievement of the milestone events above in this Section 8.1(c) shall be determined based on annual Net Sales of the Products in the Field in the Territory in a Calendar Year. Each milestone

payment in this Section 8.1(c) shall be payable only once upon first achievement of the milestone event. [***].

8.2 Royalty Payments.

(a) **Earned Royalties.** During the applicable Royalty Term, Bausch Health shall make quarterly non-refundable, non-creditable (provided that specified costs incurred by Bausch Health pursuant to Section 4.1(a), Section 4.3 or Section 8.2(e) may be credited against such payments, as described in Section 4.1(a), Section 4.3 or Section 8.2(e), as the case may be) royalty payments to Clearside on Net Sales of all Products sold in the Territory during the applicable Calendar Quarter, as calculated by multiplying the applicable royalty rate set forth below by the corresponding amount of Net Sales of all such Products sold in the Territory for such Calendar Quarter. Notwithstanding the foregoing, no such royalties shall be due or payable by Bausch Health on the first Thirty Million Dollars ($30,000,000) of aggregate Net Sales of all Products, calculated on a cumulative (and not annual) basis. Once cumulative Net Sales on all Products in the Territory achieves Thirty Million Dollars ($30,000,000), royalties will then be calculated as follows: (i) on Net Sales of each XIPERE Product, and the applicable royalty rates below for XIPERE Products will be applied, and (ii) on Net Sales of each Other Product, and the royalty rate below for Other Products will be applied.

Annual Net Sales in the Territory	Royalty Rate
Annual Net Sales of XIPERE Products:	
Portion of annual Net Sales up to and including [***]	[***]
Portion of annual Net Sales above [***]	[***]
Annual Net Sales of Other Products	[***]

Notwithstanding the above, for the Calendar Year in which the cumulative Net Sales on all Products in the Territory first achieves Thirty Million Dollars ($30,000,000), the calculation of annual Net Sales for the purposes of determining the royalty rate on XIPERE Products for such Calendar Year shall be calculated commencing with the first dollar after the achievement of such cumulative Net Sales of Thirty Million Dollars ($30,000,000). In addition, for XIPERE Products, each royalty rate set forth in the table immediately above shall only be applied to the annual Net Sales of the XIPERE Product within the applicable royalty range. For example, royalties due to Clearside for annual Net Sales of the XIPERE Product of [***] would be calculated as follows:

Royalty = [***] * [***]= [***]
[***] * [***] = [***]
[***]

(b) **Royalty Term**. On a country-by-country and Product-by-Product basis, Bausch Health shall pay royalties under Section 8.2(a) on Net Sales of such Product in such country in the Territory during the period of time beginning on the First Commercial Sale of such Product in such country in the Territory and ending on the later of (i) the date of expiration of the last Valid Claim that Covers such Product in such country in the Territory, (ii) the date of

expiration or loss of all Regulatory Exclusivity for such Product in such country in the Territory, and (iii) ten (10) years after First Commercial Sale of such Product in such country in the Territory (the "**Royalty Term**"). Following the expiration of the Royalty Term for a Product in a country in the Territory, the rights and licenses granted by Clearside to Bausch Health pursuant to Section 2.1 shall be deemed to be fully paid-up, perpetual, and irrevocable with respect to such Product in such country and no royalties will be payable by Bausch Health to Clearside on the Net Sales of such Product in such country under Section 8.2(a) and Net Sales of such Product in such country in the Territory shall not be included in the calculation of Net Sales for the purposes of determining such royalties under Section 8.2(a).

(c) [***]. In any Calendar Quarter during the Royalty Term for a Product and country for which there is no longer (i) [***] or (ii) [***], the royalties due to Clearside pursuant to this Section 8.2 for such Product in such country will be reduced by [***] of the amount otherwise due under Section 8.2(a) for such Calendar Quarter. Subject to Section 8.2(d) and Section 8.2(e), the royalties payable on the Net Sales of such Product in such country shall remain at the reduced rate set forth above, unless (i) Clearside provides written notice to Bausch Health, together with sufficient evidence, that either (a) [***] or (b) [***], and (ii) the Parties mutually agree, acting reasonably and in good faith, that (a) [***] or (b) [***]. In such event, but subject to Section 8.2(d) and Section 8.2(e), the royalty payable on the Net Sales of such Product in such country shall be increased to the rate set out in Section 8.2(a), commencing in the Calendar Quarter in which the conditions set forth in subsections (i) and (ii) of the foregoing sentence have been satisfied, until such time as there is no longer (a) [***] or (b) [***], at which time, the royalties due to Clearside pursuant to this Section 8.2 for such Product in such country will be reduced by [***] of the amount otherwise due under Section 8.2(a) for such Calendar Quarter. The royalty rate shall not be increased retroactively for any prior Calendar Quarters. If, following a reduction of the royalty under this Section 8.2(c), Clearside fails to give the notice described above with respect to a Calendar Quarter, it shall be deemed to have agreed to the continuation of the lower royalty rate for such Calendar Quarter.

(d) [***]. If [***] during the Royalty Term for such Product in such country, and [***], the royalty rates provided in Section 8.2(a) for such Product shall be reduced in such country by [***] (i.e., [***]) for the Calendar Quarter in which the [***] and for each Calendar Quarter in the remainder of such Royalty Term. If the reduction in this Section 8.2(d) applies, then the reduction in Section 8.2(c) will not also apply. For the purposes of this Section 8.2(d), [***].

(e) **Third Party IP**. If Bausch Health or any of its Affiliates or Sublicensees is required to obtain a right or license to any Patent, Know-How or other intellectual property right of a Third Party that would be infringed by the Development, Manufacture or Commercialization or other use or exploitation of a XIPERE Product in the Territory, then Bausch Health may deduct from any royalty payments due to Clearside on Net Sales of such XIPERE Product under this Section 8.2 [***] of [***]; provided that in no event will the royalties payable to Clearside on Net Sales of such XIPERE Product in such Calendar Quarter be reduced on account of this Section 8.2(e) by more than [***] of the amounts otherwise payable under Section 8.2(a), (c) or (d), as applicable. If Bausch Health or any of its Affiliates or Sublicensees is required to obtain a right or license to any Patent, Know-How or other intellectual property right of Third Party that would be

infringed by the Development, Manufacture or Commercialization or other use or exploitation of an Other Product in the Territory, then [***].

8.3 Royalty Report and Payment. Within [***] after each Calendar Quarter in which the First Commercial Sale of any Product occurs in the Territory, Bausch Health shall provide Clearside with a report that contains the following information for the applicable Calendar Quarter, on a Product-by-Product and country-by-country basis: (a) the amount of gross sales of Products, (b) the gross selling price and the number of units of all Products sold in each country of the Territory, (c) an itemized calculation of Net Sales showing separately each type of reduction provided for in the definition of "Net Sales", (d) a calculation of the royalty payment due on such Net Sales in Dollars, including the exchange rate, where applicable, and (e) whether any of the milestone payments under Section 8.1(c) above has been earned during such Calendar Quarter. Concurrent with the delivery of the applicable quarterly report, Bausch Health shall pay to Clearside in Dollars the royalties owed with respect to Net Sales for such Calendar Quarter and, if applicable, the payment of any milestone payments under Section 8.1(c) that has been earned during such Calendar Quarter.

8.4 Currency; Exchange Rate. All payments to be made by Bausch Health to Clearside under this Agreement shall be made in Dollars by bank wire transfer in immediately available funds to a bank account designated by written notice from Clearside. When conversion of payments from any foreign currency is required to be undertaken by Bausch Health, the United States Dollar equivalent shall be calculated using [***].

8.5 Late Payments. If Clearside does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to Clearside from the due date until the date of payment at [***] or the maximum applicable legal rate, if less. The interest payment shall be due from the day the original payment was due until the day that the payment was received by Clearside; provided, that, with respect to any disputed payments, no interest payment shall be due until such dispute is resolved and the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

8.6 Financial Records and Audits. Bausch Health shall (and shall ensure that its Affiliates and Sublicensees will) maintain complete and accurate records in accordance with GAAP and in sufficient detail to confirm the accuracy of Net Sales and royalty payments due under this Agreement. Bausch Health shall (and shall ensure that its Affiliates and Sublicensees will) maintain such records for a period of [***]. Upon prior notice and not more often than once each Calendar Year and in the Calendar Year immediately following expiration or termination of this Agreement, Bausch Health shall permit an independent certified public accountant selected by Clearside or Emory and reasonably acceptable to Bausch Health to examine such records during regular business hours for the sole purpose of verifying for Clearside the accuracy of the Net Sales and royalty reports provided by Bausch Health under this Agreement. Clearside shall bear the cost of such audit unless such audit reveals an underpayment by Bausch Health of more than [***] of the amount actually due for the time period being audited, in which case Bausch Health shall reimburse Clearside for the costs of such audit. Bausch Health shall pay to Clearside any underpayment discovered by such audit within [***] after the accountant's report (subject to the

right of Bausch Health to dispute such findings), plus interest from the original due date. Clearside shall pay to Bausch Health any overpaid amounts discovered by such audit within [***] after the accountant's report (subject to the right of Clearside to dispute such findings). Bausch Health shall include in each relevant sublicense granted by it a provision requiring the Sublicensee to maintain records of sales of Products made pursuant to such sublicense and to grant access to such records to the same extent and under the same obligations as required of Bausch Health under this Agreement.

8.7 **Taxes**. The royalties, milestones, and other amounts payable by Bausch Health to Clearside pursuant to this Agreement (collectively, the "**Payments**") shall not be reduced on account of any taxes unless required by Applicable Law. Clearside alone shall be responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted and paid on Clearside's behalf by Bausch Health) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The Parties will cooperate in good faith to obtain the benefit of any relevant tax treaties to minimize as much as reasonably possible any taxes which may be levied on any Payments. Bausch Health shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if Clearside is entitled under any applicable tax treaty to a reduction of the rate of, or the elimination of, applicable withholding tax, it may deliver to Bausch Health or the appropriate Governmental Authority (with the assistance of Bausch Health to the extent that this is reasonably required and is expressly requested in writing), as applicable, the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Bausch Health of its obligation to withhold tax, and Bausch Health shall apply the reduced rate of withholding tax, or dispense with withholding tax, as the case may be; provided, that Bausch Health has received evidence of Clearside's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [***] prior to the time that the Payment is due. If, in accordance with the foregoing, Bausch Health withholds any amount, it shall make timely payment to the proper taxing authority of the withheld amount, and send to Clearside proof of such payment within [***] following that latter payment. Each Party shall provide the other with commercially reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of Clearside. Notwithstanding the foregoing, if Bausch Health changes the tax residency of the paying entity, including as a result of an assignment or sublicense of this Agreement or any rights or obligations thereunder and, as a result of such change, withholding taxes are imposed on amounts payable hereunder that were not otherwise applicable as of the Effective Date ("**Incremental Withholding Taxes**"), then Bausch Health shall be solely responsible for the amount of such Incremental Withholding Taxes that is not otherwise creditable or utilizable in the current year by Clearside (such amount, the "**Excess Amount**") and shall increase the amounts payable to Clearside by such Excess Amount.

8.8 **Third Party Payments**.

(a) If Clearside or its Affiliates Controls any Patent or Know-How after the Effective Date through a license from a Third Party ("**Third Party IP**") that would be included in the definition of Licensed IP on the basis that it is necessary for the Development, Manufacture or Commercialization of XIPERE Products in the Field in the Territory, then such Third Party IP

shall be included in the definition of Licensed IP, and Bausch Health shall reimburse Clearside for [***] of any payments made to such Third Party as a result of the Development, Manufacture, and Commercialization of XIPERE Products by or on behalf of Bausch Health in the Territory; provided that, if legally permissible and subject to confidentiality obligations of Clearside to any Third Parties, prior to entering into any such Third Party license for Third Party IP, Clearside shall notify Bausch Health of the proposed license and the Parties shall meet to discuss the proposed terms of such license.

(b) If Clearside or its Affiliates Controls any Third Party IP that would be included in the definition of Licensed IP either (i) on the basis that it is useful (but not necessary) for the Development, Manufacture or Commercialization of XIPERE Products in the Field in the Territory or (ii) on the basis that it is useful or necessary for the Development, Manufacture or Commercialization of Other Products in the Field in the Territory, then Clearside shall promptly inform Bausch Health of the terms of such license and such Third Party IP, and Bausch Health shall inform Clearside within [***] after receipt of such notice whether Bausch Health wishes to include such Third Party IP in the Licensed IP. If Bausch Health so elects, the Parties shall negotiate, in good faith and acting reasonably, the terms under which such Third Party IP shall be included in the Licensed IP, including the amount Bausch Health shall reimburse Clearside with respect to milestones and royalties payable by Clearside to such Third Party directly as a result of the Development, Manufacture, and Commercialization of XIPERE Products or Other Products (as the case may be) by or on behalf of Bausch Health in the Territory.

(c) For clarity, Clearside shall be solely responsible for all costs and payments owed to a Third Party directly as a result of the Development, Manufacture, and Commercialization of Products by or on behalf of Bausch Health in the Territory under an agreement existing as of the Effective Date (and any amendments thereto, whether executed prior to or after the Effective Date).

(d) Notwithstanding anything to the contrary in this Agreement, if Bausch Health does not elect to include any particular Third Party IP in the Licensed IP pursuant to Section 8.8(b), or such Third Party IP is not included pursuant to Section 8.8(a), then the Licensed IP will not include such Third Party IP.

ARTICLE 9
CONFIDENTIALITY

9.1 Nondisclosure Obligation.

(a) For the Term of this Agreement and [***] thereafter, the Party receiving the Confidential Information of the other Party (such receiving Party, the "**Receiving Party**") shall keep confidential and not publish, make available or otherwise disclose any Confidential Information to any Third Party, without the express prior written consent of the Party that disclosed such Confidential Information (the "**Disclosing Party**"); *provided* however, the Receiving Party may disclose the Confidential Information of the Disclosing Party to those of its Affiliates, officers, directors, employees, agents, consultants, and independent contractors (including Sublicensees) of such Receiving Party who need to know the Confidential Information in

connection with this Agreement and are bound by confidentiality obligations at least as restrictive as this Agreement with respect to such Confidential Information. The Receiving Party shall exercise at least the same degree of care it would exercise to protect its own confidential information (and in no event less than a reasonable standard of care) to keep confidential the Confidential Information. The Receiving Party shall use the Confidential Information solely in connection with the purposes of this Agreement. Notwithstanding the foregoing, Clearside may provide an unredacted copy of this Agreement to Emory for the purpose of complying with the Emory Agreement.

(b) Notwithstanding the foregoing, it will not be considered a breach of this Agreement if the Receiving Party discloses Confidential Information to comply with a lawfully issued court or governmental order or with a requirement of Applicable Law or the rules of any internationally recognized stock exchange; *provided* that: (i) if legally permitted, the Receiving Party gives prompt written notice of such disclosure requirement to the Disclosing Party and cooperates with the Disclosing Party's efforts to oppose or limit such disclosure or obtain a protective order for such Confidential Information, and (ii) if such disclosure requirement is not quashed or a protective order is not obtained, the Receiving Party shall only disclose those portions of the Confidential Information that it is legally required to disclose and shall make a reasonable effort to obtain confidential treatment for the disclosed Confidential Information.

9.2 Scientific Publication. Each Party and its Affiliates shall have the right to make disclosures pertaining to Products to Third Parties in publications in accordance with the following procedure: the publishing Party shall provide the non-publishing Party with an advance copy of the proposed publication at least [***] prior to submission for any publication, and the non-publishing Party may review and comment on the proposed publication, which the publishing Party shall consider in good faith. In addition, if the non-publishing Party informs the publishing Party that such proposed publication contains the Know-How or Confidential Information of the non-publishing Party, the publishing Party shall delay or prevent such publication as follows: (a) with respect to a patentable invention, such publication shall be delayed sufficiently long (not to exceed [***]) to permit the timely preparation and filing of a patent application; and (b) with respect to Confidential Information of such non-publishing Party, such Confidential Information shall be deleted from the publication.

9.3 Publicity; Use of Names.

(a) Each of the Parties agrees not to disclose to any Third Party the terms and conditions of this Agreement or make any public announcement concerning the Agreement without the prior approval of the other Party, except to advisors (including consultants, financial advisors, attorneys and accountants) or potential and existing investors, acquirers, or sublicensees on a need to know basis, in each case under circumstances that reasonably protect the confidentiality thereof, or to the extent required by Applicable Laws, including securities laws. The Party preparing any such public announcement shall provide the other Party with a draft thereof at least [***] prior to the date on which such Party would like to make the public announcement.

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

(b) The Parties shall agree upon the initial press release to announce the execution of this Agreement; thereafter, Clearside and Bausch Health may each disclose to Third Parties the information contained in such press releases without the need for further approval by the other.

(c) The Parties acknowledge that either or both Parties may be obligated to file under applicable Laws a copy of this Agreement with the U.S. Securities and Exchange Commission or other Governmental Authorities. Each Party may make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party shall provide the other Party with a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's reasonable comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

(d) Neither Party shall use the name, trademark, trade name, or logo of the other Party or any of its Affiliates or their respective employees in any publicity or news release relating to this Agreement or its subject matter without the prior express written permission of the other Party.

9.4 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use, or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 9. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief under as a remedy for any breach or threatened breach of this Article 9.

ARTICLE 10
REPRESENTATIONS, WARRANTIES, AND COVENANTS

10.1 Representations, Warranties, and Covenants of Each Party. Each Party represents and warrants, and covenants to the other Party as of the Effective Date that:

(a) it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder;

(b) (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms;

(c) it is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or from performing its obligations under this Agreement;

(d) in the course of performing its obligations or exercising its rights under this Agreement, it shall comply with all Applicable Laws (including Anti-Corruption Laws) and shall not employ or engage any party who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority;

(e) the execution and delivery of this Agreement and the performance of such Party's obligations hereunder: (i) do not conflict with or violate such Party's corporate charter and bylaws or any requirement of applicable Laws; and (ii) do not violate, breach, constitute a default, or require any consent under any oral or written contractual obligation of such Party (including, in the case of Clearside, the Emory Agreement); and

(f) it shall not, during the Term, grant any right, license, consent, or privilege to any Third Party or otherwise undertake any action, either directly or indirectly, that would conflict with the rights granted to the other Party or interfere with any obligations of such Party set forth in this Agreement.

10.2 Representations and Warranties of Clearside. Clearside represents and warrants to Bausch Health that as of the Effective Date:

(a) it has the right under the Licensed IP to grant the licenses to Bausch Health as purported to be granted under Section 2.1 of this Agreement, and it has not granted any license or other right under the Licensed IP that is inconsistent or would reasonably be anticipated to interfere with the licenses granted to Bausch Health under Section 2.1;

(b) it is the legal and beneficial owner of or otherwise Controls all Licensed IP;

(c) it has not received any written notice from any Third Party asserting or alleging that the Development of Products or the Device prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

(d) to the Knowledge of Clearside, no Third Party is infringing or misappropriating any Licensed IP;

(e) to the Knowledge of Clearside, the Development, Manufacture, and/or Commercialization of the XIPERE Products or the Device in the Field in the Territory in accordance with this Agreement does not infringe or misappropriate any Patent or Know-How owned or controlled by a Third Party;

(f) there is no pending, or to the Knowledge of Clearside, threatened action or proceeding alleging that the practice of the Licensed IP (including the Development, Manufacture, and Commercialization of Products in accordance with this Agreement) infringes, misappropriates, or otherwise violates any intellectual property rights of any Third Party;

(g) there are no pending, and to the Knowledge of Clearside, no threatened, adverse actions, suits or proceedings (including interferences, reissues, reexaminations, cancellations, oppositions, nullity actions, invalidation actions or post-grant reviews) against Clearside involving the Licensed IP or Products;

(h) there are no claims, judgments, or settlements against or amounts with respect thereto owed by Clearside or any of its Affiliates relating to the Licensed IP;

(i) except as otherwise set out in Exhibit 10.2(i) hereto, it has not received any communications from any Regulatory Authority describing any matters specific to a XIPERE Product or the Device that may be necessary to be overcome to obtain Regulatory Approval of any XIPERE Product;

(j) it has provided Bausch Health with a true and complete copy of the Emory Agreement;

(k) the Emory Agreement is in full force and effect and there has been no default of or under the Emory Agreement as a result of any action or omission of Clearside or its Affiliates or, to the Knowledge of Clearside, the actions or omissions of Emory;

(l) Clearside has not waived any of its rights under the Emory Agreement;

(m) Exhibit 1.64 sets forth a complete and accurate list of all Licensed Patents in existence (including whether such Licensed Patents are owned or licensed by Clearside), all of which are owned or Controlled by Clearside or its Affiliates;

(n) to the Knowledge of Clearside, the issued patents in the Licensed Patents are valid and enforceable without any claims, challenges, oppositions, nullity actions, interferences, inter-partes reexaminations, inter-partes reviews, post-grant reviews, derivation proceedings, or other proceedings pending or threatened;

(o) Clearside has filed and prosecuted patent applications within the Licensed Patents owned by Clearside in good faith and complied with all duties of disclosure with respect thereto;

(p) all application, registration, maintenance, and renewal fees in respect of the Licensed Patents have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of maintaining the Licensed Patents set forth on Exhibit 1.64;

(q) Clearside and its Affiliates have obtained from all individuals listed as inventors in the Licensed IP, effective assignments of all ownership rights of such individuals in such Licensed IP, either pursuant to written agreement or by operation of law;

(r) to the Knowledge of Clearside, no officer or employee of Clearside or its Affiliates is subject to any agreement with any other Third Party that requires such officer or employee to assign any interest in any Licensed IP to any Third Party;

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

(s) except as expressly set forth in the Emory Agreement, none of Clearside, Emory or their respective Affiliates have entered into a government funding relationship that would result in rights to the XIPERE Product or Device residing in the U.S. Government, National Institutes of Health, National Institute for Drug Abuse, or other agency, and the licenses granted hereunder are not subject to overriding obligations to the U.S. Government as set forth in Public Law 96 517 (35 U.S.C. 200 204), as amended, or any similar obligations under the Applicable Laws of any other country; and

(t) Clearside has disclosed to Bausch Health all material information contained in the XIPERE NDA or otherwise known to it and its Affiliates with respect to the safety and efficacy of the Device and the XIPERE Products.

10.3 NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

10.4 Compliance with Emory Agreement. Clearside agrees to comply with the terms and conditions of the Emory Agreement. Clearside shall not assign, amend or modify any term of, terminate or waive, release or assign any rights or claims under, the Emory Agreement, in each chase that would have a material adverse effect on Bausch Health's rights hereunder, except with the prior written consent of Bausch Health. Clearside shall remain solely responsible for the payment of royalty, milestone, and other payment obligations, if any, under the terms of the Emory Agreement and all such payments under the Emory Agreement shall be made promptly by Clearside in accordance with the terms of the Emory Agreement. Clearside shall not breach or otherwise be in default under the Emory Agreement in a manner that would permit Emory to terminate the Emory Agreement or otherwise diminish the scope or exclusivity of the licenses granted to Bausch Health hereunder. In the event that Clearside receives notice of an alleged breach or default by Clearside or its Affiliates under the Emory Agreement, where termination of the Emory Agreement or any diminishment of the scope or exclusivity of the licenses granted to Bausch Health hereunder is being or could be sought by Emory or result from such breach or default, then Clearside will promptly, but in no event less than [***] thereafter, provide written notice thereof to Bausch Health and grant Bausch Health the right (but not the obligation) to cure such alleged breach or default.

10.5 Non-Solicit. Without the prior written consent of the other Party, each of Clearside and Bausch Health agrees that, [***], neither it nor any of its Affiliates will directly or indirectly solicit for purposes of hiring any person employed by the other Party or any of their Affiliates or who was employed by the other Party or any of their Affiliates within the then prior [***], or in any manner seek to induce any such person to leave his or her employment; provided, however,

that this restriction shall not apply to: (a) conducting any general solicitation not specifically targeted at any such employee; or (b) hiring any employee who responds to such general advertising or who approaches such Party or its Affiliates without any solicitation or inducement to leave the employ of such other Party or its Affiliates.

ARTICLE 11
INDEMNIFICATION

11.1 By Bausch Health. Bausch Health shall indemnify and hold harmless Clearside, its Affiliates, the Indemnitees (as defined in the Emory Agreement), and their directors, officers, employees and agents (individually and collectively, the "**Clearside Indemnitees**") from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) incurred in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, "**Losses**") first arising after the Effective Date to the extent arising from (a) the Development, Manufacture or Commercialization of Products by Bausch Health or any of its Affiliates or Sublicensees, including product liability claims to the extent arising from the Development, Manufacture or Commercialization of Products by Bausch Health or any of its Affiliates or Sublicensees, (b) the negligence or willful misconduct of Bausch Health or any of its Affiliates or Sublicensees, or (c) Bausch Health's breach of any of its representations or warranties made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement, in each case of clauses (a) through (c), except to the extent such Losses arise out of a claim for which Clearside has an obligation to indemnify under Section 11.2.

11.2 By Clearside. Clearside shall indemnify and hold harmless Bausch Health, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**Bausch Health Indemnitees**") from and against all Losses to the extent arising from (a) the negligence or willful misconduct of Clearside or any of its Affiliates or sublicensees, (b) Clearside's breach of any of its representations or warranties made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement, or (c) the Development, Manufacture, or Commercialization of Products by or on behalf of Clearside or any of its Affiliates or sublicensees under this Agreement or outside the Territory or Field or prior to the Effective Date, including product liability claims to the extent arising from such Development, Manufacture, or Commercialization of Products by or on behalf of Clearside or any of its Affiliates or sublicensees, in each case of clauses (a) through (c), except to the extent such Losses arise out of a claim for which Bausch Health has an obligation to indemnify under Section 11.1.

11.3 Procedure.

(a) *Defined Terms*. Either of the Bausch Health Indemnitees or the Clearside Indemnitees is an "**Indemnitee**" for the purpose of this Article 11, and the Party that is obligated to indemnify the Indemnitee under Section 11.1 or Section 11.2 shall be the "**Indemnifying Party**."

(b) *Defense*. If any such claims or actions are made, the Indemnifying Party shall defend the Indemnitee at the Indemnifying Party's sole expense using counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnitee, provided that the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The Indemnifying Party has the sole right to control the defense of any such claim or action, subject to the terms of this Article 11.

(c) *Settlement*. The Indemnifying Party may settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment (a) with prior written notice to the Indemnitee but without the consent of the Indemnitee where the only liability to the Indemnitee is the payment of money and the Indemnifying Party makes such payment, or (b) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld or delayed.

(d) *Notice*. The Indemnitee shall notify the Indemnifying Party in writing promptly, and in any event within [***], of any claim, demand, action or other proceeding under Sections 11.1 or 11.2, provided, that the failure to provide timely notice of a claim, demand, action or other proceeding shall not limit an Indemnitee's right for indemnification hereunder except to the extent such failure results in actual prejudice to the Indemnifying Party. The Indemnitee shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect thereto.

(e) *Permission by Indemnifying Party*. The Indemnitee may not settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment in any such action or other proceeding or make any admission as to liability or fault without the express written permission of the Indemnifying Party.

11.4 Insurance. Without limiting Bausch Health's indemnity obligations under this Article 11, Bausch Health shall maintain Third Party insurance or self-insurance, including product liability insurance, with respect to its activities hereunder in amounts customary to such insurance and sufficient to meet its obligations under this Agreement. Without limiting Clearside's indemnity obligations under this Article 11, Clearside shall maintain Third Party insurance, including product liability insurance, with respect to its activities hereunder in amounts customary to such insurance and sufficient to meet its obligations under this Agreement.

ARTICLE 12
INTELLECTUAL PROPERTY

12.1 Ownership of Inventions.

(a) *General*. Subject to Section 12.1(b), ownership of all Inventions is based on inventorship, as determined in accordance with the rules of inventorship under United States patent laws. Each Party owns all Inventions that are made solely by its and its Affiliates' employees, agents, and independent contractors during the performance of activities under this Agreement ("**Sole Inventions**"). The Parties jointly own all Inventions that are made jointly by the employees, agents, and independent contractors of one Party and its Affiliates together with the employees, agents, and independent contractors of the other Party and its Affiliates ("**Joint Inventions**"). Patents claiming the Joint Inventions are "**Joint Patents**." Each Party owns an undivided half

interest in the Joint Inventions, and each Party shall be entitled to practice, license (through multiple tiers), assign (its respective interest only) and otherwise exploit the Joint Inventions and Joint Patents without a duty of accounting or an obligation to seek consent from the other Party (subject to the licenses granted to the other Party under this Agreement).

(b) *Assigned Improvements*. Except pursuant to the terms of Section 4.8 above, Bausch Health shall not make any modifications, changes, improvements or inventions related to the Device without the prior written consent of Clearside. Notwithstanding the foregoing and Section 12.1(a), Clearside shall solely own all right, title and interest to all Sole Inventions or Joint Inventions that primarily [***] (collectively, "**Assigned Improvements**"). Bausch Health shall promptly disclose to Clearside all Assigned Improvements, including all invention disclosure or other similar documents submitted to Bausch Health by its or its Affiliates' employees, agents, Sublicensees or contractors relating to such Assigned Improvements, and shall also promptly respond to reasonable requests from Clearside for additional information relating to such Assigned Improvements. Bausch Health shall and hereby does assign to Clearside all right, title and interest to all Assigned Improvements. Bausch Health shall take (and cause its employees, agents, contractors and Sublicensees to take) such further actions reasonably requested by Clearside to evidence such assignment and to obtain patent and other intellectual property rights protection for such Assigned Improvements. Bausch Health shall obligate its Affiliates, Sublicensees and contractors to assign all Assigned Improvements to Bausch Health so that Bausch Health can comply with its obligations under this Section 12.1(b), and Bausch Health shall promptly obtain such assignment. The licenses grant in Section 2.1 from Clearside to Bausch Health will include a license to the Assigned Improvements and any Patents, Know-How and other intellectual property rights therein.

(c) *License*. During the Term, Bausch Health hereby grants to Clearside a non-exclusive, fully paid, royalty-free and sublicensable license (through multiple tiers) under the Bausch Health IP to research, Develop, make, have made, use, sell, offer for sale, import and otherwise Commercialize XIPERE Products (i) in the Retained Field in the Territory and (ii) outside the Territory.

12.2 Patent Prosecution.

(a) As between the Parties, Clearside has the first right to file, prosecute and maintain all Licensed Patents and Joint Patents throughout the world. Clearside shall be responsible for the cost and expenses of filing, prosecuting and maintaining the Licensed Patents and the Joint Patents that are not Product-Specific Patents inside and outside the Territory, and Bausch Health shall be responsible for and shall reimburse Clearside for [***] of the reasonable documented out-of-pocket costs and expenses of filing, prosecuting and maintaining the Product-Specific Patents in the Territory. Clearside shall keep Bausch Health reasonably informed of the status of such Licensed Patents and Joint Patents in the Territory. Clearside shall promptly provide Bausch Health with all material correspondence received from any patent authority in the Territory in connection with respect to any Licensed Patent or Joint Patent and shall promptly provide Bausch Health with drafts of all proposed material filings and correspondence to any patent authority in the Territory with respect to any such Licensed Patent or Joint Patent for Bausch

Health's review and comment prior to the submission of such proposed filings and correspondences.

(b) Clearside shall notify Bausch Health of any decision to cease prosecution or maintenance of any Licensed Patents that [***] (the "**Product-Specific Patents**") or Joint Patents in the Territory. Clearside shall provide such notice at least [***] prior to any filing or payment due date, or any other due date that requires action, in connection with such Product-Specific Patent or Joint Patent in the Territory. Clearside shall permit Bausch Health, at Bausch Health's discretion and at Bausch Health's sole expense, to continue prosecution and maintenance of such Product-Specific Patent or Joint Patent, as applicable, in the Territory, at Bausch Health's cost. Clearside shall use commercially reasonable efforts to continue to prosecute and maintain (or cause the prosecution and maintenance of) any Licensed Patents in the Territory that are not Product-Specific Patents.

(c) Each Party shall provide the other Party all reasonable assistance and cooperation in the patent prosecution efforts under this Section 12.2, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

(d) Clearside, in consultation with Bausch Health, may select which, if any, Licensed Patents for which a Patent Term Extension is to be sought or obtained with respect to the Products in the Territory.

12.3 Patent Enforcement.

(a) Each Party shall promptly notify the other of becoming aware of any alleged or threatened infringement by a Third Party of any Licensed Patents and any related declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any of the Licensed Patents in the Territory (collectively "**Product Infringement**").

(b) As between the Parties, Bausch Health has the first right to bring and control any legal action in the Field in the Territory in connection with such Product Infringement of (i) a Product-Specific Patent and (ii) with Clearside's prior written consent, which shall not be unreasonably withheld, any other Licensed Patent, in each case (i) and (ii) which Product Infringement relates to a Third Party generic product submitted under an Abbreviated New Drug Application or under section 505(b)(2) of the FD&C Act or such other Generic Product, in each case, for which the reference listed drug (or equivalent) is a Product in the Field in the Territory, at its own expense as it reasonably determines appropriate. If Bausch Health does not bring such legal action with respect to any such Product Infringement within [***] after the notice provided pursuant to Section 12.3(a), or such shorter period as necessary to avoid loss of rights, then Clearside may bring and control such legal action in connection with such Product Infringement in the Territory at its own expense as it reasonably determines appropriate.

(c) As between the Parties, Clearside has the sole right to bring and control any legal action in connection with any Product Infringement, other than as set out in Section 12.3(b), at its own expense as it reasonably determines appropriate.

(d) The enforcing Party shall keep the other Party reasonably informed as to any courses of action it pursues pursuant to this Section 12.3. At the request and expense of the Party bringing an action under Section 12.3(b) above, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Law to pursue such action. In connection with any such enforcement action, the Party bringing the action shall not enter into any settlement admitting the invalidity or non-infringement of, or otherwise impairing the other Party's rights in the Licensed Patents without the prior written consent of the other Party.

(e) Any recoveries resulting from enforcement action relating to a claim of Product Infringement shall be first applied against payment of each Party's costs and expenses in connection therewith. If Clearside is the enforcing Party and the Product Infringement relates to a Third Party's manufacture, use or sale of a Product, or a product that directly competes with a Product, in the Territory and the Field, (i) [***] of any such recoveries in excess of such costs and expenses shall be retained by Clearside and (ii) Clearside shall distribute [***] of any such recoveries in excess of such costs and expenses to Bausch Health. If Bausch Health is the enforcing Party, Bausch Health shall retain any such recoveries in excess of such costs and expenses, which are deemed Net Sales of Products and subject to royalty payment in Section 8.2 (but shall not be deemed to be Net Sales for the purposes of any milestone payments in Section 8.1).

(f) Clearside has the exclusive right to bring and control any legal action to enforce the Licensed Patents against any infringement that is not a Product Infringement or is outside the Territory, in each case at its own expense and as it reasonably determines appropriate, and may retain all recoveries.

12.4 Defense.

(a) Each Party shall notify the other in writing of any allegations it receives from a Third Party that the Development or Commercialization of any Product or any embodiment of any technology or intellectual property licensed by a Party under this Agreement infringes the intellectual property rights of such Third Party. Such notice shall be provided promptly, but in no event after more than [***] following receipt of such allegations. Such written notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties.

(b) In such event, the Parties shall agree how best to mitigate or control the defense of any such legal proceeding, agree whether to enter into a joint defense agreement to, among other reasons, preserve the confidentiality of communications or cooperation between the Parties in relation to such defense, and determine which Party is best suited to assume the primary responsibility for the conduct of the defense of any such claim at their expense. The other Party may participate and be separately represented in any such suit at its sole option and at its own expense. Each Party shall reasonably cooperate with the Party conducting the defense of the claim. If a Party or any of its Affiliates have been individually named as a defendant in a legal proceeding relating to the alleged infringement of a Third Party's Patents or other intellectual property right

as a result of such Party's Development or Commercialization of Products, then that Party shall conduct the defense and the other Party shall be allowed to join in such action, at its own expense.

(c) The Parties shall keep each other informed of the status of and of their respective activities regarding any infringement litigation initiated by a Third Party concerning a Party's Development or Commercialization of Products or settlement thereof; *provided*, however, that no settlement or consent judgment or other voluntary final disposition of a suit under this Section 12.4 may be undertaken by a Party without the consent of the other Party which consent shall not be unreasonably withheld or delayed.

ARTICLE 13
TERM AND TERMINATION

13.1 **Term**. This Agreement is effective as of the Effective Date, and will continue in effect until the expiration of all Royalty Terms for all Products and countries in the Territory, unless earlier terminated in accordance with Section 13.2 (the "**Term**"). Upon the expiration of the Term, all rights and licenses granted by Clearside to Bausch Health pursuant to Section 2.1 shall survive and shall become fully paid-up, perpetual, and irrevocable.

13.2 **Termination**.

(a) **Termination for Failure to Receive Approval**. Bausch Health may terminate this Agreement immediately upon written notice to Clearside if the FDA has not approved the XIPERE NDA by February 28, 2021; provided that, such termination right shall expire on the earlier of (i) [***] or (ii) [***].

(b) **Termination by Bausch Health for Convenience**. Bausch Health may terminate this Agreement in its entirety upon one hundred eighty (180) days' prior written notice; *provided*, that Bausch Health may not exercise such right to terminate until [***].

(c) **Termination for Material Breach**. This Agreement may be terminated upon written notice by either Party if the other Party materially breaches this Agreement and such breach has not been cured within [***] (or [***] for failure to make payment) after notice requesting cure of such breach. If the allegedly breaching Party in good faith disputes such material breach and provides written notice of that dispute to the other Party within the applicable period set forth above, the matter shall be addressed under the dispute resolution provisions in Article 14, and the termination shall not become effective unless and until it has been determined under Article 14 that the allegedly breaching Party is in material breach of this Agreement. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder. Notwithstanding anything to the contrary set forth in this Section 13.2(c), if the breaching Party can reasonably establish that the material breach is limited to, and only has an impact on, one (1) country in the Territory or one (1) Product, then the non-breaching Party shall only be entitled to terminate this Agreement with respect to such country or such Product, as the case may be, and the termination of the Agreement with respect to such country or such Product, as applicable, shall not impact the breaching Party's rights in the other country in the Territory or with respect to other Products, as applicable.

(d) **Termination for Insolvency**. Either Party may terminate this Agreement upon delivery of written notice to the other Party if (i) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (ii) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [***] of its filing, or (iii) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

(e) **Termination for Patent Challenge**. Except to the extent the following is unenforceable under the laws of a particular jurisdiction, this Agreement shall terminate automatically in its entirety immediately if Bausch Health, its Affiliates, or Sublicensees, individually or in association with any other person or entity, commences a legal action challenging the validity, enforceability or scope of any Licensed Patents in a court or other governmental agency of competent jurisdiction, including a reexamination or opposition proceeding.

(f) **Termination for Required Clinical Trial**. In the event that, pursuant to Section 4.1 herein, the FDA requires an additional Clinical Trial to be conducted prior to Regulatory Approval of the XIPERE NDA (other than the Additional Clearside Development Work), and either (A) Clearside initially notifies Bausch in writing that it will not conduct such Clinical Trial at its costs or (B) Clearside notifies Bausch in writing that Clearside intends to conduct such Clinical Trial at its cost and subsequently notifies Bausch in writing that Clearside will not conduct such Clinical Trial at its cost, then, in each case of (A) and (B), Bausch Health may, in its sole discretion, terminate this Agreement upon written notice to Clearside, such notice to be provided within sixty (60) days of receipt of notice from Clearside of Clearside's determination not to conduct such Clinical Trial at its cost.

13.3 **Effect of Termination**. Upon any termination of this Agreement (other than by Bausch Health pursuant to Section 13.2(c) or Section 13.2(d)):

(a) **License**. All licenses and other rights granted by Clearside to Bausch Health under the Licensed IP shall terminate, all sublicenses granted by Bausch Health shall terminate, and all other rights, licenses, and obligations of the Parties hereunder shall terminate.

(b) **Regulatory Submissions; Data**. Bausch Health shall, and shall cause its Affiliates and Sublicensees to, promptly assign and transfer to Clearside, at no cost to Clearside, all Regulatory Submissions and Regulatory Approvals of each Product, data from all studies conducted by or on behalf of Bausch Health, its Affiliates or Sublicensees on Products; provided that (i) Bausch Health may retain one copy for its records and (ii) the obligation to assign and transfer such Regulatory Submissions and Regulatory Approvals for the Other Products shall be subject to any Third Party rights in such Regulatory Submissions and Regulatory Approvals.

(c) **Inventory**. Clearside may purchase from Bausch Health any or all of the inventory of Products held by Bausch Health or its Affiliates as of the date of termination at a price equal to the cost of goods for such inventory, provided that (i) such inventory complies with

specifications and (ii) the obligation to sell such inventory of Other Products shall be subject to any Third Party rights in such inventory. Clearside shall notify Bausch Health within [***] after the date of termination whether Clearside elects to exercise such right; provided, that, in the event Clearside exercises such right to purchase such inventory, Bausch Health shall grant, and hereby does grant, a royalty-free right and license to any trademarks, names, and logos of Bausch Health contained therein for a period of [***] from the date of such exercise solely to permit the orderly sale of such inventory.

(d) **Transition Assistance**. Bausch Health shall, and shall cause its Affiliates and Sublicensees to, reasonably cooperate with Clearside to facilitate the orderly transition of the Development and Commercialization of Products to Clearside (subject to any Third Party rights with respect to the Other Products), including to facilitate the assignment, upon request of Clearside, of any agreements or arrangements with Third Party vendors (including distributors) solely to Develop, promote, distribute, sell or otherwise Commercialize Products.

(e) **Licenses**. Bausch Health hereby grants to Clearside, effective upon such termination, a non-exclusive, worldwide, sublicensable (through multiple tiers) license, under any Bausch Health IP, to Develop, Manufacture, have Manufactured, Commercialize and otherwise use and exploit Products. The license under this Section 13.3(e) (i) will have no payments associated with the license for XIPERE Products and (ii) will be royalty-bearing (but will have no other associated payments) for the license for Other Products. The royalty rate for Other Products will be [***], and royalties will be calculated, paid and reported in accordance with Article 8 and related defined terms, *mutatis mutandis*.

(f) **Sublicenses**. In Clearside's sole discretion, sublicense agreements entered into by Bausch Health or any of its Affiliates with a Sublicensee pursuant to this Agreement may survive the termination of this Agreement. Bausch Health shall, at the request of Clearside, assign any such sublicense to Clearside or one (1) or more of its Affiliates and, upon such assignment, Clearside or its Affiliate(s), as applicable, shall assume such sublicense, as applicable; provided, that, at Clearside's request, Bausch Health shall promptly provide to Clearside copies of each such sublicense for purposes of Clearside determining whether to instruct Bausch Health to assign such sublicense to Clearside or its Affiliate(s). For clarity, any sublicense agreement entered into by Bausch Health with any of its Affiliates shall terminate upon the termination of this Agreement.

(g) In the case of a termination of a country or Product only, the terms of Sections 13.3(a) through 13.3(f) shall apply only to such terminated country or such terminated Product, *mutatis mutandis*.

13.4 Upon termination of this Agreement by Bausch Health in accordance with Section 13.2(c) or 13.2(d):

(a) all rights and licenses granted by Bausch Health to Clearside hereunder shall terminate.

(b) Bausch Health shall be released from its Development and Commercialization obligations.

(c) the licenses granted to Bausch Health pursuant to Section 2.1 shall remain in effect [***].

(d) the Parties' rights and obligations pursuant to Sections 2.2, 4.8, 5.3(a), 5.6, 5.8, 5.9, 6.2, 7.1, 7.5 and 7.6 and Article 12, and any surviving obligations under Section 13.8, shall survive.

(e) In the case of a termination of a country or Product only, the terms of Sections 13.4(a) through 13.4(d) shall apply only to such terminated country or such terminated Product, *mutatis mutandis*.

13.5 Effect of Termination. In addition to the provisions of Section 13.3, upon any termination of this Agreement by Bausch Health pursuant to Section 13.2(a) or Section 13.2(f), within [***] of the effective date of such termination, Clearside shall refund to Bausch Health the full amount of the up-front payment paid by Bausch Health to Clearside pursuant to Section 8.1(a) (namely the amount of five million United States Dollars (US$5,000,000)), by bank wire transfer in immediately available funds to a bank account designated by written notice from Bausch Health.

13.6 Return of Confidential Information. Upon expiration or termination of this Agreement, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party and, if deleted or destroyed, provide to the other Party a certificate of destruction of such records and materials; *provided* that a Party may keep one copy of such materials for legal archival purposes subject to continuing confidentiality obligations.

13.7 Effect of Termination of Emory Agreement. If the Emory Agreement terminates for any reason, Bausch Health shall, from the effective date of termination of the Emory Agreement, automatically become a direct licensee of Emory with respect to the rights originally sublicensed to Bausch Health by Clearside under this Agreement; *provided*, that Bausch Health (a) did not cause the termination of the Emory Agreement, (b) agrees to comply with all the terms of the Emory Agreement, and (c) assumes the responsibilities of Clearside under the Emory Agreement to the extent applicable to the rights originally sublicensed to Bausch Health by Clearside under this Agreement.

13.8 Survival. Termination of this Agreement for any reason shall not release either Party of any obligation or liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination. Notwithstanding anything herein to the contrary, termination of this Agreement by a Party shall be without prejudice to other remedies such Party may have at law or equity. Without limiting the foregoing, the following provisions shall survive the termination or expiration of this Agreement for any reason: Sections 8.4, 8.5, 8.6, 8.7, 10.3, 11.1, 11.2, 11.3, 12.1, 13.3, 13.4, 13.5, 13.6, 13.8, 15.2, 15.4, 15.5, 15.6, 15.8, 15.10, 15.12 and 15.13 and Articles 9 and 14.

ARTICLE 14
DISPUTE RESOLUTION

14.1 **General**. The Parties recognize that a dispute may arise relating to this Agreement (a "**Dispute**"). Any Dispute, including Disputes that may involve the Affiliates of any Party, shall be resolved in accordance with this Article 14.

14.2 **Continuance of Rights and Obligations During Pendency of Dispute Resolution**. If there are any Disputes in connection with this Agreement, including Disputes related to termination of this Agreement under Article 13, all rights and obligations of the Parties shall continue until such time as any Dispute has been resolved in accordance with the provisions of this Article 14.

14.3 **Escalation**. Any claim, Dispute, or controversy as to the breach, enforcement, interpretation or validity of this Agreement shall be referred to a member of each Party's executive management team (the "**Executive Officers**") for attempted resolution. If the Executive Officers are unable to resolve such Dispute within [***] of such Dispute being referred to them, the Parties hereby agree that either Party may initiate litigation in a court of competent jurisdiction located in [***]. The Parties hereby irrevocably: (a) consent to the personal jurisdiction of and exclusive venue of the [***]; and (b) waive any jurisdictional or venue objections to such courts, including forum non conveniens. Each Party further agrees that service of any process, summons, notice, or document by U.S. registered mail or internationally recognized overnight courier service to such Party's respective address set forth herein shall be effective service of process for any action, suit, or proceeding in New York with respect to any matters to which it has submitted to jurisdiction in this Section 14.3.

14.4 **Waiver of Jury Trial**. TO THE EXTENT NOT PROHIBITED BY APPLICABLE LAW THAT CANNOT BE WAIVED, THE PARTIES HEREBY WAIVE, AND COVENANT THAT THEY WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT, OR OTHERWISE), ANY RIGHT TO TRIAL BY JURY IN ANY ACTION ARISING IN WHOLE OR IN PART UNDER OR IN CONNECTION WITH THIS AGREEMENT, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE. THE PARTIES AGREE THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY, AND BARGAINED-FOR AGREEMENT BETWEEN THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT WILL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

14.5 **Injunctive Relief**. Notwithstanding anything to the contrary in this Article 14, in the event of a breach of any covenant or agreement set forth in this Agreement, money damages may be inadequate and, in such case, the other Party would not have adequate remedy at law and that the non-breaching Party, in addition and supplementary to other rights and remedies existing in their favor, may apply to any court of law or equity of competent jurisdiction for specific performance, injunctive relief, and/or other relief in order to enforce or prevent any violations of such covenants or agreements (without posting a bond or other security), and the breaching Party will not oppose the granting of an injunction, specific performance, and other equitable relief on

the basis that the non-breaching Party has an adequate remedy at law or an award of specific performance is not an appropriate remedy for any reason at law or equity.

ARTICLE 15

MISCELLANEOUS

15.1 **Force Majeure**. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God or any other deity, or acts, omissions or delays in acting by any Governmental Authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

15.2 **Assignment**. Neither Party may assign this Agreement to a Third Party without the other Party's prior written consent (such consent not to be unreasonably withheld); except that either Party may make such an assignment without the other Party's consent to (a) a successor to substantially all of the business of the Party to which this Agreement relates (whether by merger, sale of stock, sale of assets or other transaction) and (b) an Affiliate for so long as such Affiliate remains and Affiliate. In connection with any assignment to an Affiliate, the assigning Party shall guarantee and remain fully liable for the performance of the Affiliate. This Agreement shall inure to the benefit of and be binding on the Parties' successors and permitted assigns. Any assignment or transfer in violation of this Section 15.2 shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights, and the non-assigning non-transferring Party shall not recognize, nor shall it be required to recognize, such assignment or transfer. Notwithstanding anything in this Agreement to the contrary, following the closing of a Change of Control of Clearside, the Parties agree that Bausch Health shall not obtain rights or access to Regulatory Approvals or Regulatory Submissions (including the rights of reference), and the Licensed IP will not include, the Patents, Know-How, or Trademarks (i) controlled by the acquiror or any of such acquiror's Affiliates at the time of closing of such Change of Control (other than Regulatory Approvals and Regulatory Submissions (including rights of reference) and the Licensed Patents, Licensed Know-How, and Licensed Marks controlled by Clearside and its Affiliates, which shall remain Licensed IP) or (ii) made by or on behalf of, or otherwise controlled or Controlled by, the acquiror or any of such acquiror's Affiliates (excluding Clearside and its Affiliates (and their officers, employees and consultants) existing prior to the closing of such Change of Control) following the closing of such Change of Control, unless such Know-How or Patent Rights are [***].

15.3 **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provisions adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable

provisions with valid, legal and enforceable provisions which, insofar as practical, implement the purposes of this Agreement.

15.4 **Notices**. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by electronic mail (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Clearside:

Clearside Biomedical Inc.
900 North Point Parkway, Suite 200
Alpharetta, GA 30005
United States of America
Attn: General Counsel
Email: [***]

with a copy to (*which shall not constitute notice*):

Cooley LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, VA 20190-5656
United States of America
Attn: [***]
Email: [***]

If to Bausch Health:

Bausch Health Ireland Limited
3013 Lake Drive
Citywest Business Campus
Dublin, Ireland
Attention: Vice President, General Manager
Email: [***]

with a copy to (*which shall not constitute notice*):

Bausch Health Companies Inc.
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807
Attention: General Counsel
Email: [***]

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by electronic mail on a Business Day; (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth Business Day following the date of mailing if sent by mail.

15.5 **LIMITATION OF LIABILITY**. EXCEPT FOR FRAUD, DAMAGES AVAILABLE FOR A PARTY'S BREACH OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH HEREIN, AND SUBJECT TO AND WITHOUT LIMITING THE INDEMNIFICATION OBLIGATIONS OF EACH PARTY WITH RESPECT TO THIRD PARTY CLAIMS UNDER SECTION 11.1 OR 11.2, NO PARTY OR ANY OF ITS AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, MULTIPLIED OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS (EVEN IF DEEMED DIRECT DAMAGES) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT.

15.6 **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of [***], without reference to any rules of conflict of laws.

15.7 **Entire Agreement; Amendments**. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, with regard to the subject matter hereof (including the licenses granted hereunder) are superseded by the terms of this Agreement. Neither Party is relying on any representation, promise, nor warranty not expressly set forth in this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

15.8 **Interpretation**. The captions to the several Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the sections of this Agreement. Notwithstanding anything to the contrary in this Agreement, any and all references in this Agreement to Patents, Know-How and Trademarks, Regulatory Approvals and Regulatory Submissions (including rights of reference), in each case, owned or Controlled by an "Affiliate" of Clearside following the closing of a Change of Control of Clearside, shall be subject to the terms of Section 15.2.

15.9 **Independent Contractors**. It is expressly agreed that Clearside and Bausch Health shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Clearside nor Bausch Health has the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

15.10 **Waiver**. The waiver by either Party of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other

right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

15.11 Designation of Affiliates. Each Party may discharge any obligations and exercise any rights under this Agreement through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

15.12 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

15.13 Construction. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (d) any reference herein to any person shall be construed to include the person's successors and assigns, (e) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (f) all references herein to Sections or Exhibits shall be construed to refer to Sections or Exhibits of this Agreement, and references to this Agreement include all Exhibits hereto, (g) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (h) provisions that require that a Party, the Parties or any committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (i) references to any specific law, rule or regulation, or Section, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (j) the word "or" is disjunctive but not necessarily exclusive. This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall be for accommodation only and shall not be binding upon the Parties.

15.14 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party may rely on the delivery of executed electronic copies of counterpart

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

execution pages of this Agreement and such electronic copies shall be legally effective to create a valid and binding agreement among the Parties.

{Signature Page Follows}

In Witness Whereof, the Parties intending to be bound have caused this License Agreement to be executed by their duly authorized representatives as of the Effective Date.

Clearside Biomedical, Inc.	**Bausch Health Ireland Limited**
By: /s/ George Lasezkay	By: /s/ Graham Jackson
Name: George Lasezkay	Name: Graham Jackson
Title: CEO	Title: Director

Exhibit 1.34

[***]

Exhibit 1.60

[***]

Exhibit 1.63

[***]

Exhibit 1.64

[***]

Exhibit 1.70

[***]

Exhibit 1.72

[***]

[***]

Exhibit 5.1

[***]

Exhibit 6.1

[***]

[***]

Exhibit 10.29

April 24, 2019

Daniel H. White
XXXXX

Re: Separation Agreement

Dear Daniel:

This letter sets forth the substance of the separation agreement (the "Agreement") which Clearside Biomedical, Inc. (the "Company") is offering to you to aid in your employment transition and which was originally provided to you on April 7, 2019. The Amended and Restated Executive Employment Agreement effective August 3, 2017 between the Company and you is referred to herein as "Employment Agreement." The Employment Agreement contains a Base Salary that has since been increased to $488,653.

1. Separation. You have tendered, and the Company has accepted, your resignation as President and Chief Executive Officer of the Company and as a Director on the Company's Board of Directors (the "Board"). Your last day of work with the Company and your employment termination date was April 7, 2019 (the "Separation Date").

2. Accrued Salary. On the next regular payroll date following the Separation Date, the Company will pay you all accrued salary earned through the Separation Date, subject to standard payroll deductions and withholdings. You will receive these payments regardless of whether or not you sign this Agreement.

3. Severance Benefits. If you execute and do not revoke this Agreement, and fully comply with your obligations hereunder, the Company shall pay and/or provide the following "Severance Benefits" in accordance with your Employment Agreement dated August 3, 2017 (the "Employment Agreement").

a. Severance Payments. The Company will pay you an amount equal to eighteen (18) months' of your Base Salary ($488,653.00 per year) in effect on the Separation Date, less legally-applicable withholdings and deductions ($732,979.50 gross severance pay before legally-applicable withholdings and deductions). These payments will be made in installments on the Company's regular payroll dates, commencing on the Company's first regular payroll date following the Effective Date as defined below, provided that the Company received the executed Agreement from you on or before that date.

b. Health Continuation Coverage Premiums. Provided you timely elect continued coverage under COBRA, the Company will cover the cost of the COBRA premium for the continuation of your health insurance benefits for the earliest of (x) eighteen (18) months following the Separation Date; (y) the date when you become eligible for health insurance coverage in connection with new employment or self-employment; or (z) the date that you cease to be eligible for COBRA continuation coverage for any reason, including plan termination.

Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then provided you remain eligible for payment in accordance with this Section 3(b), in lieu of paying the COBRA premiums, the Company will instead pay you on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings for the remainder of the COBRA Payment Period. If you become eligible for coverage under another employer's group health plan through self-employment or otherwise cease to be eligible for COBRA during the period provided in this clause, you must immediately notify the Company of such event, and all payments and obligations under Section 3(b) only will cease.

c. Enhanced Vesting. The Company will provide enhanced vesting of your unvested stock options, as described below in Section 6 of the Agreement.

d. Enhanced Exercise Rights. Although not required under your Employment Agreement, the Company will provide you with enhanced exercise rights as to your stock options, as described below in Section 6 of the Agreement.

4. Section 409A.

a. Notwithstanding anything to the contrary herein, the following provisions apply to the extent severance benefits provided herein are subject to Section 409A of the Internal Revenue Code (the "Code") and the regulations and other guidance thereunder and any state law of similar effect (collectively "Section 409A"). Severance benefits shall not commence until you have a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "separation from service"). Each installment of severance is a separate "payment" for purposes of Treas. Reg. Section 1.409A-2(b)(2)(i), and the severance benefits are intended to satisfy the exemptions from application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4) and 1.409A-1(b)(9). The parties acknowledge that the exemptions from application of Section 409A to severance benefits are fact specific, and any later amendment of this Agreement to alter the timing, amount or conditions that will trigger payment of severance benefits may preclude the ability of severance benefits provided under this Agreement to qualify for an exemption.

b. It is intended that this Agreement shall comply with the requirements of Section 409A, and any ambiguity contained herein shall be interpreted in such manner so as to avoid adverse personal tax consequences under Section 409A. Notwithstanding the foregoing, the Company shall in no event be obligated to indemnify you for any taxes or interest that may be assessed by the Internal Revenue Service pursuant to Section 409A of the Code to payments made pursuant to this Agreement.

5. Benefit Plans.

Your participation as an employee in the Company's group health insurance plans will end on the last day of the month in which the Separation Date occurs. Thereafter, to the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, and subject to your eligibility under Section 3(b) of this Agreement to receive COBRA reimbursements, you will be eligible to continue your group health insurance benefits at your own expense.

Your participation in Employer-Sponsored Group Life Insurance and Short and Long Term Disability Insurance will cease as of the last day of the month in which the Separation Date occurs.

Deductions for the 401(k) Plan will end with your last regular paycheck. You will receive information by mail concerning 401(k) plan rollover procedures should you be a participant in this program.

6. Stock Options.

a. You were granted options to purchase a total of 959,890 shares of the Company's common stock (collectively, the "Options") pursuant to the applicable plan pursuant to which each such Option was granted (either the Company's 2011 Stock Incentive Plan, as amended, or the Company's 2016 Equity Incentive Plan) (as applicable to such Option, the "Plan") and stock option agreements and any other documents between you and the Company setting forth the terms of the Options (the "Option Documents"). Under the terms of the Plan and your stock option grants, vesting of the Options will cease as of the Separation Date.

b. Notwithstanding anything to the contrary in the applicable Plan or the Option Documents, if you comply fully with the terms of Section 3 of this Agreement, then the unvested portion of your Options that would have vested over the eighteen (18) month period following the Separation Date in accordance with the applicable time-based vesting schedule had you remained continuously employed by the Company during such period will be automatically vested and exercisable as of the Separation Date. Your rights to exercise your options as to any vested shares will be as set forth in the applicable Plan.

c. Notwithstanding anything to the contrary in the applicable Plan or the Option Documents, if you comply fully with the terms of Section 3 of this Agreement, the Options may be exercised as to any vested shares subject to the Options through the earlier of: (i) ninety days following the date of the Board's 2020 annual stockholders meeting, or (ii) the original expiration date applicable to each Option, unless terminated earlier in accordance with the terms of the applicable Plan and Option Documents. Except as provided in this Agreement, all terms, conditions and limitations applicable to the Options will remain in full force and effect pursuant to the applicable Plan and Option Documents; provided however, you acknowledge that this Section 6 sets forth the full agreement between the parties as to the treatment of your Options as of the Separation Date and that you are not entitled to any other options to purchase shares of the Company's common stock. To the extent the Options are "incentive stock options" under the Internal Revenue Code, an extension of the exercise period of the Options may cause them to lose such status and instead be treated as non-qualified stock options for federal tax purposes. You

acknowledge that the Company is not providing tax advice to you and that you have been advised by the Company to seek independent tax advice with respect to the exercise and modification of the Options.

7. Other Compensation or Benefits. You acknowledge that, except as expressly provided in this Agreement, you will not receive any additional compensation, severance or benefits, including under the Employment Agreement, after the Separation Date.

8. Expense Reimbursements. You agree that, within ten (10) days of the Separation Date, you will submit your final documented expense reimbursement statement reflecting all business expenses you incurred through the Separation Date, if any, for which you seek reimbursement. The Company will reimburse you for reasonable business expenses pursuant to its regular business practice.

9. Return of Company Property. Following the Separation Date, you represent that you returned to the Company all Company documents (and all copies thereof) and other Company property that, to your good faith belief and personal knowledge formed after making a diligent search, you have had in your possession at any time, including, but not limited to, Company files, notes, drawings, records, business plans and forecasts, financial information, specifications, computer-recorded information, tangible property (including, but not limited to, computers), credit cards, entry cards, identification badges and keys; and, any materials of any kind that contain or embody any proprietary or confidential information of the Company (and all reproductions thereof). You have coordinated the return of Company property from your laptop computer with Charles A. Deignan, Chief Financial Officer, to his confirmed satisfaction, based upon his review and your representation that you have returned Company property in your possession. If you timely execute and do not revoke this Agreement, because the Company finds that any Company files and data stored on the computer are restored to Company possession, the Company is allowing you to keep permanent possession of your laptop computer.

10. Proprietary Information and Post-Termination Obligations. You acknowledge your continuing obligations under your Proprietary Information and Inventions Agreement dated August 31, 2011 (the "Proprietary Information Agreement") not to use or disclose any confidential or proprietary information of the Company and to refrain from certain solicitation and competitive activities. A copy of your Proprietary Information Agreement is attached hereto as Exhibit A. If you have any doubts as to the scope of the restrictions in your agreement, you should contact Charles A. Deignan, Chief Financial Officer, immediately to assess your compliance. As you know, the Company will enforce its contract rights. Please familiarize yourself with the enclosed Proprietary Information Agreement which you signed. Confidential information that is also a "trade secret," as defined by law, may be disclosed (A) if it is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, in the event that you file a lawsuit for retaliation by the Company for reporting a suspected violation of law, you may disclose the trade secret to your attorney and use the trade secret information in the court proceeding, if you: (A) file any document containing the trade secret under seal; and (B) do not disclose the trade secret, except pursuant to court order.

11. Confidentiality. The provisions of this Agreement will be held in strictest confidence by you and the Company and will not be publicized or disclosed in any manner whatsoever; provided, however, that: (a) you may disclose this Agreement to your immediate family; (b) the parties may disclose this Agreement in confidence to their respective attorneys, accountants, auditors, tax preparers, and financial advisors; (c) the Company may disclose this Agreement as necessary to fulfill standard or legally required corporate reporting or disclosure requirements; and (d) the parties may disclose this Agreement insofar as such disclosure may be necessary to enforce its terms or as otherwise required by law. In particular, and without limitation, you agree not to disclose the terms of this Agreement to any current or former Company employee. Notwithstanding the foregoing, nothing in this Agreement shall limit your right to voluntarily communicate with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, other federal government agency or similar state or local agency or to discuss the terms and conditions of your employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act.

12. Non-Disparagement. Both you and the Company agree not to disparage the other party, and the other party's officers, directors, employees, shareholders and agents, in any manner likely to be harmful to them or their business, business reputation or personal reputation; provided that both you and the Company will respond accurately and fully to any question, inquiry or request for information when required by legal process. The Company's obligations under this Section are limited to Company representatives with knowledge of this provision. Notwithstanding the foregoing, nothing in this Agreement shall limit your right to voluntarily communicate with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, other federal government agency or similar state or local agency or to discuss the terms and conditions of your employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act. In the event that you need a job reference for a future potential employer, you will direct all requests to the Chief Financial Officer. In response to any such requests/inquiries, the Chief Financial Officer will only confirm dates of employment, job title and your voluntary resignation from the Company.

13. Cooperation after Termination. During the time that you are receiving payments and other benefits under this Agreement, you agree to cooperate fully with the Company in all matters relating to the transition of your work and responsibilities on behalf of the Company, including, but not limited to, any present, prior or subsequent relationships and the orderly transfer of any such work and institutional knowledge to such other persons as may be designated by the Company, by making yourself reasonably available during regular business hours.

14. Release by You. In exchange for the payments and other consideration under this Agreement, to which you would not otherwise be entitled, and except as otherwise set forth in this Agreement, you, on behalf of yourself and, to the extent permitted by law, on behalf of your spouse, heirs, executors, administrators, assigns, insurers, attorneys and other persons or entities, acting or purporting to act on your behalf (collectively, the "Employee Parties"), hereby generally

and completely release, acquit and forever discharge the Company, its parents and subsidiaries, and its and their officers, directors, managers, partners, agents, representatives, employees, attorneys, shareholders, predecessors, successors, assigns, insurers and affiliates (the "Company Parties") of and from any and all claims, liabilities, demands, contentions, actions, causes of action, suits, costs, expenses, attorneys' fees, damages, indemnities, debts, judgments, levies, executions and obligations of every kind and nature, in law, equity, or otherwise, both known and unknown, suspected and unsuspected, disclosed and undisclosed, arising out of or in any way related to agreements, events, acts or conduct at any time prior to and including the execution date of this Agreement, including but not limited to: all such claims and demands directly or indirectly arising out of or in any way connected with your employment with the Company or the termination of that employment; claims or demands related to salary, bonuses, commissions, stock, stock options, or any other ownership interests in the Company, vacation pay, fringe benefits, expense reimbursements, severance pay, or any other form of compensation; claims pursuant to any federal, state or local law, statute, or cause of action; tort law; or contract law (individually a "Claim" and collectively "Claims"). The Claims you are releasing and waiving in this Agreement include, but are not limited to, any and all Claims that any of the Company Parties:

- has violated its personnel policies, handbooks, contracts of employment, or covenants of good faith and fair dealing;
- has discriminated against you on the basis of age, race, color, sex (including sexual harassment), national origin, ancestry, disability, religion, sexual orientation, marital status, parental status, source of income, entitlement to benefits, any union activities or other protected category in violation of any local, state or federal law, constitution, ordinance, or regulation, including but not limited to: the Age Discrimination in Employment Act, as amended ("ADEA"); Title VII of the Civil Rights Act of 1964, as amended; the Civil Rights Act of 1991; 42 U.S.C. § 1981, as amended; the Equal Pay Act; the Americans With Disabilities Act; the Genetic Information Nondiscrimination Act; the Family and Medical Leave Act; the Georgia Fair Employment Practices Act; the Georgia Equal Pay Act; the Georgia Prohibition on Age Discrimination in Employment Act; the Georgia Equal Employment for Persons with Disabilities Code; the Employee Retirement Income Security Act; the Employee Polygraph Protection Act; the Worker Adjustment and Retraining Notification Act; the Older Workers Benefit Protection Act; the anti-retaliation provisions of the Sarbanes-Oxley Act, or any other federal or state law regarding whistleblower retaliation; the Lilly Ledbetter Fair Pay Act; the Uniformed Services Employment and Reemployment Rights Act; the Fair Credit Reporting Act; and the National Labor Relations Act;
- has violated any statute, public policy or common law (including but not limited to Claims for retaliatory discharge; negligent hiring, retention or supervision; defamation; intentional or negligent infliction of emotional distress and/or mental anguish; intentional interference with contract; negligence; detrimental reliance; loss of consortium to you or any member of your family and/or promissory estoppel).

Notwithstanding the foregoing, other than events expressly contemplated by this Agreement you do not waive or release rights or Claims that may arise from events that occur after the date this waiver is executed and you are not releasing any right of indemnification, being defended at Company expense (if applicable), and being insured under the Company's D & O and other applicable insurance policies you may have for any liabilities arising from your actions within the course and scope of your employment with the Company or within the course and scope of your role as a member of the Board and/or an officer of the Company. Also excluded from this Agreement are any Claims which cannot be waived by law, including, without limitation, any rights you may have under applicable workers' compensation laws and your right, if applicable, to file or participate in an investigative proceeding of any federal, state or local governmental agency. For the avoidance of doubt, nothing in this Agreement shall prevent you from challenging the validity of the release in a legal or administrative proceeding. Nothing in this Agreement shall prevent you from filing, cooperating with, or participating in any proceeding or investigation before the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal government agency, or similar state or local agency ("Government Agencies"), or exercising any rights pursuant to Section 7 of the National Labor Relations Act. You further understand this Agreement does not limit your ability to voluntarily communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, you are otherwise waiving, to the fullest extent permitted by law, any and all rights you may have to individual relief based on any Claims that you have released and any rights you have waived by signing this Agreement. If any Claim is not subject to release, to the extent permitted by law, you waive any right or ability to be a class or collective action representative or to otherwise participate in any putative or certified class, collective or multi-party action or proceeding based on such a Claim in which any of the Company Parties is a party. This Agreement does not abrogate your existing rights under any Company benefit plan or any plan or agreement related to equity ownership in the Company; however, it does waive, release and forever discharge Claims existing as of the date you execute this Agreement pursuant to any such plan or agreement.

15. Release by the Company. In exchange for you signing, dating, and returning this Agreement to the Company, allowing the applicable release contained herein to become effective, and complying with your obligations to the Company as set forth in this Agreement, the Company hereby generally and completely releases you, your heirs, beneficiaries, executors, administrators, trustees and assigns from any and all known claims, liabilities and obligations that arise out of or are in any way related to events, acts, conduct, or omissions prior to or on the date the Company signs this Agreement provided, however, that this Release shall not extend to: (i) any claims arising after the date this Agreement is signed, including without limitation any claims for breach of this Agreement; (ii) claims arising at any time from your contractual, statutory, and common law obligations to refrain from the unauthorized use or disclosure of the Company's confidential, proprietary, or trade secret information; or (iii) claims arising at any time from your willful misconduct, fraudulent conduct, or violations of applicable law. The Company represents and

warrants that it has no knowledge or information at this time of any potential or suspected violation of the types listed in subsections (ii) or (iii).

16. Your Acknowledgments and Affirmations/Effective Date of Agreement. You acknowledge that you are knowingly and voluntarily waiving and releasing any and all rights you may have under the ADEA, as amended. You also acknowledge and agree that (i) the consideration given to you in exchange for the waiver and release in this Agreement is in addition to anything of value to which you were already entitled, and (ii) that you have been paid for all time worked, have received all the leave, leaves of absence and leave benefits and protections for which you are eligible, and have not suffered any on-the-job injury for which you have not already filed a Claim. You affirm that all of the decisions of the Company Parties regarding your pay and benefits through the date of your execution of this Agreement were not discriminatory based on age, disability, race, color, sex, religion, national origin or any other classification protected by law. You affirm that you have not filed or caused to be filed, and are not presently a party to, a Claim against any of the Company Parties. You further affirm that you have no known workplace injuries or occupational diseases. You acknowledge and affirm that you have not been retaliated against for reporting any allegation of corporate fraud or other wrongdoing by any of the Company Parties, or for exercising any rights protected by law, including any rights protected by the Fair Labor Standards Act, the Family Medical Leave Act or any related statute or local leave or disability accommodation laws, or any applicable state workers' compensation law. You further acknowledge and affirm that you have been advised by this writing that: (a) your waiver and release do not apply to any rights or Claims that may arise after the execution date of this Agreement; (b) you have been advised hereby that you have the right to consult with an attorney prior to executing this Agreement; (c) you have been given twenty-one (21) days to consider this Agreement (although you may choose to voluntarily execute this Agreement earlier and if you do you will sign the Consideration Period waiver below) and you specifically agree that negotiated changes to this Agreement after April 24, 2019, whether or not material, do not extend the 21-day Consideration Period; (d) you have seven (7) days following your execution of this Agreement to revoke this Agreement; and (e) this Agreement shall not be effective until the date upon which the revocation period has expired unexercised (the "Effective Date"), which shall be the eighth day after this Agreement is executed by you.

17. No Admission. This Agreement does not constitute an admission by you or the Company of any wrongful action or violation of any federal, state, or local statute, or common law rights, including those relating to the provisions of any law or statute concerning employment actions, or of any other possible or claimed violation of law or rights.

18. Breach. You agree that your right to continue to receive the Severance Benefits described in Section 3 is conditioned upon your continued compliance with the terms of this Agreement and committing no material breach of any of its terms. You and the Company acknowledge that it may be impossible to assess the damages caused by a violation of the terms of Sections 9, 10, 11 and 12 of this Agreement and further agree that any threatened or actual violation or breach of those Sections of this Agreement will constitute immediate and irreparable injury to the enforcing party, and, in addition to any and all other damages and remedies available upon such breach of this Agreement, the enforcing party shall be entitled to an injunction to prevent the

breaching party from violating or breaching this Agreement. If either party is successful in whole or part in any legal or equitable action to enforce this Agreement, then the enforcing party can collect from the other party all of the costs, including reasonable attorneys' fees, incurred in enforcing the terms of this Agreement.

19. Miscellaneous. This Agreement, including Exhibit A, constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to this subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified by the court so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of Georgia as applied to contracts made and to be performed entirely within Georgia.

If this Agreement is acceptable to you, please sign below and return it to me on or before the date that is twenty-one (21) days after you receive this Agreement. The Company's offer contained herein will automatically expire if we do not receive the fully signed Agreement within this timeframe.

I wish you good luck in your future endeavors.

[signatures to follow on next page]

Sincerely,

CLEARSIDE BIOMEDICAL, INC.

By: /s/ Leslie Zacks
Name: Leslie Zacks
Title: General Counsel and CCO

AGREED TO AND ACCEPTED:

/s/ Daniel H. White
Daniel H. White

Exhibit A – Proprietary Information and Inventions Agreement

CONSIDERATION PERIOD

I, Daniel H. White, understand that I have the right to take at least 21 days from April 24, 2019 to consider whether to sign this Agreement, which I received on April 24, 2019. If I elect to sign this Agreement before 21 days have passed, I understand I am to sign and date below this paragraph to confirm that I knowingly and voluntarily agree to waive the 21-day consideration period.

AGREED:

/s/ Daniel White
Signature

April 27, 2019
Date

Exhibit A

Proprietary Information and Inventions Agreement

OPTION AND LICENSE AGREEMENT

BY AND BETWEEN

REGENXBIO INC.

AND

CLEARSIDE BIOMEDICAL, INC.

August 29, 2019

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

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OPTION AND LICENSE AGREEMENT

This Option and License Agreement (the "**Agreement**") is entered into as of August 29, 2019 (the "**Effective Date**"), by and between Clearside Biomedical, Inc., a Delaware corporation with a place of business at 900 North Point Parkway, Suite 200, Alpharetta, Georgia 30004 ("**Clearside**") and REGENXBIO Inc., a Delaware corporation with a place of business at 9600 Blackwell Road, Suite 210, Rockville, Maryland 20850 ("**REGENXBIO**"). Clearside and REGENXBIO may each be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, REGENXBIO is engaged in the research, development and commercialization of gene therapy products that utilize adeno-associated virus ("**AAV**") vectors for the treatment of various diseases and conditions, including diseases and conditions of the eye;

WHEREAS, Clearside has developed and owns or controls rights to a minimally invasive device that is capable of delivering therapy to specific portions of the eye (as further defined below, the "**Clearside Device**");

WHEREAS, REGENXBIO and Clearside have entered into that certain Technology Access Agreement dated as of May 23, 2019, pursuant to which Clearside has granted certain rights to REGENXBIO to evaluate the use of the Clearside Device in connection with REGENXBIO's products (the "**Technology Access Agreement**"); and

WHEREAS, as contemplated by the Technology Access Agreement, REGENXBIO and Clearside are entering into this Agreement to provide REGENXBIO with certain rights to develop and commercialize products that are administered to the patient using a Clearside Device.

NOW THEREFORE, in consideration of the premises and mutual covenants set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS.

When used in this Agreement, the following capitalized terms have the meanings set forth in this Article 1.

1.1 "**AAV**" is defined in the recitals.

1.2 "**AAV Active Substance**" means any biological molecule, compound or other active ingredient or biologically active substance that is encoded or delivered by an AAV vector.

1.3 "**Acquirer**" means, collectively, with respect to a Party: (a) any Third Party that, after the closing of a Change of Control, controls (within the meaning set forth in the definition of Affiliate) such Party; and (b) such Third Party's Affiliates existing immediately prior to the closing of such Change of Control.

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

1.4 "**Affiliate**" means, with respect to any Person, any other Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or, is under common control with such Person. As used in this definition and the definition of Acquirer only, the term "control" will mean, as to any Person, (a) direct or indirect ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting interests or other ownership interests in the Person in question; or (b) possession, directly or indirectly, of the power to generally direct or cause the direction of management or policies of the Person in question (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.5 "**Agreement**" is defined in the introduction to this Agreement.

1.6 "**Alternative Manufacture Election**" is defined in Section 5.4.2(a).

1.7 "**Applicable Law**" means any law or statute, any rule or regulation (including written governmental interpretations thereof, the guidance related thereto, or the application thereof) issued by a Governmental Authority or Regulatory Authority and any judicial, governmental, or administrative order, judgment, decree, or ruling, in each case as applicable to the subject matter and the parties at issue.

1.8 "**Batten Disease**" means all neuronal ceroid lipofuscinose disorders.

1.9 "**BLA**" means a Biologics License Application, or similar application for marketing approval of a product submitted to the FDA, or a foreign equivalent of the FDA.

1.10 "**Breaching Party**" is defined in Section 10.2.1.

1.11 "**Business Day**" will mean any day other than a Saturday, Sunday, or United States federal holiday.

1.12 "**Calendar Quarter**" means any of the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31 of any Calendar Year, except that the first Calendar Quarter of the Term will commence on the Effective Date and the last Calendar Quarter will end on the last day of the Term.

1.13 "**Calendar Year**" means (a) for the first Calendar Year during the Term, the period commencing on the Effective Date and ending on December 31 of the year during which the Effective Date occurs, (b) for the last Calendar Year, the period commencing on January 1 of the last year of the Term, and ending on the last day of the Term, and (c) each interim period of twelve (12) months commencing on January 1 and ending on December 31.

1.14 "**Change of Control**" means, with respect to a Party, (a) a merger, reorganization or consolidation of such Party with or into a Third Party which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the ultimate parent of the surviving entity immediately after such merger, reorganization or consolidation, (b) a Third Party becoming the

beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party other than as a result of a *bona fide* financing transaction of such Party or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's business or assets to which this Agreement relates.

1.15 "**Clearside**" is defined in the introduction to this Agreement.

1.16 "**Clearside Device**" means a drug delivery product or device that is Covered by the Clearside Technology.

1.17 "**Clearside Indemnified Party**" is defined in Section 11.2.

1.18 "**Clearside Inventions**" is defined in Section 7.5.2.

1.19 "**Clearside Know-How**" means all Know-How that: (a) is Controlled by Clearside or any of its Affiliates as of the Effective Date or becomes Controlled by Clearside or any of its Affiliates (excluding an Acquirer) during the Term; and (b) is necessary or useful for Development or Commercialization of a device for delivery of therapeutic agents (including an AAV Active Substance) to the suprachoroidal space of the eye, the use or Manufacture of any such device, or administration of any AAV Active Substance using any such device. Without limiting the foregoing, Clearside Know-How includes Know-How relating to: (x) administration of any biological molecule, compound or other active ingredient or biologically active substance using the Clearside Device; and (y) design of pre-clinical and clinical studies to test the safety and efficacy of the Clearside Device.

1.20 "**Clearside Manufacturing Know-How**" has the meaning set forth in Section 3.3.

1.21 "**Clearside Patent Right**" means any and all Patent Rights Controlled by Clearside or any of its Affiliates as of the Effective Date or that become Controlled by Clearside or any of its Affiliates (excluding an Acquirer) during the Term that Cover a device for delivery of therapeutic agents (including an AAV Active Substance) to the suprachoroidal space of the eye, the use or Manufacture of any such device, or administration of any AAV Active Substance using any such device. The Clearside Patent Rights existing as of the Effective Date include the Patent Rights listed in Exhibit A.

1.22 "**Clearside Safety Stock**" is defined in Section 5.4.1(b).

1.23 "**Clearside Technology**" means the Clearside Patent Rights and the Clearside Know-How.

1.24 "**Commercial License**" is defined in Section 2.2.

1.25 "**Commercial License Terms**" is defined in Section 2.2.

1.26 "**Commercial Milestone"** is defined in Section 6.3.

1.27 "**Commercial Milestone Payment**" is defined in Section 6.3.

1.28 "**Commercial Supply Agreement**" is defined in Section 5.3.

1.29 "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of or sale of a product, including activities related to marketing, promoting, distributing and importing such product, and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization and "**Commercialized**" has a corresponding meaning.

1.30 "**Commercially Reasonable Efforts**" means, with respect to the performance of Development or Commercialization activities with respect to Covered Product, [***].

1.31 "**Confidential Information**" of a Party means all Know-How or other information, including proprietary information and materials (whether or not patentable) regarding such Party's technology, products, business or objectives, that is communicated in any way or form by the Disclosing Party to the Receiving Party, either prior to the Effective Date pursuant to the Confidentiality Agreement or after the Effective Date of this Agreement, and whether or not such Know-How or other information is identified as confidential at the time of disclosure.

1.32 "**Confidentiality Agreement**" means [***].

1.33 "**Control**" or "**Controlled**" means, with respect to any item of information, including Know-How, or with respect to any Intellectual Property: the possession (whether by ownership interest or license, other than pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party access to or a license under such item or right, as provided herein, without violating the terms of any agreement or other arrangements with any Third Party.

1.34 "**Cover**", "**Covering**" or "**Covered**" means, with respect to any Intellectual Property and an activity or product, that the performance of such activity or the making, having made, using, selling, offering for sale, importing, reproduction, creation of derivative works based upon, display, distribution, Development, Commercialization or other exploitation of such product would, absent a license to such Intellectual Property, infringe, violate or misappropriate such Intellectual Property in the applicable country.

1.35 "**Covered Product**" means any AAV Active Substance that is planned or anticipated to be administered using, or is actually administered using, a Clearside Device; provided however, Covered Product excludes any AAV Active Substance that was actually administered through a method other than the Clearside Device.

1.36 "**Development**" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, qualification and validation, clinical studies, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or

required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. When used as a verb, "**Develop**" means to engage in Development.

1.37 "**Development Milestone"** means the events that trigger Development Milestone Payments as described in Section 6.2.

1.38 "**Development Milestone Payment**" means the payments set forth in Section 6.2.

1.39 "**Development Order**" is defined in Section 5.2.1.

1.40 "**Disclosing Party**" is defined in Section 8.1.

1.41 "**Distributor**" means any Person(s) appointed by REGENXBIO or any of its Affiliates or its or their Sublicensees to distribute, market and sell Covered Product, with or without packaging rights, in one or more countries in the Territory, in circumstances where the Person purchases Covered Product from REGENXBIO or its Affiliates or its or their Sublicensees but does not otherwise make any royalty or other payment to REGENXBIO or its Affiliates or its or their Sublicensees with respect to its Intellectual Property related to such Covered Product.

1.42 "**Dollars**" or "**$**" means United States Dollars.

1.43 "**Drug Approval Application**" means a BLA, IND or other applications or dossier filed with a Regulatory Authority for the purpose of seeking Regulatory Approval, as applicable.

1.44 "**Effective Date**" is defined in the introduction to this Agreement.

1.45 "**EGT Licensor**" means Emory University and The Georgia Tech Research Corporation.

1.46 "**EGT Licensed Technology**" is defined in Section 3.6.

1.47 "**EGT Patent Rights**" means those Patent Rights licensed to Clearside under the Emory/Georgia Tech Agreement.

1.48 "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.49 "**Emory/Georgia Tech Agreement**" means the License Agreement between Emory University, The Georgia Tech Research Corporation and Clearside, dated July 4, 2012, as amended April 2, 2014, December 2, 2016 and April 1, 2018.

1.50 "**European Union**" means the economic, scientific and political organization of member states known as the European Union as it may be constituted from time to time during the Term.

1.51 "**Escrow Agent**" means an escrow agent mutually agreed between the Parties.

1.52 "**Escrow Agreement**" is defined in Section 5.4.3(a).

1.53 "**Escrow Materials**" is defined in Section 5.4.3(a).

1.54 "**Escrow Release**" is defined in Section 5.4.3(b).

1.55 "**Existing Supplier**" is defined in Section 5.1.2.

1.56 "**Exploit**" means to make, have made, use, sell, offer for sale, import and otherwise exploit, including to Develop, Commercialize, or Manufacture. "**Exploitation**" means the act of Exploiting.

1.57 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.58 "**FDCA**" means the United States Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.59 "**Field**" means the treatment of all forms wet age-related macular degeneration, diabetic retinopathy, retinal vein occlusion, diabetic macular edema, myopic choroidal neovascularization, polypoidal choroidal vasculopathy, pathologic myopia and Batten Disease.

1.60 "**First Commercial Sale**" means, with respect to a Covered Product and a country, the first sale for monetary value for use or consumption to the end user of such Covered Product in such country after Regulatory Approval for such Covered Product has been obtained in such country. Sales prior to receipt of Regulatory Approval for such Covered Product, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," will not be construed as a First Commercial Sale.

1.61 "**Forecast**" is defined in Section 5.2.1.

1.62 "**GAAP**" means generally accepted accounting principles, as consistently applied in the manner used for external reporting.

1.63 "**GDPR**" means the General Data Protection Regulation (EU) 2016/679.

1.64 "**GMP**" means the principle of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use as required by Applicable Law, including quality/technical arrangements required under Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), European Commission Directive 2003/94/EC, EudraLex Volume 4 and FDA 21 CFR Parts 11, 210, 211, 600-680, 820 as well as any successor legislation, any national legislation implementing the aforesaid Directive and any relevant guidance relating thereto.

1.65 "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any nation, supranational body, state, county, city or other political subdivision.

1.66 "**Intellectual Property**" means (a) Patent Rights; (b) copyrights in both published and unpublished works (including any registrations, applications and renewals for any of the foregoing) and other rights of authorship; (c) Know-How; (d) trademarks; and (e) all other Intellectual Property and proprietary rights throughout the world.

1.67 "**IND**" means (i) an investigational new drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other countries or regulatory jurisdictions, such as a Clinical Trial Application ("**CTA**") and (ii) all supplements and amendments that may be filed with respect to the foregoing.

1.68 "**Indemnified Party**" is defined in Section 11.4.1.

1.69 "**Indemnifying Party**" is defined in Section 11.4.1.

1.70 "**Indication**" means a separate and distinct disease, disorder, syndrome or other medical condition in humans for which a Covered Product is intended to treat, prevent, diagnose, monitor or ameliorate.

1.71 "**Insolvency Proceedings**" is defined in Section 10.2.4.

1.72 "**Invented**" means with respect to Intellectual Property, Intellectual Property that: (a) with respect to patentable Intellectual Property, is "invented" as determined in accordance with US Patent law; (b) with respect to copyrightable Intellectual Property, is "authored" as determined in accordance with US copyright law; or (c) with respect to all other Intellectual Property, is first developed, created or otherwise established. "**Invent**" and "**Invention**" have correlating meanings.

1.73 "**Joint Inventions**" is defined in Section 7.5.2.

1.74 "**Know-How**" means any invention, discovery, data, information, process, method, technique, material, technology, result or other know-how, whether or not patentable.

1.75 "**Knowledge**" or "**Knows**" means the actual knowledge of: (i) Clearside's [***] as of the Effective Date; (ii) [***]; and (iii) [***]; in each case, after performing reasonable inquiry of the employees having responsibilities in Clearside's organization with respect to the relevant subject matters.

1.76 "**Liability**" is defined in Section 11.2.

1.77 "**Manufacture**" and "**Manufacturing**" means all activities related to the production, manufacture, processing, formulation, filling, finishing, packaging, labeling, shipping and holding of a product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control, in each case as applicable to a therapeutic product or device.

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

1.78 Net Sales.

1.78.1 "**Net Sales**" means, with respect to Covered Product for any period, the gross amount billed or invoiced by REGENXBIO, its Affiliates or its or their Sublicensees for the sale of Covered Product to Third Parties (including Distributors), less deductions for the following, consistent with GAAP and REGENXBIO's standard accounting practices:

(i) [***];

(ii) [***];

(iii) [***];

(iv) [***];

(v) [***];

(vi) [***];

(vii) [***]; and

(viii) [***].

1.78.2 Any of the deductions listed above that involves a payment by REGENXBIO, its Affiliates or its or their Sublicensees will be taken as a deduction in the Calendar Quarter in which the payment is accrued by such entity. For purposes of determining Net Sales, Covered Product will be deemed to be sold when invoiced and a "sale" will not include transfers or dispositions of such Covered Product for pre-clinical or clinical purposes or as samples, in each case, without charge. REGENXBIO's, its Affiliates' or its or their Sublicensees' transfer of Covered Product to an Affiliate or Sublicensee will not result in any Net Sales, unless such Covered Product is consumed by such Affiliate or Sublicensee in the course of its commercial activities.

1.78.3 With respect to each Covered Product in each country in the Territory, from and after the expiration of the Royalty Term for such Covered Product in such country, sales of such Covered Product in such country will be excluded from Net Sales.

1.78.4 In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements will be allocated among products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with REGENXBIO's, its Affiliates' or its or their Sublicensees' existing allocation method; provided that any such allocation will be reasonable and done in accordance with Applicable Law, including any price reporting laws, rules and regulations.

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

1.78.5 Subject to the above, Net Sales will be calculated in accordance with the standard internal policies and procedures of REGENXBIO, its Affiliates or its or their Sublicensees, which must be in accordance with GAAP.

1.78.6 For the avoidance of doubt, no Net Sales will be deemed to have occurred with respect to an AAV Active Substance that is administered through a method other than the Clearside Device.

1.79 "**Non-Breaching Party**" is defined in Section 10.2.1.

1.80 "**Non-Prosecuting Party**" is defined in Section 7.1.3.

1.81 "**Notice Period**" is defined in Section 10.2.1.

1.82 "**Option**" is defined in Section 2.

1.83 "**Option Exercise Notice**" is defined in Section 2.2.

1.84 "**Option Exercise Date**" is defined in Section 2.2.

1.85 "**Option Term**" means the period commencing on the Effective Date and continuing until the earlier of (i) [***] after expiration of the Technology Access Agreement, and (ii) the early termination of the Technology Access Agreement.

1.86 "**Party**" and "**Parties**" is defined in the introduction to this Agreement.

1.87 "**Patent Rights**" means any and all (a) patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) all patents-of-addition, reissues, reexaminations, reviews (including *inter partes* reviews), and extensions or restorations by existing or future extension or restoration mechanisms, including patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) any other form of government-issued right substantially similar to any of the foregoing and (f) all United States and foreign counterparts of any of the foregoing.

1.88 "**Payment"** is defined in Section 6.7.1.

1.89 "**Person**" means any individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization (whether or not having a separate legal personality), including a government or political subdivision or department or agency of a government.

1.90 "**Pharmacovigilance Agreement**" is defined in Section 4.2.3.

1.91 "**Phase II Clinical Trial**" means a human clinical study of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(b), or a similar clinical study prescribed by the relevant Regulatory Authorities or Applicable Law in a country other than the United States.

1.92 "**Phase III Clinical Trial**" means a human clinical study of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(c) and that is designed or intended to (a) establish that the product is safe and efficacious for its intended use, (b) define warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.

1.93 "**Prosecuting Party**" is defined in Section 7.1.3.

1.94 "**Quality Agreement**" means each agreement outlining the division of roles and responsibilities between the Parties and setting forth the terms and conditions on which the Parties shall conduct their quality activities, including quality control and quality assurance, in connection with the Manufacture and supply of Clearside Devices.

1.95 "**Receiving Party**" is defined in Section 8.1.

1.96 "**REGENXBIO**" is defined in the introduction to this Agreement.

1.97 "**REGENXBIO Indemnified Party**" is defined in Section 11.3.

1.98 "**REGENXBIO Inventions**" is defined in Section 7.5.2.

1.99 "**Regulatory Approval**" means, with respect to a country in the Territory, any and all approvals (including Drug Approval Applications), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a biopharmaceutical product in such country, including, where applicable, (a) pricing or reimbursement approval in such country where required for marketing or selling, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (c) labeling approval.

1.100 "**Regulatory Authority**" means any Governmental Authorities regulating or otherwise exercising authority with respect to the Exploitation of a product in the Territory, including the FDA in the United States and the EMA in the European Union.

1.101 "**Regulatory Documentation**" means: all (i) applications (including all Drug Approval Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals); (ii) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files; and (iii) clinical and other data contained or relied upon in any of the foregoing; in each case ((i), (ii) and (iii)) relating to a biopharmaceutical product.

1.102 "**Representatives**" is defined in Section 8.2.1.

1.103 "**Royalty Term**" means, with respect to each Covered Product and each country in the Territory, the period beginning on the date of the First Commercial Sale of such Covered Product in such country and ending on the later to occur of: (a) the expiration or invalidation of the last Valid Claim of a Clearside Patent Right in such country that Covers such Covered Product or the administration thereof, or (b) seven (7) years after the date of the First Commercial Sale in the applicable country.

1.104 "**Safety Stock**" is defined in Section 5.4.1(a).

1.105 "**Safety Stock Price**" is defined in Section 5.4.1(a).

1.106 "**SEC**" means the United States Securities and Exchange Commission.

1.107 "**Sublicense**" is defined in Section 3.2.

1.108 "**Sublicensee**" means a Person other than an Affiliate or a Distributor that is granted a Sublicense.

1.109 "**Supply Failure**" is defined in Section 5.4.2(a).

1.110 "**Supply Failure Notice**" is defined in Section 5.4.2(a).

1.111 "**SVB Lien**" is defined in Section 9.2.2.

1.112 "**Technology Access Agreement**" is defined in the Recitals.

1.113 "**Term**" is defined in Section 10.1.

1.114 "**Terminated Territory**" means, on a Covered Product-by-Covered Product basis: each country with respect to which this Agreement is terminated for such Covered Product by REGENXBIO pursuant to Section 10.2.5(b) or, if this Agreement with respect to such Covered Product is terminated in its entirety, the entire Territory.

1.115 "**Termination Notice**" is defined in Section 10.2.1.

1.116 "**Territory**" means the entire world, other than the Terminated Territory.

1.117 "**Third Party**" means any Person other than REGENXBIO, Clearside or their respective Affiliates.

1.118 "**Third Party Claim**" is defined in Section 11.4.1.

1.119 "**Transfer Price**" means the price at which Clearside will supply the Clearside Device, other than Safety Stock, to REGENXBIO (or its affiliates or Sublicensees), which price will (a) be [***] for each Clearside Device supplied under this Agreement; and (b) with respect to Clearside Devices delivered pursuant to the Commercial Supply Agreement, the Transfer Price

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will be subject to revision pursuant to the formula set forth in the Commercial Supply Agreement; provided that the Transfer Price will not be reduced below [***] as a result of such revision.

1.120 "**Valid Claim**" means (a) a claim of any issued and unexpired Patent Rights (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) whose validity, enforceability or patentability has not been affected by (i) irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer or (ii) a holding, finding or decision of invalidity, unenforceability or non-patentability by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal, or (b) a claim of a pending Patent Rights application that was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal of the application; provided that such prosecution has not been ongoing for more than seven (7) years from its earliest priority date and provided further that if, thereafter, a patent containing such claim issues, then such claim will thereafter be considered a Valid Claim in accordance with subclause (a) above.

2. OPTION.

2.1. **Option**. In consideration of the technology access fee paid by REGENXBIO under Section 2 of the Technology Access Agreement, Clearside hereby grants to REGENXBIO an exclusive option to enter into the Commercial License on the terms set forth in this Agreement (the "**Option**"). The Option is exclusive, and during the Option Term Clearside must not: (a) grant any license to any Third Party under the Clearside Technology to Exploit Clearside Devices for delivery of an AAV Active Substance in the Field in the Territory; or (b) enter into any agreement or arrangement with any other Person (including a covenant not to assert) that would have the effect of enabling such Person to Exploit Clearside Devices for delivery of an AAV Active Substance in the Field in the Territory.

2.2. **Exercise of Option**. The Option will be exercisable at REGENXBIO's option during the Option Term. REGENXBIO may exercise the Option by providing Clearside written notice of REGENXBIO's exercise of such Option at any time prior to the expiration of the Option Term (such notice, the "**Option Exercise Notice**"). The license set forth in Section 3.1 (the "**Commercial License**"), and the terms set forth in Articles 3, 4, 5, 6 and 7 (collectively, the "**Commercial License Terms**") will automatically become effective upon receipt by Clearside of the Option Exercise Notice (the "**Option Exercise Date**").

2.3. **End of Option Term**. If REGENXBIO does not exercise the Option prior to the end of the Option Term, this Agreement shall automatically terminate in accordance with Section 10.1, Clearside will have no further obligation to REGENXBIO with respect to the Option, REGENXBIO will have no further rights under the Clearside Technology, and, for clarity, the Commercial License Terms will not come into effect.

3. LICENSES AND RELATED GRANTS OF RIGHTS. This Article 3 will automatically come into effect upon REGENXBIO's exercise of the Option.

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3.1. **Commercial License**. Subject to the terms and conditions of this Agreement, Clearside hereby grants to REGENXBIO and its Affiliates an exclusive (including with regard to Clearside and its Affiliates), nontransferable (except as set forth in Section 12.1), sublicensable (as set forth in Section 3.2), right and license, under the Clearside Technology and all Patent Rights and Know-How Covering Joint Inventions, to Exploit Clearside Devices for use in connection with Covered Products in the Field in the Territory; provided, however, REGENXBIO covenants that it will not, and it will not permit Third Parties or its Affiliates or Sublicensees to, Manufacture Clearside Devices except as permitted pursuant to Sections 5.4.2 or 5.4.3 or the Commercial Supply Agreement.

3.2. **Sublicenses**. Clearside agrees that REGENXBIO has the right to grant sublicenses of the licenses set forth in Section 3.1 (each, a "**Sublicense**"), through multiple tiers of Sublicensees upon receipt of Clearside's prior written consent, not to be unreasonably withheld, conditioned or delayed; provided that any such Sublicenses will be consistent with the terms and conditions of this Agreement. Notwithstanding the foregoing, REGENXBIO has the right to grant sublicenses of the licenses set forth in Section 3.1 without such consent to its Distributors and to any contractors or commercial partners performing activities in furtherance of REGENXBIO's or its Affiliates' Development, Manufacture or Commercialization of Covered Products. In addition, any Sublicense involving a license under the EGT Patent Rights will be subject to the terms set forth in the Emory/Georgia Tech Agreement, a redacted copy of which is attached to this Agreement as Exhibit B.

3.3. **Transfer of Know-How**. Clearside will provide REGENXBIO with all assistance reasonably required in order to transfer the Clearside Know-How to REGENXBIO, except that Clearside will not be required to transfer Clearside Know-How related to Manufacture of the Clearside Device ("**Clearside Manufacturing Know-How**") to REGENXBIO except in accordance with Section 5.4. The foregoing assistance will include Clearside making available to REGENXBIO, including at REGENXBIO's facilities or the Facilities of REGENXBIO's Affiliates, those of Clearside's employees or contractors as REGENXBIO may reasonably request for purposes of transferring the Clearside KnowHow to REGENXBIO or for purposes of REGENXBIO acquiring expertise on the practical application of such Clearside Know-How. For any such assistance that REGENXBIO requests be provided on-site, such on-site support will be provided at such times as mutually agreed between the Parties. REGENXBIO will reimburse Clearside at a rate of [***] per Clearside employee or independent contractor per hour of support provided following receipt of written invoices in reasonable detail, provided however that the first [***] hours of support will be provided without charge; provided, further, that REGENXBIO will reimburse Clearside for all reasonable travel expenses in connection with providing such support.

3.4. **Confirmatory Patent License**. Clearside will, if requested to do so by REGENXBIO, immediately enter into confirmatory license agreements in such form as may be reasonably requested by REGENXBIO for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory as REGENXBIO considers appropriate. Clearside shall provide to REGENXBIO all such assistance as shall be reasonably required in connection with the above mentioned activities upon REGENXBIO's reasonable request, which request shall not be unreasonably refused, withheld or delayed, and shall promptly provide

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REGENXBIO with all information and sign all documents required in order to complete activities mentioned above in this Section 3.4.

3.5. **Exclusivity Covenants**.

3.5.1. **Clearside Obligations**. Without limiting the exclusive nature of the Commercial License, Clearside covenants that, during the Term, it and its Affiliates will not: (a) other than fulfillment of Clearside's obligations under this Agreement, the Commercial Supply Agreement or any other supply arrangement between the Parties, Exploit Clearside Devices for use with any AAV Active Substance in the Field in the Territory; (b) grant any Third Party any rights under the Intellectual Property Rights Controlled by Clearside or its Affiliates to Exploit Clearside Devices for use with any AAV Active Substance in the Field in the Territory; (c) except pursuant to the Commercial Supply Agreement, sell, offer for sale, import or otherwise transfer any Clearside Devices for use with any AAV Active Substance to a Third Party for use in the Field in the Territory; or (d) otherwise enable any Third Party to Exploit Clearside Devices for use with any AAV Active Substance in the Field in the Territory.

3.5.2. **REGENXBIO Obligations**. REGENXBIO covenants that it will not enter into a commercial relationship for the use of any Third Party device or technology for the administration of an AAV Active Substance to the suprachoroidal space in the Field that infringes on any Clearside Intellectual Property that is the subject of this Agreement.

3.6. **Emory/Georgia Tech Agreement**. All licenses and other rights granted to REGENXBIO with respect to the EGT Patent Rights under this Agreement are subject to the rights and obligations of Clearside under Articles 2 and 11 and Sections 4.4, 10.3 and 12.7 of the Emory/Georgia Tech Agreement and REGENXBIO shall comply with such provisions applicable to the rights granted to REGENXBIO hereunder in all material respects. Clearside may not amend the Emory/Georgia Tech Agreement in a manner that diminishes the rights granted under this Agreement or that places material obligations on REGENXBIO that are not expressly included in this Agreement without REGENXBIO's prior written consent. For the avoidance of doubt, REGENXBIO is not and shall not be obligated to make any payments to EGT Licensor under the Emory/Georgia Tech Agreement, except to the extent that REGENXBIO becomes a direct licensee pursuant to Section 2.5.5 thereof.

3.7. **Reserved Rights**. With respect to the EGT Patent Rights, the Commercial License is subject to EGT Licensor's right, on behalf of itself, its employees and research collaborators, to make, have made, use, import, and transfer products Covered by the EGT Patent Rights and practice the "Licensed Technology" as defined in the Emory/Georgia Tech Agreement (the "**EGT Licensed Technology**") for research, educational and non-commercial and humanitarian clinical purposes, subject to the following limitations: Clearside will use commercially reasonable efforts to cause EGT Licensor not to engage in any human use of any of the EGT Licensed Technology in the Field without express written consent of REGENXBIO and not to transfer microneedles to any Third Party for research purposes in the Field without REGENXBIO's permission, such permission not to be unreasonably withheld. Clearside will provide REGENXBIO written notice immediately after it receives any request from EGT Licensor for any such use. Should

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REGENXBIO not provide a response within seven (7) business days of a request for permission, permission will be presumed. Should REGENXBIO deny permission to transfer microneedles for research, educational and non-commercial and humanitarian clinical purposes, then Clearside or REGENXBIO (as directed by REGENXBIO) will provide the microneedles requested to the Third Party for such purposes on reasonable and appropriate terms and conditions.

4. DEVELOPMENT, COMMERCIALIZATION AND MANUFACTURE OF COVERED PRODUCT. This Article 4 will automatically come into effect upon REGENXBIO's exercise of the Option.

4.1. **Diligence**. REGENXBIO will use Commercially Reasonable Efforts to Develop, seek Regulatory Approval for and Commercialize Covered Product for treatment, prevention or palliation of: (a) wet age-related macular degeneration; and (b) at least one other indication within the Field other than Batten Disease; in each case in the U.S. and European Union. Within [***] after the Effective Date, REGENXBIO will provide a written summary of REGENXBIO's planned Development and Commercialization activities for Covered Product in the Field in the Territory for the subsequent [***] period. REGENXBIO shall provide Clearside with an update of such written summary within [***] after the Option Exercise Date and within [***] after the end of each Calendar Year thereafter through the Royalty Term.

4.2. **Development**. Subject to Section 4.1, REGENXBIO will have the sole right and responsibility, at its sole expense and in its sole discretion, for all aspects of the Development of Covered Product. Without limiting the generality of the foregoing, REGENXBIO will have the sole right and obligation, at its sole expense, to: (a) file all Drug Approval Applications and make all other filings with the Regulatory Authorities, and to otherwise seek all Regulatory Approvals for Covered Product in the Territory, as well as to conduct all correspondence and communications with Regulatory Authorities regarding such matters; (b) report all Adverse Events related to Covered Product sold by REGENXBIO, its Affiliates or Sublicensees to Regulatory Authorities if and to the extent required by Applicable Law; and (c) provide Clearside with safety data as defined by and within the timelines outlined in the Pharmacovigilance Agreement (defined below).

4.2.1. **Regulatory Approvals.**

(a) As between the Parties, REGENXBIO will have the sole right to prepare, obtain and maintain Drug Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals and other submissions and to conduct communications with the Regulatory Authorities, for Covered Product in the Field in the Territory. Clearside and its Affiliates will support REGENXBIO, as may be reasonably necessary and at REGENXBIO's expense, in obtaining Drug Approval Applications and Regulatory Approvals for Covered Product in the Field in the Territory and in the activities in support thereof, including providing all documents or other materials Controlled by Clearside or any of its Affiliates as may be necessary or useful for REGENXBIO or any of its Affiliates or its or their Sublicensees to obtain Regulatory Approvals for Covered Product in the Field in the Territory. In particular: (i) Clearside will provide to REGENXBIO, in a timely manner so as not to delay the filing of any Drug Approval Application or any Regulatory Approval, chemistry, manufacturing and controls

information in Clearside's possession as is required to enable REGENXBIO to make the relevant submission for each IND/CTA or any Regulatory Approval; (ii) Clearside will provide all support reasonably useful or necessary to enable REGENXBIO to respond to any request of any Regulatory Authority in respect of any Drug Approval Application or Regulatory Approval; (iii) Clearside will provide a letter of authorization granting REGENXBIO the right of reference to Clearside's device master file number [***] and any other relevant Regulatory Document as is reasonably useful or necessary for Covered Product in the Field in the Territory and (iv) Clearside will notify REGENXBIO of any amendments or supplemental filings relating to Clearside's device master file number [***] or any other relevant Regulatory Document provided under subclause (iii) that would affect REGENXBIO's ability to Develop, Manufacture, or Commercialize the Covered Product.

(b) Except to the extent prohibited by Applicable Law, all Regulatory Documentation (including all Regulatory Approvals) relating to Covered Product in the Field with respect to the Territory created by REGENXBIO will be owned by and will be held in the name of, REGENXBIO or its designated Affiliate, Sublicensee or designee.

(c) REGENXBIO shall provide Clearside with copies of all relevant Regulatory Documentation to the extent making claims relating to the Clearside Device or containing statements relating to the Clearside Device that are not previously publicly available or previously approved by Clearside at least [***] prior to submission for review and comment by Clearside, and REGENXBIO shall consider in good faith any comments received from Clearside. In addition, REGENXBIO shall notify Clearside of material correspondences received from any Regulatory Authority to the extent including information that might reasonably affect any Regulatory Approval for the Clearside Device as soon as reasonably practical after receipt.

(d) REGENXBIO will inform Clearside of any safety related regulatory action related to the Clearside Device, queries or requests for inspection within the timelines outlined in the Pharmacovigilance Agreement and the Quality Agreement. REGENXBIO will provide Clearside the opportunity to review and comment on any response to any of the foregoing prior to finalization and submission thereof.

4.2.2. **Recalls, Suspensions or Withdrawals.**

(a) REGENXBIO will notify Clearside as soon as reasonably practical following its determination that any event, incident or circumstance relating to the Clearside Device has occurred that may result in the need for a recall, market suspension or market withdrawal of Covered Product Exploited by REGENXBIO, its Affiliates or Sublicensees in the Territory and will include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, REGENXBIO will have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal in the Territory. If a recall, market suspension or market withdrawal of Covered Product Exploited by REGENXBIO, its Affiliates or Sublicensees is mandated by a Regulatory Authority in the Territory, as between the Parties, REGENXBIO will initiate such a recall, market suspension or market withdrawal in compliance with Applicable Law. For all recalls, market

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suspensions or market withdrawals undertaken pursuant to this Section 4.2.2(a), as between the Parties, REGENXBIO will be solely responsible for the execution and Clearside will reasonably cooperate in all such efforts. REGENXBIO will be responsible for all costs of any recall, market suspension or market withdrawal of Covered Product in the Territory, except in the event and to the extent that a recall, market suspension or market withdrawal resulted from Clearside's or its Affiliate's material breach of its obligations hereunder or from Clearside's or its Affiliate's fraud, negligence or willful misconduct, in which case, Clearside will bear the expense of such recall, market suspension or market withdrawal. In the event of a recall, market suspension or market withdrawal undertaken pursuant to this Section 4.2.2(a), REGENXBIO will keep Clearside reasonably informed with respect to such recall, market suspension or market withdrawal.

(b) Clearside will notify REGENXBIO following its determination that any event, incident or circumstance has occurred that may result in the need for a recall, market suspension or market withdrawal of Clearside Devices in the Territory and will include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, Clearside will have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal of Clearside Devices in the Territory. If a recall, market suspension or market withdrawal of Clearside Devices in the Territory is mandated by a Regulatory Authority in the Territory, as between the Parties, Clearside will initiate such a recall, market suspension or market withdrawal in compliance with Applicable Law. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 4.2.2(b), as between the Parties, Clearside will be solely responsible for the execution and REGENXBIO will reasonably cooperate in all such efforts. Clearside will be responsible for all costs of any recall, market suspension or market withdrawal of Clearside Devices, except in the event and to the extent that a recall, market suspension or market withdrawal resulted from REGENXBIO's or its Affiliate's material breach of its obligations hereunder or from REGENXBIO's or its Affiliate's fraud, negligence or willful misconduct, in which case, REGENXBIO will bear the expense of such recall, market suspension or market withdrawal. In the event of a recall, market suspension or market withdrawal undertaken pursuant to this Section 4.2.2(b), Clearside will keep REGENXBIO reasonably informed with respect to such recall, market suspension or market withdrawal.

4.2.3. **Global Safety Database**. REGENXBIO will establish, hold and maintain (at REGENXBIO's cost and expense) the global safety database for Covered Product Exploited by REGENXBIO, its Affiliates or Sublicensees in the Territory. Subject to the terms and conditions of the Pharmacovigilance Agreement (as defined below) to be entered into by the Parties after the Effective Date, Clearside and its Affiliates will provide REGENXBIO with all information necessary for REGENXBIO to comply with its pharmacovigilance responsibilities in the Territory, including, as applicable, any adverse events involving the Clearside Device (including outside the Field), in each case in the form reasonably requested by REGENXBIO. Within [***] after the Effective Date, the Parties will develop and agree in writing upon a safety data exchange agreement ("**Pharmacovigilance Agreement**") that will enable each Party to comply with its legal and regulatory obligations in the Territory relating to Covered Product and Clearside Devices.

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4.2.4. **Development Services**. To the extent REGENXBIO desires Clearside to assist with any Development of Covered Product, Clearside Devices or the Clearside Technology (excluding any assistance required in Section 3.3, elsewhere in this Section 4.2 or otherwise expressly required under this Agreement), the Parties will negotiate in good faith the terms of an appendix to this Agreement which will set forth the work to be provided, and any consideration therefor. Such Development assistance may include, without limitation, updates to the Clearside Device (including minor updates), and co-development of new devices Covered by the Clearside Technology. Any such appendix will be incorporated into this Agreement upon execution by the Parties.

4.3. **Commercialization and Manufacture of Covered Product**. As between the Parties, REGENXBIO (itself or through its Affiliates or its or their Sublicensees) will have the sole right to Commercialize and Manufacture, subject to Section 5, Covered Product (but not Manufacture the Clearside Devices except in accordance with Sections 5.4.2 or 5.4.3) in the Field and in the Territory at its sole cost and expense. Without limiting the obligations set forth in Section 4.1, Clearside further acknowledges that REGENXBIO is in the business of Exploiting pharmaceutical products and nothing in this Agreement will be construed as restricting such business or imposing on REGENXBIO the duty to Exploit Covered Product for which royalties are payable hereunder to the exclusion of, or in preference to, any other product or in any way other than in accordance with its normal commercial practices.

4.4. **Booking of Sales; Distribution**. As between the Parties, REGENXBIO will have the sole right to invoice and book sales, establish all terms of sale (including pricing and discounts) and warehouse and distribute Covered Product in the Territory and perform or cause to be performed all related services. Subject to Section 4.2.2, as between the Parties, REGENXBIO will handle all returns, recalls or withdrawals, order processing, invoicing, collection, distribution and inventory management with respect to Covered Product in the Territory.

5. MANUFACTURE AND SUPPLY OF CLEARSIDE DEVICES. This Article 5 will automatically come into effect upon REGENXBIO's exercise of the Option.

5.1. **General Obligation; Continuity of Supply**.

5.1.1. **General Obligations**. Clearside will (directly or through a Third Party supplier) Manufacture and supply all of REGENXBIO's requirements of Clearside Devices for use with Covered Product pursuant to this Agreement and the Commercial Supply Agreement.

5.1.2. **Existing Supply**. Clearside currently obtains Clearside Devices from Gerresheimer Regensburg GMBH (the "**Existing Supplier**"). Clearside will ensure material compliance at all times with the terms of its agreement with the Existing Supplier, and will ensure that such agreement is not terminated unless and until: (a) REGENXBIO has provided its prior written consent (not to be unreasonably withheld); and (b) either (i) REGENXBIO has entered into its own agreement with the Existing Supplier for supply of the Clearside Devices or (ii) Clearside has established and qualified another supplier for the Clearside Devices that is acceptable to REGENXBIO (in REGENXBIO's reasonable discretion). Upon REGENXBIO's reasonable

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request, Clearside will facilitate negotiations between the Existing Supplier and REGENXBIO with respect to an agreement for supply of the Clearside Devices.

5.2. **Preclinical and Clinical Manufacture and Supply of Clearside Devices**.

5.2.1. **Development Orders**. Clearside will supply all Clearside Devices required by REGENXBIO for Development of Covered Product in accordance with the specifications attached hereto as Exhibit C, including all Clearside Devices required for clinical trials or otherwise as needed to apply for, seek, obtain and maintain Regulatory Approval for Covered Product or the use of the Clearside Device in connection with Covered Product. The Parties will agree upon and approve in writing a Quality Agreement that will apply with respect to the Manufacture of such Clearside Devices. All Clearside Devices supplied by Clearside must be Manufactured in accordance with such specifications and the applicable Quality Agreement. REGENXBIO will not, and will not permit its Affiliates, Sublicensees and Third-Party Manufacturers to, modify or alter the Clearside Device without Clearside's prior written consent. Any modification or alteration of the Clearside Device by Clearside on behalf of REGENXBIO will be at REGENXBIO's sole cost and expense; provided, that Clearside will be under no obligation to modify or alter the Clearside Device. REGENXBIO may place orders for Clearside Devices needed during the Development phase (a "**Development Order**") at least [***] prior to the requested delivery date, and, provided Development Orders are placed within such time period, Clearside will deliver such Clearside Devices within such time period. Within [***] after the Effective Date, REGENXBIO will provide to Clearside an initial non-binding [***] rolling forecast of Development Orders (the "**Forecast**"). Thereafter, REGENXBIO will provide an updated Forecast for the subsequent [***] period no later than [***] of each subsequent Calendar Quarter. Clearside will use commercially reasonable efforts to ensure that the Existing Supplier or another supplier qualified in accordance with this Agreement has at all times sufficient manufacturing capacity to satisfy such Development Orders.

5.2.2. **Pricing; Payment**. Clearside will invoice REGENXBIO for the Clearside Devices at the Transfer Price, and REGENXBIO will pay all undisputed amounts in such invoices within [***] of receipt. In the event REGENXBIO disputes any portion of an invoice, it shall notify Clearside in writing within [***] after receipt of invoice. The Parties shall use good faith efforts to resolve such dispute.

5.3. **Commercial Manufacture and Supply of Clearside Devices**. At an appropriate time during Development of Covered Product, the Parties, together with the Existing Supplier, will negotiate in good faith and enter into an agreement for commercial supply of the Clearside Device ("**Commercial Supply Agreement**") and a Quality Agreement. The Commercial Supply Agreement will provide for supply of the Clearside Device at the Transfer Price, and the Commercial Supply Agreement and Quality Agreement will otherwise contain mutually agreed terms and conditions consistent with this Agreement, in addition to other terms that are reasonable and customary, including provisions to ensure quality and audit by or on behalf of REGENXBIO.

5.4. **Supply Protection**.

5.4.1. **Safety Stock**.

(a) Clearside will purchase and store (at REGENXBIO's expense as set forth below) safety stock of excess unsterilized Clearside Devices of at least the greater of (a) [***] Clearside Devices or (b) [***] supply of Clearside Devices pursuant to REGENXBIO's most recent forecast (the "**Safety Stock**"). REGENXBIO's price for the Safety Stock (the "**Safety Stock Price**") will be equal to the price at which Clearside purchased the Clearside Devices from the Existing Supplier, as evidenced by invoices or other supporting documentation. Clearside will invoice REGENXBIO for Safety Stock at the Safety Stock Price, and REGENXBIO will pay all such invoices within [***] of receipt. Title to the Safety Stock will pass to REGENXBIO upon payment of the relevant invoice for such Safety Stock. Within [***] days after fulfillment of an order from Safety Stock (which may be done only as set forth below), REGENXBIO will pay to Clearside the amount by which the Transfer Price exceeds the Safety Stock Price. Clearside will store the Safety Stock at REGENXBIO's sole cost and expense. Any such storage costs will be evidenced by invoices or other supporting documentation and will be at reasonable market rates. Clearside will maintain a regular rotation of such Safety Stock as necessary to avoid expiration or other spoilage. Upon written request by REGENXBIO, Clearside will transfer the Safety Stock to a neutral Third Party identified by REGENXBIO and reasonably acceptable to Clearside at REGENXBIO's sole cost and expense and, upon such request, risk of loss will pass to REGENXBIO. Clearside shall provide an update regarding its current Safety Stock of Clearside Devices upon REGENXBIO's request. Notwithstanding anything to the contrary set forth in this Agreement or the Commercial Supply Agreement, Clearside may only use Safety Stock to fill any shortfall in quantities of Clearside Devices ordered by REGENXBIO that Clearside is unable to supply despite commercially reasonable efforts after obtaining REGENXBIO's express written consent, such consent not to be unreasonably withheld, conditioned or delayed, in which case the used Safety Stock will be replaced as soon as possible. For clarity, Safety Stock may not be used for any other purpose. REGENXBIO will have the right to inspect Safety Stock in the location it is held at reasonable times and upon reasonable prior written notice to Clearside. In addition, upon REGENXBIO's request, Clearside will make available its relevant books and records to REGENXBIO in order for REGENXBIO to verify the Safety Stock Price and storage costs charged to REGENXBIO. From time to time, REGENXBIO and Clearside may review Safety Stock levels required to be maintained under this Section 5.4.1(a) and make mutually agreeable adjustments.

(b) In addition to the Safety Stock, Clearside will purchase and store (at Clearside's expense) safety stock of excess unsterilized Clearside Devices of at least the greater of (a) [***] Clearside Devices or (b) [***] supply of Clearside Devices pursuant to REGENXBIO's most recent forecast (the "**Clearside Safety Stock**").

5.4.2. **Supply Failure.**

(a) Subject to the provisions of the Commercial Supply Agreement, if during the term of the Commercial Supply Agreement, Clearside fails to supply REGENXBIO with at least [***] of the quantities of Clearside Devices that Clearside is obligated to supply (provided such quantities do not exceed REGENXBIO's most recent forecast) on at least [***] occasions in any consecutive [***] period for any reason other than due to the material breach by REGENXBIO of the Commercial Supply Agreement (a "**Supply Failure**"), REGENXBIO may,

at its sole discretion, upon not less than [***] written notice to Clearside (a "**Supply Failure Notice**"): (i) require Clearside to supply the undelivered Clearside Devices at a future date to be agreed upon by the Parties; and/or (ii) elect to have one or more Third Parties identified by REGENXBIO Manufacture Clearside Devices (an "**Alternative Manufacturer Election**"), in which case REGENXBIO will require its Third Party Manufacturer to only Manufacture and sell such Clearside Devices for REGENXBIO's and its Affiliates' and Sublicensees' Exploitation in connection with Covered Product within the scope of the Commercial License.

(b) Upon the occurrence of a Supply Failure and an Alternative Manufacturer Election: (i) REGENXBIO (or its designated Third Party manufacturer) will have the right to Manufacture Clearside Devices within the scope of the license under Section 3.1, and (ii) Clearside shall transfer the Clearside Manufacturing technology to REGENXBIO and any Third Party Manufacturers identified by REGENXBIO as specified in the following sentence. Clearside shall promptly (x) disclose to REGENXBIO and any such Third Party Manufacturer all Clearside Manufacturing Know-How; (y) provide REGENXBIO or any such Third Party Manufacturer with the training, documentation and other information Controlled by Clearside and relating to the use of the Manufacturing process as may be necessary for REGENXBIO and such Third Party Manufacturers to Manufacture Clearside Devices; and (z) make appropriately trained personnel available for consultation and advice upon REGENXBIO's reasonable request and expense to the extent reasonably necessary to provide technical assistance necessary to enable REGENXBIO or such Third Party Manufacturers to Manufacture Clearside Devices.

5.4.3. **Escrow**.

(a) Within [***] after REGENXBIO's request, the Parties and the Escrow Agent will enter into an agreement pursuant to which the Escrow Materials will be deposited with the Escrow Agent and released to REGENXBIO under certain conditions (the "**Escrow Agreement**"). REGENXBIO will pay the Escrow Agent's fees arising under such Escrow Agreement. Promptly after execution of the Escrow Agreement, Clearside will, to the extent Controlled by Clearside, deposit copies of the complete design history file for the Clearside Device, including the device master record and all documents referenced within. For clarity, this includes but is not limited to copies of all design requirements, specifications, technical drawings, standard operating procedures, component lists, and supplier lists relating to Manufacture of the Clearside Device and any other written materials maintained by Clearside or its Affiliates that are necessary for or used in the Manufacture of the Clearside Device (the "**Escrow Materials**"). The deposit of the Escrow Materials with the Escrow Agent will not affect Clearside's right, title or interest in or to the Escrow Materials.

(b) The Escrow Agreement will require the Escrow Agent to release the Escrow Materials to REGENXBIO in the event an Insolvency Proceeding is instituted by or against Clearside or in the event of an Alternative Manufacturer Election if Clearside does not fulfill its obligations under Section 5.4.2(b)(x), (y) and (z) (any such event, "**Escrow Release**"). In the event of an Escrow Release, REGENXBIO will be entitled to full use of the Escrow Materials as necessary or useful to Manufacture Clearside Devices in furtherance of REGENXBIO's exercise of the Commercial License. After Escrow Release, REGENXBIO will

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have the right to use the Escrow Materials and will have the right to Manufacture Clearside Devices within the scope of the license under Section 3.1.

5.5. **GMP**. The Parties or their Affiliates will execute, as reasonably requested by REGENXBIO, agreements, such as a Quality Agreement, necessary or useful to ensure that all Clearside Devices and their intermediates and manufacturing facilities comply with GMP and all Applicable Laws. Clearside shall notify REGENXBIO in writing promptly after receiving Knowledge thereof, before any supplier or manufacturer implements any changes in Manufacturing processes for any Clearside Devices that would have regulatory relevance to any Covered Product. Such notice shall be given promptly after Clearside receiving Knowledge thereof. Clearside shall use commercially reasonable efforts to secure for REGENXBIO the opportunity to conduct full chemistry, manufacturing and controls due diligence and environmental, health and safety audits of Clearside Device suppliers and manufacturers prior to entering into any agreement and periodically thereafter, and Clearside shall use commercially reasonable efforts to obligate any such supplier or manufacturer to implement the changes and improvements stemming from such audits.

6. PAYMENTS TO CLEARSIDE. This Article 6 will automatically come into effect upon REGENXBIO's exercise of the Option.

6.1. **Option Exercise Fee**. In partial consideration of the rights granted by Clearside to REGENXBIO hereunder and subject to the terms and conditions of this Agreement, REGENXBIO will pay to Clearside Two Million Dollars ($2,000,000), against which the technology access fee paid pursuant to Section 2 of the Technology Access Agreement is fully creditable, within thirty (30) days after REGENXBIO's receipt of an invoice from Clearside for such amount that is issued by Clearside on or after the receipt of the Option Exercise Notice.

6.2. **Development and Regulatory Milestone Payments**.

6.2.1. **Milestone Payments**. In partial consideration of the rights granted by Clearside to REGENXBIO hereunder and subject to the terms and conditions of this Agreement, upon the occurrence of the corresponding event described in the table below, whether such milestone is achieved by REGENXBIO, an Affiliate or a Sublicensee, the corresponding payment will be due:

Development Milestones (USD)	**Development Milestone Payment**		
	First Occurrence	**Second Occurrence**	**Third Occurrence**
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
Total	[***]	[***]	[***]

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Notwithstanding the foregoing:

(a) only one (1) occurrence of a given Development Milestone will be payable for the same Covered Product for a single Indication;

(b) only two (2) occurrences of a given Development Milestone will be payable for Covered Products including the same AAV Active Substance; and

(c) Development Milestones will not be payable for any Covered Product for the treatment of Batten Disease.

Examples of the calculation of Development Milestones payable under this Section 6.2.1 are attached hereto as Exhibit D.

6.2.2. **Notice; Payments**. Within [***] after the occurrence of a Development Milestone, REGENXBIO will send Clearside a written notice identifying the Covered Product that achieved the Development Milestone and the Development Milestone Payment Amount set forth above with respect to such Development Milestone. Thereafter, Clearside will promptly invoice REGENXBIO for the achievement of the Development Milestone, identifying in its invoice the Covered Product, the Development Milestone achieved and the amount of the Development Milestone Payment, and such Development Milestone Payment will be due within [***] after REGENXBIO's receipt of such invoice.

6.2.3. **Milestones Payable Only Once**. For clarity, each Development Milestone Payment will be payable only once regardless of the number of Covered Products to achieve the Development Milestone, and the maximum total Development Milestone Payments payable for all Covered Products under this Agreement will not exceed Thirty-Four Million Dollars ($34,000,000).

6.3. **Commercial Milestones**. In partial consideration of the rights granted by Clearside to REGENXBIO hereunder and subject to the terms and conditions of this Agreement, REGENXBIO will make the following payments (each such amount, a "**Commercial Milestone Payment**"), following the first occurrence of each event described in the table below (each, a "**Commercial Milestone**") for Covered Products, whether such milestone is achieved by REGENXBIO, an Affiliate and/or a Sublicensee:

Commercial Milestone	**Commercial Milestone Payment**
For the first Calendar Year during the Term in which the aggregate of all Net Sales of Covered Products for such Calendar Year exceeds [***]	$[***]

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Commercial Milestone	Commercial Milestone Payment
For the first Calendar Year during the Term in which the aggregate of all Net Sales of Covered Products for such Calendar Year exceeds [***]	[***]
For the first Calendar Year during the Term in which the aggregate of all Net Sales of Covered Products for such Calendar Year exceeds [***]	[***]
For the first Calendar Year during the Term in which the aggregate of all Net Sales of Covered Products for such Calendar Year exceeds [***]	[***]
For the first Calendar Year during the Term in which the aggregate of all Net Sales of Covered Products for such Calendar Year exceeds [***]	[***]
Total	[***]

Within [***] after the occurrence of a Commercial Milestone, REGENXBIO will send Clearside a written notice identifying the Commercial Milestone and the Commercial Milestone Payment Amount set forth above with respect to such Commercial Milestone. Thereafter, Clearside will promptly invoice REGENXBIO for the achievement of the Commercial Milestone and such Commercial Milestone Payment will be due within [***] after REGENXBIO's receipt of such invoice.

Clearside acknowledges and agrees that the sales levels set forth in this Section 6.3 will not be construed as representing an estimate or projection of anticipated sales of Covered Products in the Territory or implying any level of diligence beyond that required pursuant to Section 4.1, and that the sales levels set forth above are merely intended to define REGENXBIO's milestone obligations in the event such sales levels are achieved.

6.4. **Royalties**.

6.4.1. **Royalty Rates**. As further consideration for the rights granted to REGENXBIO hereunder and subject to the terms and conditions of this Agreement, during the Royalty Term, REGENXBIO will pay to Clearside a royalty in the amount of [***] of Net Sales of Covered Products by REGENXBIO, its Affiliates and Sublicensees, subject to the royalty reductions set forth below. REGENXBIO will have no obligation to pay any royalty with respect to Net Sales of Covered Product in any country after the Royalty Term for such Covered Product

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in such country has expired. Following the expiration of the Royalty Term for Covered Product in a country, the grants in Section 3.1 will become fully-paid, royalty-free, perpetual and irrevocable for such Covered Product in such country, and no further royalties will be payable.

6.4.2. **Royalty Reductions.**

(a) **Anti-Stacking**. If, in connection with the Manufacture, use or Commercialization of Covered Product, REGENXBIO is obligated to pay royalties to Clearside and any Third Parties solely in order to Exploit the Clearside Device (including administration of Covered Product using the Clearside Device) that, in the aggregate, exceed [***] of Net Sales for Covered Product, then the royalty owed to Clearside for that Covered Product will be reduced by an amount calculated in accordance with the formula set forth in Exhibit E.

Notwithstanding the foregoing, Section 6.4.2(a) will not reduce any single royalty payment payable to Clearside by more than [***] of what it would otherwise be payable by operation of Section 6.4.1. Credits not exhausted in any Calendar Quarter may be carried into future Calendar Quarters, subject to the foregoing sentence.

(b) **No Valid Claim**. If, during the Royalty Term, no Valid Claim of the Clearside Patent Rights exists that Covers the Clearside Device in the Territory, then: (i) the royalty that would otherwise be payable will be reduced to [***] for the remainder of the Royalty Term, if any; and (ii) if there is another microneedle device that is Commercialized by a Third Party in such country that would have infringed a claim of the Clearside Patents if such claim was a Valid Claim, the royalty will be further reduced to [***].

6.5. **Royalty Payments and Reports**. REGENXBIO will calculate all amounts payable to Clearside pursuant to Section 6.3 at the end of each Calendar Quarter, which amounts will be converted to Dollars, in accordance with Section 6.6. REGENXBIO will pay to Clearside the royalty amounts due with respect to a given Calendar Quarter within [***] after the end of such Calendar Quarter. Each payment of royalties due to Clearside will be accompanied by a statement of the amount of gross sales, Net Sales, and number of units of Covered Product(s) in each country in the Territory during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter, which calculation shall include the itemized deductions for Covered Products for each country included in the calculation of Net Sales. REGENXBIO will also include in such reports any additional information reasonably requested by Clearside to calculate Net Sales attributable to its Affiliates and Sublicensees.

6.6. **Currency; Payment Instructions; Late Payments**. All amounts payable and calculations hereunder will be in Dollars, and all payments due under this Agreement will be made by wire transfer in immediately available funds to an account designated by Clearside in advance of such payment, or by other mutually acceptable means. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party will convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate's or Sublicensee's standard conversion methodology consistent with GAAP. If any payment due to either Party under this

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Agreement is not paid when due, then such paying Party will pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of [***] basis points above the U.S. effective federal funds rate, as adjusted each Business Day and published by the Federal Reserve Bank of New York through its website (https://apps.newyorkfed.org/markets/autorates/fed%20funds) (or in the event that the U.S. effective federal funds rate is no longer an applicable reference rate, such reasonably equivalent alternative as may be selected by mutual agreement exercising reasonable discretion), such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest. Notwithstanding the previous sentence, the total payable interest rate will never be less than [***] basis points.

6.7. **Taxes**.

6.7.1. **General**. The milestones, royalties and other amounts payable by REGENXBIO to Clearside pursuant to this Agreement (each, a "**Payment**") will be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Except as provided in this Section 6.7, Clearside will be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from Payments and remitted by REGENXBIO) levied on account of, or measured in whole or in part by reference to, any Payments it receives. REGENXBIO will deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if Clearside is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to REGENXBIO or the appropriate governmental authority (with the assistance of REGENXBIO to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve REGENXBIO of its obligation to withhold such tax and REGENXBIO will apply the reduced rate of withholding or dispense with withholding, as the case may be; provided that REGENXBIO has received evidence, in a form reasonably satisfactory to REGENXBIO, of Clearside's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [***] prior to the time that the Payments are due. If, in accordance with the foregoing, REGENXBIO withholds any amount, it will pay to Clearside the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to Clearside proof of such payment within [***] following such payment.

6.8. **Financial Records**. REGENXBIO will, and will cause its Affiliates and its and their Sublicensees to, keep complete and accurate financial books and records pertaining to the Development and Commercialization of Covered Product hereunder to the extent required to calculate and verify all amounts payable hereunder. REGENXBIO will, and will cause its Affiliates and its and their Sublicensees to, retain such books and records until [***] after the end of the period to which such books and records pertain.

6.9. **Audit**. Upon Clearside's or EGT Licensors' request, REGENXBIO will, and will cause its Affiliates and its and their Sublicensees to, permit an independent, nationally recognized accounting firm designated by Clearside or EGT Licensor and reasonably acceptable to REGENXBIO, at reasonable times and upon reasonable notice, to audit the books and records

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maintained pursuant to Section 6.8 to ensure the accuracy of all reports and payments under this Agreement. Such examinations may not be conducted more than [***] in any [***] period and are limited to the preceding [***] period. The cost of this audit will be borne by Clearside, unless the audit reveals a variance of more than [***] from the reported amounts, in which case REGENXBIO will reimburse Clearside for the accounting firm's fees in performing the audit. If such audit concludes that (a) additional amounts were owed by REGENXBIO, REGENXBIO will pay the additional amounts or (b) excess payments were made by REGENXBIO, Clearside will reimburse or credit such excess payments, in either case ((a) or (b)), within [***] after the date on which such audit is completed.

6.10. **Confidentiality**. The Receiving Party will treat all information subject to review under this Article 6 in accordance with the confidentiality provisions of Article 8 and the Parties will cause the Auditor to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

7. PATENT MATTERS; OWNERSHIP OF INTELLECTUAL PROPERTY. This Article 7 will automatically come into effect upon REGENXBIO's exercise of the Option.

7.1. **Filing, Prosecution and Maintenance of Patent Rights**.

7.1.1. **EGT Patent Rights**. The EGT Licensor will be responsible for filing for, prosecution and maintenance of the EGT Patent Rights in accordance with the terms of the Emory/Georgia Tech Agreement. Clearside will provide REGENXBIO with all information that is provided to Clearside by the EGT Licensor with respect to the EGT Patent Rights related to use of the Clearside Device for delivery of an AAV Active Substance in the Field in accordance with Article 7 of the Emory/Georgia Tech Agreement promptly and with sufficient time for REGENXBIO to review and comment thereon. If Clearside and EGT Licensor elect not to continue to seek or maintain any EGT Patent Rights related to use of the Clearside Device for delivery of an AAV Active Substance in the Field, then: (a) to the extent REGENXBIO is the sole exclusive sublicensee of such EGT Patent Rights (including, for clarity, to the extent the subject matter of the EGT Patent Rights relates to the use of the Clearside Device for delivery of an AAV Active Substance in the Field), Clearside will provide REGENXBIO with timely notice and will provide REGENXBIO with a reasonable opportunity to assume responsibility for the continued prosecution and maintenance of such EGT Patent Rights, or (b) to the extent REGENXBIO is not the sole exclusive sublicensee of such EGT Patent Rights, Clearside will provide REGENXBIO with timely notice and REGENXBIO and the other exclusive licensees will negotiate in good faith regarding the assumption of responsibility for the continued prosecution and maintenance of such EGT Patent Rights.

7.1.2. **Other Clearside Patent Rights**. For any Clearside Patent Rights not covered by Section 7.1.1, this Section 7.1.2 will apply. Clearside has the first right, at its discretion and using counsel it selects, to prepare, file, prosecute and maintain all Clearside Patent Rights in Clearside's name in the Territory. Clearside will: (i) instruct such patent counsel to provide REGENXBIO with copies of all filings and formal correspondences relating to the Clearside

Patent Rights related to use of the Clearside Device for delivery of an AAV Active Substance in the Field to and from the United States Patent and Trademark Office and any other patent office (including copies of each patent application, office action, response to office action, request for terminal disclaimer, and request for reissue or reexamination of any patent or patent application) and (ii) keep REGENXBIO advised of the status of actual and prospective patent filings related to use of the Clearside Device for delivery of an AAV Active Substance in the Field. Clearside will give REGENXBIO the opportunity to provide and will reasonably consider comments on the preparation, filing, prosecution and maintenance of the Clearside Patent Rights related to use of the Clearside Device for delivery of an AAV Active Substance in the Field. Each Party will treat any consultation regarding the preparation, filing, prosecution and maintenance of the Clearside Patent Rights, along with any information disclosed by each Party in connection therewith (including any information concerning patent expenses), as Confidential Information. If Clearside elects not to continue to seek or maintain any Clearside Patent Rights related to use of the Clearside Device for delivery of an AAV Active Substance in the Field, then: (a) to the extent REGENXBIO is the sole exclusive licensee of such Clearside Patent Rights (including, for clarity, to the extent the subject matter of the Clearside Patent Rights relates to the use of the Clearside Device for delivery of an AAV Active Substance in the Field), Clearside will provide REGENXBIO with timely notice and will provide REGENXBIO with a reasonable opportunity to assume responsibility for the continued prosecution and maintenance of such Clearside Patent Rights, or (b) to the extent REGENXBIO is not the sole exclusive licensee of such Clearside Patent Rights, Clearside will provide REGENXBIO with timely notice and REGENXBIO and the other exclusive licensees will negotiate in good faith regarding the assumption of responsibility for the continued prosecution and maintenance of such Clearside Patent Rights.

7.1.3. **Information Sharing**. Clearside (if Clearside or EGT Licensor is the prosecuting party under Section 7.1.1 or Section 7.1.2) or REGENXBIO (if REGENXBIO or an Affiliate or Sublicensee is the prosecuting party under Section 7.1.1 or Section 7.1.2) (as applicable, the "**Prosecuting Party**"), will: (i) instruct such patent counsel to provide the other Party (the "**Non-Prosecuting Party**") with copies of all filings and formal correspondences relating to such Clearside Patent Rights to and from the United States Patent and Trademark Office and any other patent office (including copies of each patent application, office action, response to office action, request for terminal disclaimer, and request for reissue or reexamination of any patent or patent application) and (ii) keep the Non-Prosecuting Party advised of the status of actual and prospective patent filings related to use of the Clearside Device for delivery of an AAV Active Substance in the Field. The Prosecuting Party will give the Non-Prosecuting Party the opportunity to provide and will reasonably consider comments on the preparation, filing, prosecution and maintenance of such Clearside Patent Rights. Each Party will treat any consultation regarding the preparation, filing, prosecution and maintenance of the Clearside Patent Rights, along with any information disclosed by each Party in connection therewith (including any information concerning patent expenses), as the other Party's Confidential Information.

7.2. **Enforcement of Rights**.

7.2.1. **Notification**. In the event that either Party becomes aware of any actual or threatened infringement of any Clearside Patent Right in the Territory by a Third Party, such Party

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will promptly notify the other Party in writing and will provide any information available to such Party relating to such infringement.

7.2.2. **Infringement of Clearside Patents.** Clearside will generally have the first right but not the obligation, to enforce the Clearside Patent Rights, including in the Field, in the Territory. Notwithstanding the foregoing, REGENXBIO will have the first right but not the obligation to enforce the Clearside Patent Rights to the extent any enforcement action solely alleges infringement of a Clearside Patent Right by the use of the Clearside Device for delivery of an AAV Active Substance in the Field in the Territory. The Party with such first right will notify the other Party of its election within [***] after notification of such Clearside Patent Right infringement pursuant to Section 7.2.1 above. In the case where Clearside has the first right to enforce the Clearside Patent Rights and elects not to pursue such action: (a) if REGENXBIO is the sole exclusive licensee with respect to such Clearside Patent Rights, REGENXBIO will have the right, but not the obligation, to commence a suit or take action relating to such infringement, subject to the terms of the Emory/Georgia Tech Agreement; or (b) if REGENXBIO is not the sole exclusive licensee with respect to such Clearside Patent Rights, REGENXBIO and the other sole exclusive licensees shall negotiate in good faith regarding the commencement of any suit or the taking of any action relating to such infringement, subject to the terms of the Emory/Georgia Tech Agreement. The Party not bringing an action with respect to Clearside Patent Right will be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party will at all times cooperate fully with the enforcing Party. Additionally, the Party not bringing an action under the Clearside Patent Rights may have an opportunity to participate in such action, at its sole cost and expense, to the extent that the Parties may mutually agree at the time the enforcing Party elects to bring such action hereunder and, whether or not the Party not bringing the action elects to participate, the Party bringing the action will provide regular updates on the status of the action to the Party not bringing the action. If the enforcing Party recovers monetary damages from any Third Party in a suit or action for infringement of Clearside Patent Rights, such recovery will be allocated: (x) first to the repayment of out-of-pocket costs and expenses of the Party(ies) with respect to the action (on a pro rata basis); (y) second, if such suit is related to EGT Patent Rights, to the payment of any amounts required to be paid to the EGT Licensor under the Emory/Georgia Tech Agreement; and (z) if Clearside (i) is not the enforcing Party, any remaining damages will be treated as Net Sales of Covered Product under this Agreement or, (ii) is the enforcing Party, any remaining damages will be retained by Clearside; provided, however, that, if Clearside is the enforcing party and such enforcement is not related to use of the Clearside Device for delivery of an AAV Active Substance in the Field, such remaining damages shall be retained by Clearside. In any action, suit or proceeding instituted under this Section 7.2, the Parties will cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party initiating such action, suit or proceeding, the other Party will join such action, suit or proceeding if necessary to establish standing in such action, suit or proceeding, and may be represented using counsel of its own choice, at such initiating Party's expense, or assign the right to enforce the patents to the Party initiating such action. Neither Party will have the right to settle any patent infringement litigation under this Section 7.2 in a manner that admits the invalidity or unenforceability of the other Party's Patent Rights or imposes on the other Party restrictions or obligations, without the written consent of such other Party (which will not be unreasonably withheld).

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

7.3. **Privileged Information**. Neither Party will be required to provide legally privileged information relating to any infringement or other matter contemplated under this Article 7 until procedures and documentation reasonably acceptable to such Party are in place to protect such privileged information.

7.4. **Patent Term Extension and Supplementary Protection Certificate**. The Parties will cooperate regarding patent term extensions for any Patent Rights covering Joint Inventions and for Clearside Patent Rights covering a Covered Product in the Field and Territory, including the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable. In the event that the Parties determine to apply for any patent term extension or supplementary protection certificate for any Patent Rights covering Joint Inventions and Clearside Patent Rights covering a Covered Product in the Field and Territory, each Party shall provide prompt and reasonable assistance, including taking such action as patent holder or co-owner as is required under any Applicable Law to obtain such extension or supplementary protection certificate.

7.5. **Ownership of Intellectual Property**.

7.5.1. **Background IP**. Subject to the licenses granted by Clearside pursuant to this Agreement, each Party owns and will continue to own all Intellectual Property: (a) owned or Controlled by such Party as of the Effective Date, or (b) except as set forth in Section 7.5.2, that are Invented solely by Representatives of such Party or its Affiliates.

7.5.2. **Inventions**. Any such Intellectual Property Invented in the course of performing Development assistance pursuant to Section 4.2.4 shall be (a) jointly owned by Clearside and REGENXBIO to the extent related to the combined use of Clearside Device and an AAV Active Substance ("**Joint Inventions**"); (b) owned solely by REGENXBIO to the extent related to an AAV Active Substance without the use of Clearside Device ("**REGENXBIO Inventions**"); (c) owned solely by Clearside to the extent related to the use of the Clearside Device alone or in combination with any substance other than an AAV Active Substance for use in the Field ("**Clearside Inventions**"). With respect to Exploitation of Joint Inventions outside the scope of the Commercial License, the Parties shall (i) first, negotiate in good faith for one or both Parties to obtain ownership or an exclusive license to the other Party's interest in all or a portion of such Joint Invention and (ii) subject to any transaction contemplated by the foregoing clause (i), neither Party shall be permitted to sublicense such Joint Invention without the other Party's prior written consent, not to be unreasonably withheld. Each Party agrees to execute any and all further instruments, forms of assignment or other documents, and take such further actions, as the other may reasonably request, in order to give effect to these ownership provisions in connection with REGENXBIO Inventions and Clearside Inventions.

8. CONFIDENTIALITY

8.1. **Protection of Confidential Information**. Except to the extent expressly authorized by this Agreement, the Parties agree that each Party (the "**Receiving Party**") receiving any Confidential Information of the other Party (the "**Disclosing Party**") will not disclose or

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disseminate Confidential Information of the Disclosing Party to any Third Party unless expressly permitted hereunder, and will not use such Confidential Information for any purpose other than in performing the Receiving Party's obligations or exercising the Receiving Party's rights hereunder. In addition, the Receiving Party will take reasonable steps to protect the Confidential Information of the Disclosing Party from unauthorized use or disclosure, which steps will be no less than those the Receiving Party takes to protect its own confidential and/or proprietary material of a similar nature. The foregoing obligations will apply equally to all copies, extracts and summaries of the Disclosing Party's Confidential Information. The obligations in this Section 8.1 will apply for a period of [***] after disclosure of the Confidential Information.

8.2. **Certain Permitted Disclosures**.

8.2.1. **Disclosure of Confidential Information.**

(a) Disclosure to Representatives. Notwithstanding the foregoing and subject to Section 8.2.1(b), the Receiving Party may disclose Confidential Information of the Disclosing Party to [***] (collectively, "**Representatives**") who have a need to know such Confidential Information in connection with the performance of the Receiving Party's obligations or the exercise of the Receiving Party's rights under this Agreement; *provided* that such Representative is bound by a confidentiality agreement with such Receiving Party that contains terms substantially similar to this Article 8.

(b) Disclosures under Applicable Law. Notwithstanding the foregoing, each Party may disclose Confidential Information of the other Party to a Third Party to the extent such disclosure is reasonably necessary to prepare, file or prosecute Patent Rights (consistent with all other limitations set forth in this Agreement), prepare submissions to Regulatory Authorities, prosecute or defend litigation, comply with Applicable Law or submit information to Governmental Authorities provided that such Third Party, if not a governmental entity, enters into a confidentiality agreement with such Party that contains terms no less restrictive than this Article 8; provided, however, that if a Party intends to make any such disclosure of the Disclosing Party's Confidential Information, to the extent it may legally do so it will give reasonable advance notice to the Disclosing Party of such disclosure to permit the Disclosing Party to use its reasonable endeavors to secure confidential treatment of such Confidential Information prior to disclosure (whether through protective orders or otherwise).

8.2.2. **Disclosure of Agreement Terms to Certain Third Parties**. The Parties may disclose only the terms or conditions of this Agreement (but not any Confidential Information of the other Party) on a need-to-know basis (a) to its legal and financial advisors to the extent such disclosure is reasonably necessary in connection with such Party's activities as expressly permitted by this Agreement, and (b) to a Third Party in connection with: (i) an actual or potential equity investment in or by, or underwriting by, such Third Party, (ii) an actual or potential merger, consolidation or similar transaction involving such Third Party, (iii) the sale or potential sale of all or substantially all of the assets of the Party or substantially all of the assets related to this Agreement to such Third Party or (iv) a potential or actual sublicensee hereunder and/or collaborator in relation to any Commercial License Terms; provided that such Party will make

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such disclosure only under appropriate conditions of confidentiality by the Third Party of confidentiality and non-use at least equivalent in scope to those set forth in this Article 8. Notwithstanding the foregoing, Clearside may provide an unredacted copy of this Agreement to the EGT Licensor for the purpose of complying with the Emory/Georgia Tech Agreement.

8.3. **Securities Law Filings and Other Disclosures**. Notwithstanding any provision of this Agreement to the contrary, either Party may disclose the terms of this Agreement to the extent required, in the advice of such Party's legal counsel, to comply with Applicable Law, including the rules and regulations promulgated by the SEC, AMF or any equivalent governmental agency in any country, or the rules of any stock exchange in which a Party is listed. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 8.3, the Parties will consult with one another on the terms of this Agreement to be redacted in making any such disclosure, with the filing Party giving due consideration to the other Party's input. Further, if a Party discloses this Agreement or any of the terms hereof in accordance with this Section 8.3, such Party will, at its own expense, maintain as confidential the portions of this Agreement and such other terms, as may be reasonably requested by the other Party provided, however, that the Parties agree that the financial terms in this Agreement must be redacted from any public disclosure except to the extent they have been previously disclosed in a press release or other publication pursuant to the Parties' mutual agreement.

8.4. **Public Announcements**. The Parties will agree upon the content of one (1) or more press releases, the release of which the Parties will coordinate after the Effective Date. Except as may be expressly permitted under Section 8.3, neither Party will make any other public announcement regarding this Agreement without the prior written approval of the other Party. Notwithstanding the foregoing, REGENXBIO and its Affiliates and its and their Sublicensees will have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding Covered Product provided such disclosure: (a) does not contain non-public or Confidential Information related to any Clearside Device; and (b) does not contain any claims relating to the use of the Clearside Device in a manner that is contrary to, or would have an adverse effect on, any Regulatory Approval held by Clearside related to the Clearside Device. For the sake of clarity, nothing in this Agreement will prevent either Party from making any public disclosure relating to this Agreement or the Clearside Device if the contents of such public disclosure have previously been made public other than through a breach of this Agreement by the issuing Party or its Affiliates.

8.5. **Return of Confidential Information**. Upon expiration or termination of this Agreement, the Receiving Party will promptly return all of the Disclosing Party's Confidential Information, including all copies thereof in any medium, except that the Receiving Party may retain one archival copy for its legal files for record keeping purposes only.

9. REPRESENTATIONS AND WARRANTIES.

9.1. **Mutual Representations and Warranties**. Each of Clearside and REGENXBIO hereby represents and warrants to the other Party that as of the Effective Date:

9.1.1. it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;

9.1.2. the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite action under the provisions of its charter, bylaws and other organizational documents, and does not require any action or approval by any of its shareholders or other holders of its voting securities or voting interests;

9.1.3. it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

9.1.4. this Agreement has been duly executed and is a legal, valid and binding obligation on each Party, enforceable against such Party in accordance with its terms;

9.1.5. the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of or default under any binding obligation existing as of the Effective Date; and

9.1.6. it does not currently employ any Person debarred by the FDA (or subject to a similar sanction of foreign equivalent), or any Person that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of foreign equivalent), in any capacity in connection with Development, Manufacture or Commercialization of Clearside Devices or Covered Product (as applicable).

9.2. **Representations and Warranties of Clearside**. Clearside hereby represents and warrants to REGENXBIO that as of the Effective Date:

9.2.1. to its Knowledge, the Patent Rights listed in Exhibit A constitute all of the Patent Rights Controlled by Clearside or its Affiliates that is or will be needed to Exploit Clearside Devices;

9.2.2. (a) Clearside and its Affiliates are the sole and exclusive owner of, or otherwise Control, the Clearside Technology, all of which are free and clear of any liens, charges and encumbrances, except for a lien granted to Silicon Valley Bank, as collateral agent under the Second Amended and Restated Loan and Security Agreement dated as of May 14, 2018, as amended by that certain Consent and First Amendment to Second Amended and Restated Loan and Security Agreement dated as of July 3, 2019 and that certain Consent and Second Amendment to Second Amended and Restated Loan and Security Agreement dated on or about the date hereof and as may be further amended from time to time (the "**SVB Lien**"), and such liens, charges and encumbrances that do not adversely affect or diminish Clearside's ability to perform its obligations or grant any license under this Agreement, (b) neither any license granted by Clearside or its Affiliates to any Third Party, nor any license granted by any Third Party to Clearside or its Affiliates conflicts with the license grants and/or contemplated license grants to REGENXBIO hereunder and (c) Clearside is entitled to grant all rights, options and licenses under the Clearside Technology existing as of the Effective Date that it purports to grant or that are otherwise

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anticipated to be granted to REGENXBIO under this Agreement, including, to its Knowledge, for the Exploitation of Covered Product;

9.2.3. there are no agreements pursuant to which Clearside has been granted any rights in, to or under the Clearside Technology except for the Emory/Georgia Tech Agreement;

9.2.4. to its Knowledge, after consultation with employees of Clearside having responsibility for or involvement in patent matters: (a) the Clearside Patent Rights existing as of the Effective Date are valid and enforceable patents, (b) no Third Party has challenged or threatened to challenge the extent, validity or enforceability of any Clearside Patent Right, and (c) Clearside has not received any written notice of, or has Knowledge of, any claim or threatened claim by any Third Party (i) asserting the misuse or non-infringement of any of the Clearside Technology, or (ii) challenging Clearside's Control of any of the Clearside Technology;

9.2.5. (a) Clearside has, to its Knowledge, after consultation with employees of Clearside having responsibility for or involvement in patent matters: complied with all applicable disclosure requirements of the United States Patent and Trademark Office or any analogous foreign Governmental Authority, in connection with the prosecution and maintenance of the Clearside Patent Rights existing as of the Effective Date, (b) the pending applications included in Clearside Patents Rights are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law, and Clearside or EGT Licensor has presented all relevant references, documents and information of which it and the inventors are aware to the relevant patent examiner at the relevant patent office and (c) it or EGT Licensor has timely paid all filing and renewal fees payable with respect to any such Clearside Patent Rights;

9.2.6. Clearside and its Affiliates have, to Clearside's Knowledge, taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Clearside Know-How existing as of the Effective Date;

9.2.7. to Clearside's Knowledge, the information provided by Clearside to REGENXBIO regarding the Clearside Technology is true and correct in all material respects and Clearside has no Knowledge of any material adverse information with respect to the Clearside Technology intended to be used in connection with the Exploitation of Covered Product that has not been disclosed to REGENXBIO;

9.2.8. to Clearside's Knowledge, there is no (a) claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or threatened against Clearside or any of its Affiliates that would materially alter REGENXBIO's rights or Clearside's obligations hereunder, or (b) judgment or settlement against or owed by Clearside or any of its Affiliates; in each case in connection with the Clearside Technology or relating to the transactions contemplated by this Agreement;

9.2.9. to Clearside's Knowledge, the use, practice or application by REGENXBIO or Clearside (or their respective Affiliates or sublicensees) of any Clearside Technology as contemplated under this Agreement does not infringe any valid claim of an issued and unexpired patent of any Third Party (excluding, for clarity, any potential infringement that might arise solely

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as a result of the combination of any Clearside Technology with any other technology or intellectual property);

9.2.10. all individuals who are current or former officers, employees, agents, advisors, consultants, contractors or other representatives of Clearside or any of its Affiliates who are inventors of any Clearside Technology have executed and delivered to Clearside or the applicable Affiliate a valid and enforceable assignment; provided, however, that for the avoidance of doubt, this Section 9.2.10 shall not apply to Intellectual Property licensed to Clearside under the Emory/Georgia Tech Agreement;

9.2.11. to Clearside's Knowledge, the development of Clearside Technology has been conducted in compliance in all material respects with all Applicable Law;

9.2.12. it has not employed (and, to Clearside's Knowledge, after making due and appropriate inquiry, has not used a contractor or consultant that has employed) any Person debarred by the FDA (or subject to a similar sanction of foreign equivalent), or any Person that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of foreign equivalent), in any capacity in connection with this Agreement; and

9.2.13. it has not entered into any definitive agreement or term sheet that would (with respect to a term sheet, if the transactions thereunder are carried out) result in a Change of Control of Clearside.

9.3. **Representations and Warranties of REGENXBIO**. REGENXBIO hereby represents and warrants to Clearside that as of the Effective Date it has or has the ability to obtain the financial and other capabilities reasonably necessary to discharge its obligations under this Agreement.

9.4. **Additional Covenants**.

9.4.1. Clearside and its Affiliates will not: (a) license, sell, assign or otherwise transfer Clearside Technology (or agree to do any of the foregoing) in a manner that conflicts with the rights granted to REGENXBIO hereunder; (b) incur or permit to exist, with respect to any Clearside Technology, any additional lien, encumbrance, charge, security interest, mortgage, liability, grant of license to Third Parties or other restriction (including in connection with any indebtedness) which conflicts with the rights granted to REGENXBIO hereunder; or (c) during the term of this Agreement, enter into any material agreements or contracts that would be inconsistent with its obligations under this Agreement; and

9.4.2. Clearside and its Affiliates will: (a) make all payments required to be made under the Emory/Georgia Tech Agreement; (b) not commit any act or permit the occurrence of any omission that it Knows would constitute a material breach of the Emory/Georgia Tech Agreement or result in the termination thereof prior to the expiration thereof in accordance with the terms thereof; (c) not amend, modify or waive any rights under the Emory/Georgia Tech Agreement in such a way as to materially adversely affect REGENXBIO's rights or obligations under this Agreement, or terminate the Emory/Georgia Tech Agreement, without REGENXBIO's

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prior written consent; (d) promptly notify REGENXBIO after receiving Knowledge of any breach of the Emory/Georgia Tech Agreement by any party thereto, the occurrence of which gives rise to a right of termination thereunder by any party thereto or causes automatic termination thereunder, and (e) use commercially reasonable efforts to enforce the terms of the Emory/Georgia Tech Agreement against each other party thereto.

9.4.3. Each Party and its Affiliates (and with respect to REGENXBIO, its Sublicensees) shall conduct the Development, Manufacture (if applicable) and Commercialization of the Clearside Devices and Covered Product (as applicable) in accordance with all Applicable Laws, including without limitation current governmental regulations concerning good laboratory practices, good clinical practices and GMP.

9.4.4. Each Party will maintain as and when necessary the financial and other capabilities reasonably necessary to discharge its obligations under this Agreement.

9.5. **Bring Downs to Representations and Warranties of Clearside**. If, upon the date of Clearside's receipt of a written inquiry from REGENXBIO in advance of REGENXBIO's anticipated exercise of the Option, Clearside has Knowledge of any event, condition, fact or circumstance occurring since the Effective Date that, if existing or occurring on or prior to the Effective Date, would have rendered inaccurate any of the representations and warranties set forth in this Article 9 (any such event, condition, fact or circumstance, an "**Update**"), Clearside will promptly thereafter deliver to REGENXBIO an amendment or supplement to such representations and warranties with respect to such Update. Following the delivery of such supplement or amendment to REGENXBIO, the representations and warranties in this Article 9 will be deemed supplemented and amended as provided in this Section 9.5 for all purposes hereunder (including for purposes of indemnification set forth in Section 11.3). For the avoidance of doubt, the existence of an Update shall not be construed as a breach of this Agreement by Clearside.

9.6. **Disclaimer**. THE FOREGOING REPRESENTATIONS AND WARRANTIES OF EACH PARTY ARE IN LIEU OF ANY OTHER REPRESENTATIONS AND WARRANTIES RELATED TO ANY SUBJECT MATTER OF THIS AGREEMENT, WHETHER ORAL OR WRITTEN, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, TITLE, NON-INFRINGEMENT OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW.

10. TERM AND TERMINATION.

10.1. **Term**.

10.1.1. The term of this Agreement will commence upon the Effective Date and, unless sooner terminated as provided in this Article 10, will expire on the earlier to occur of: (a) expiry of the Option Term (if REGENXBIO does not exercise the Option) and (b) on a country-by-country, Covered Product-by-Covered Product basis, expiry of the Royalty Term (the "**Term**"). For the avoidance of doubt, the term of any Commercial Supply Agreement or Quality Agreement

will be governed by the terms of such agreement and will not be affected by termination of this Agreement unless otherwise set forth in the Commercial Supply Agreement or Quality Agreement.

10.1.2. The term of the Commercial License (and associated Commercial License Terms) will begin on the Option Exercise Date and if not earlier terminated in accordance with the terms of this Article 10, continue until the expiration of the relevant Royalty Term. Following the expiration of the Royalty Term for Covered Product in a country, the grants in Section 3.1 will become fully-paid, royalty-free, perpetual and irrevocable for Covered Product in such country.

10.2. **Termination**.

10.2.1. **Material Breach**. In the event that either Party (the "**Breaching Party**") is in material breach in the performance of any of its material obligations under this Agreement in addition to any other right and remedy the other Party (the "**Non-Breaching Party**") may have, the Non-Breaching Party may terminate this Agreement in its entirety by providing [***] (the "**Notice Period**") prior written notice (the "**Termination Notice**") to the Breaching Party and specifying the breach and its claim of right to terminate; provided that: (a) the termination will not become effective at the end of the Notice Period if the Breaching Party cures the breach specified in the Termination Notice during the Notice Period; provided, further, that, to the extent such breach is curable, the Breaching Party's cure right will be extended for up to an additional [***] if the Breaching Party commences actions to cure such breach within the Notice Period and thereafter diligently continues such actions; and (b) if either Party initiates a dispute resolution procedure under Section 12.11 as permitted under this Agreement within the Notice Period to resolve the dispute for which termination is being sought and is diligently pursuing such procedure, the termination will become effective only if such breach remains uncured for [***] after the resolution of the dispute through such dispute resolution procedure.

10.2.2. **Patent Challenge**. Unless unenforceable under Applicable Law, Clearside may terminate this Agreement upon written notice to REGENXBIO if REGENXBIO, its Affiliates (excluding an Acquirer) or Sublicensees, individually or in association with any other person or entity, commences a legal action challenging the validity, enforceability or scope of any Clearside Patent Rights or EGT Licensed Technology in a court or other governmental agency of competent jurisdiction, including a reexamination or opposition proceeding and, with respect to any action commenced by a Sublicensee, (a) such proceeding is not terminated within [***] after REGENXBIO's receipt of written notice from Clearside or (b) REGENXBIO does not terminate the Sublicense within such [***] period.

10.2.3. **Termination by REGENXBIO**. REGENXBIO may terminate this Agreement in respect of one or more Covered Products:

(a) in the Territory immediately upon written notice to Clearside that, after exercising Commercially Reasonable Efforts, REGENXBIO in good faith determines that it is not advisable for REGENXBIO to continue to Develop or Commercialize Covered Product due to safety or efficacy concerns; or

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(b) in the Territory or on a country-by-country basis, for any or no reason, upon [***] prior written notice to Clearside.

10.2.4. **Termination for Insolvency**. In the event that either Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [***] after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [***] of the filing thereof or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course (the events described in subsections (a) though (g), collectively, "**Insolvency Proceedings**"), then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

10.2.5. **Consequences of Termination.**

(a) **Termination in the Entire Territory**. In the event of a termination of this Agreement for the entire Territory with respect to Covered Product for any reason, all rights and licenses granted by either Party with respect to such Covered Product hereunder will immediately terminate.

(b) **Termination in a Terminated Territory**. In the event of a termination of this Agreement with respect to Covered Product for a Terminated Territory (but not in the case of any termination of this Agreement in its entirety):

(i) REGENXBIO will not, and will not permit any of its Affiliates or any of its and their Sublicensees or Distributors to Exploit Clearside Devices for use with Covered Product directly or indirectly (A) to any Person for commercial use in the Terminated Territory or (B) to any Person in the Territory that REGENXBIO knows, or any of its Affiliates or any of its or their Sublicensees or Distributors knows, is likely to Exploit Clearside Devices for use with Covered Product for commercial use in the Terminated Territory or assist another Person to do so.

(ii) Notwithstanding the termination of REGENXBIO's licenses and other rights under this Agreement, solely upon termination of this Agreement by REGENXBIO because of a Clearside material breach or Clearside Insolvency Proceeding, REGENXBIO will have the nonexclusive right for [***] after the effective date of such termination to sell or otherwise dispose of all Clearside Devices for use with Covered Product then in its inventory and any in-progress inventory as though this Agreement had not terminated, and such sale or disposition will not constitute infringement of Clearside's or its Affiliates' Patent Rights or other intellectual property or other proprietary rights. For the avoidance of doubt, REGENXBIO will continue to make payments thereon as provided in Section 6.3 and 6.4 (as if this Agreement had not terminated).

(c) **Emory/Georgia Tech Agreement**. In addition, if the Emory/Georgia Tech Agreement terminates for any reason, REGENXBIO shall, unless this

Agreement also terminates, from the effective date of such termination, automatically become a direct licensee of Emory/Georgia Tech with respect to the rights sublicensed to REGENXBIO by Clearside, provided REGENXBIO did not cause the termination of the Emory/Georgia Tech Agreement. In such case, REGENXBIO agrees to comply with all the terms of the Emory/Georgia Tech Agreement and assumes the responsibilities of Clearside thereunder, to the extent applicable to the rights granted to REGENXBIO under this Agreement.

10.3. **Remedies**. Except as otherwise expressly provided herein, termination of this Agreement in whole or in part in accordance with the provisions hereof will not limit remedies that may otherwise be available in law or equity.

10.4. **Survival of Certain Obligations**.

10.4.1. Expiration or termination of this Agreement in whole or in part will not relieve the Parties of any obligation that accrued before such expiration or termination.

10.4.2. The following provisions will survive expiration or termination of this Agreement: Articles 1 (Definitions) (to the extent necessary for interpretation of any surviving provisions), 6 (Payments to Clearside) (to the extent of payment obligations that accrued prior to the effective date of termination), 8 (Confidentiality), 11 (Limitation of Liability, Indemnification and Insurance), and 12 (Miscellaneous), and Sections 4.2.2 (Recalls, Suspensions or Withdrawals), 7.5 (Ownership of Intellectual Property), 10.2.5 (Consequences of Termination), 10.3 (Remedies), and 10.4 (Survival of Certain Obligations). For the avoidance of doubt, any other Section that explicitly states it survives expiration or termination of this Agreement will so survive.

10.4.3. If this Agreement is terminated with respect to Covered Product for a Terminated Territory but not in its entirety, then following such termination the foregoing provisions of this Agreement will remain in effect with respect to the Terminated Territory (to the extent they would survive and apply in the event the Agreement expires or is terminated in its entirety or as otherwise necessary for any of REGENXBIO and its Affiliates and its and their Sublicensees to exercise their rights in the Territory) and all provisions not surviving in accordance with the foregoing will terminate upon termination of this Agreement with respect to such Covered Product for the Terminated Territory and be of no further force and effect (and for the avoidance of doubt all provisions of this Agreement will remain in effect for such Covered Product with respect to all countries in the Territory other than the Terminated Territory).

11. LIMITATION ON LIABILITY, INDEMNIFICATION AND INSURANCE.

11.1. **No Consequential Damages**. EXCEPT WITH RESPECT TO LIABILITY ARISING (I) FROM A BREACH OF ARTICLE 8 or SECTION 3.5, (II) FROM ANY WILLFUL MISCONDUCT OR INTENTIONALLY WRONGFUL ACT (INCLUDING FRAUD AND FRAUDULENT MISREPRESENTATION), (III) TO THE EXTENT SUCH PARTY MAY BE REQUIRED TO PROVIDE INDEMNIFICATION UNDER SECTION 11.2 OR 11.3, THEN, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT WILL EITHER PARTY OR ITS AFFILIATES BE LIABLE UNDER THIS AGREEMENT FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES,

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WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE SUFFERED BY EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES OR REPRESENTATIVES.

11.2. **Indemnification by REGENXBIO**. REGENXBIO will indemnify, defend and hold harmless Clearside, its Affiliates, the EGT Licensors, and each of its and their respective employees, officers, directors and agents (each, a "**Clearside Indemnified Party**") from and against any and all liability, loss, damage, expense (including reasonable attorneys' fees and expenses) and cost (collectively, a "**Liability**") that the Clearside Indemnified Party may incur or be required to pay to one or more Third Parties to the extent resulting from or arising out of:

11.2.1. [***];

11.2.2. [***]; or

11.2.3. [***];

provided that such indemnity will not apply to the extent Clearside has an indemnification obligation pursuant to Section 11.3 for such Liability, as to which Liability each Party will indemnify the other to the extent of their respective liability for such Liability.

11.3. **Indemnification by Clearside**. Clearside will indemnify, defend and hold harmless REGENXBIO, its Affiliates, sublicensees, contractors, distributors and each of its and their respective employees, officers, directors and agents (each, a "**REGENXBIO Indemnified Party**") from and against any and all Liabilities that the REGENXBIO Indemnified Party may incur or be required to pay to one or more Third Parties to the extent resulting from or arising out of:

11.3.1. [***];

11.3.2. [***]; or

11.3.3. [***]; provided that such indemnity will not apply to the extent REGENXBIO has an indemnification obligation pursuant to Section 11.2 for such Liability, as to which Liability each Party will indemnify the other to the extent of their respective liability for such Liability.

11.4. **Procedure**.

11.4.1. **Notice**. Each Party will notify the other Party in writing in the event it becomes aware of a claim for which indemnification may be sought hereunder. In the event that any Third Party asserts a claim or other proceeding with respect to any matter for which a Party (the "**Indemnified Party**") is entitled to indemnification hereunder (a "**Third Party Claim**"), then the Indemnified Party will promptly notify the Party obligated to indemnify the Indemnified Party (the "**Indemnifying Party**") thereof; *provided*, *however*, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party will relieve the Indemnifying Party from

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any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

11.4.2. **Control**. The Indemnifying Party will have the right, exercisable by notice to the Indemnified Party within [***] after receipt of notice from the Indemnified Party of the assertion of any Third Party Claim, to participate in and to assume the defense thereof with counsel of its choice, which counsel will be reasonably acceptable to the Indemnified Party; provided that an Indemnified Party will have the right to retain its own counsel at its own expense.

11.4.3. **Settlement**. The Indemnifying Party will not be liable for any damages with respect to any Third Party Claim that is settled or compromised by the Indemnified Party without the Indemnifying Party's prior written consent, not to be unreasonably withheld, conditioned or delayed. No offer of settlement, compromise or settlement by the Indemnifying Party will be binding on an Indemnified Party without the Indemnified Party's prior written consent (not to be unreasonably withheld, conditioned or delayed), unless such settlement or compromise (i) fully releases the Indemnified Party without any liability, loss, cost or obligation, and (ii) admits no liability, wrongdoing or other admission against interest on the part of the Indemnified Party.

11.5. **Insurance.**

11.5.1. **In General**. Each Party will have and maintain, at its sole cost and expense, adequate liability insurance, (including product liability insurance, employers liability, statutory Workers Compensation and contractual liability) to protect against potential liabilities and risk arising out of activities to be performed under this Agreement and any agreement related hereto and upon such terms (including coverages, deductible limits and self-insured retentions) as are customary in the pharmaceutical industry generally for the activities to be conducted by such Party under this Agreement, but in no event less than [***] per occurrence for personal injury and [***] per occurrence for property damage. Such liability insurance program will insure against all types of liability, including personal injury, physical injury or property damage arising out of such Party's activities hereunder. All insurance coverage required under this Agreement shall be primary to any coverage carried by an Indemnified Party, shall waive all rights of subrogation against any additional insured and shall be placed with insurers whose A.M. Best's rating is at least [***]. Such liability insurance program will require any insurance carrier to provide the Parties with no less than [***] written notice of any change in the terms or coverage of the policy or its cancellation and, if written on a "claims made" basis, either Party will provide coverage for [***] after termination of this Agreement. This Section 11.5 will not create any limitation on the Parties' liability under this Agreement. Such insurance information will be kept in confidence in the same manner as any other Confidential Information disclosed by the Parties hereunder.

12. MISCELLANEOUS.

12.1. **Assignment**. The rights arising under this Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed; provided, however, that either Party may assign such rights without the consent of the other Party (a) to any of its Affiliates; or (b) to any Person

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acquiring all or substantially all of its assets or business to which this Agreement relates, whether by merger, sale of assets, operation of law or otherwise. In all cases, the assigning Party will provide the other Party with prompt written notice of any such assignment. No assignment of rights under this Agreement will act as a novation. Any assignment not in accordance with this Section 12.1 will be void.

12.2. **Rights in Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement by Clearside are and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that REGENXBIO, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Clearside under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, REGENXBIO will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in REGENXBIO's possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon REGENXBIO's written request therefor, unless Clearside elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of Clearside upon written request therefor by REGENXBIO.

12.3. **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

12.4. **Force Majeure**. Any delay in performance by any Party under this Agreement will not be considered a breach of this Agreement if and to the extent caused by occurrences beyond the reasonable control of the Party affected, potentially including but not limited to acts of God, embargoes, governmental restrictions, strikes (but not strikes of the delayed Party) or other concerted acts of workers, fire, flood, earthquakes, explosions, riots, wars, civil disorder, rebellion or sabotage. The Party suffering such occurrence will immediately notify the other Party, and any time for performance hereunder will be extended by the actual time of delay caused by the occurrence.

12.5. **Notices**. All communications required to be made under this Agreement will be sent to the addresses set out below, or to such other addresses as may be designated by one Party to the other by notice pursuant hereto, by (a) internationally recognized overnight courier which notice shall be effective the next Business Day; (b) prepaid registered or certified US mail, return receipt requested, which notice shall be effective seven (7) days of deposit; or (c) email, which notice shall be effective on the next Business Day, provided such notice is followed by either of the notice methods set forth in subclauses (a) and (b).

All correspondence to REGENXBIO will be addressed as follows:

REGENXBIO Inc.
9600 Blackwell Road
Suite 210
Rockville, MD 20850
Attention: Chief Executive Officer

with a copy to:

REGENXBIO Inc.
9600 Blackwell Road
Suite 210
Rockville, MD 20850
Attention: General Counsel
Email: [***]

All correspondence to Clearside will be addressed as follows:

Clearside Biomedical, Inc.
900 North Point Parkway, Suite 200
Alpharetta, GA 30005
Attention: CEO

with a copy to:

Clearside Biomedical, Inc.
900 North Point Parkway, Suite 200
Alpharetta, GA 30005
Attention: General Counsel

12.6. **Amendment**. No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

12.7. **Waiver**. No waiver by either Party hereto of any breach or default hereunder will be deemed a waiver as to any subsequent or similar breach or default. The failure of any Party to assert any of its rights under this Agreement or otherwise will not constitute a waiver of such rights.

12.8. **Severability**. If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same will not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such clause or portion thereof had never been contained in this Agreement, and there will be deemed substituted therefor such provision as will

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most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law.

12.9. **Headings**. The headings herein are for convenience purposes only and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.

12.10. **Governing Law**. This Agreement will be governed by the laws of the State of Delaware, without regard to its choice of law principles, provided, that the United Nations Convention on Contracts for the International Sale of Goods will not apply.

12.11. **Dispute Resolution**. Any dispute, controversy or claim that may arise relating to the terms of this Agreement, the interpretation thereof or the compliance of the Parties therewith will be referred to the CEO of Clearside and the CEO of REGENXBIO (or their respective designee who has the authority to make decisions on behalf of such Party) who will negotiate in good faith to resolve the dispute. If any dispute is not resolved by these individuals (or their designees) within [***] after such dispute is referred to them, or such longer period as they may mutually agree, either Party may resort to the federal courts of the State of Delaware for resolution of the dispute. Notwithstanding anything to the contrary in this Agreement, if either Party in its sole judgment believes that any such dispute could cause it irreparable harm, including disputes or matters related to intellectual property, such Party (i) will be entitled to seek equitable relief in order to avoid such irreparable harm and (ii) will not be required to follow the procedures set forth in this Section 12.11. The provisions of this Section 12.11 will survive the termination or expiration of this Agreement.

12.12. **Entire Agreement**. This Agreement, including any Exhibits hereto and thereto, constitute and contain the complete, final and exclusive understanding and agreement of the Parties and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof, including the Confidentiality Agreement which is hereby terminated effective as of the Effective Date. Notwithstanding the foregoing, unless and until the Option is exercised in accordance with Section 2.2 of this Agreement or the Technology Access Agreement is terminated in accordance with its terms, the Technology Access Agreement will remain in full force and effect.

12.13. **Independent Contractors**. Both Parties are independent contractors under this Agreement. Nothing herein contained will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

12.14. **Cumulative Rights**. The rights, powers and remedies hereunder will be in addition to, and not in limitation of, all rights, powers and remedies provided at law or in equity, or under any other agreement between the Parties. All of such rights, powers and remedies will be cumulative, and may be exercised successively or cumulatively.

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

12.15. **Counterparts**. This Agreement may be executed in two (2) counterparts, each of which will be an original and both of which will constitute together the same document. Counterparts may be signed and delivered by facsimile or PDF file, each of which will be binding when received by the applicable Party.

12.16. **Interpretation**. Unless the context of this Agreement otherwise requires: (a) words of one gender include the other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms "hereof," "herein," "hereby," and other similar words refer to this entire Agreement; (d) the words "include", "includes", and "including" when used in this Agreement will be deemed to be followed by the words "without limitation", unless otherwise specified; (e) the terms "Article" and "Section" refer to the specified Article and Section of this Agreement; and (f) the word "withheld" in the phrases "withheld unreasonably" or "unreasonably withheld" and other forms of such words, will be deemed to be followed by the words "conditioned or delayed," and (g) the use of "or" is not intended to be exclusive unless expressly indicated otherwise.

12.17. **No Third Party Rights or Obligations**. Notwithstanding a Clearside Indemnified Party, other than the EGT Licensors, or a REGENXBIO Indemnified Party's right to indemnification under Section 11.2 and 11.3 (which, for clarity, must be exercised through a Party and may not be exercised directly by such Persons), no provision of this Agreement will be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement; provided, however, that the EGT Licensors may directly enforce their rights hereunder. However, either Party may decide, in its sole discretion, to use one or more of its Affiliates to perform its obligations and duties hereunder, provided that such deciding Party will remain liable hereunder for the performance by any such Affiliates of any such obligations.

[Signature page follows.]

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

REGENXBIO INC.

By: /s/ Kenneth Mills

Name: Kenneth Mills

Title: President & CEO

CLEARSIDE BIOMEDICAL, INC.

By: /s/ George Lasezkay

Name: George Lasezkay

Title: CEO

EXHIBIT A
[***]

EXHIBIT B
[***]

EXHIBIT C
[***]

EXHIBIT D
[***]

EXHIBIT E
[***]

RELEASE AND SETTLEMENT AGREEMENT

This Release and Settlement Agreement ("**Agreement**") is entered into by and between Clearside Biomedical, Inc., a Delaware corporation (the "**Company**"), and Brion Raymond ("**Employee**") (collectively, the "**Parties**").

is Agreement provides the Employee with good and valuable consideration provided that the Employee first signs, and does not revoke, this Agreement according to its terms.

NOW, THEREFORE, in consideration of the agreements, representations, covenants and mutual promises contained herein and other good and valuable consideration recited, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. Employee's employment with the Company shall terminate on December 30, 2019 (the "**Last Date of Employment**"), although employee will be provided pay as if he worked through December 31, 2019. Employee expressly acknowledges and agrees that he has waived any right to notice as set forth in Paragraph 3 (or otherwise) of the February 20, 2018 Executive Employment Agreement, the Employment Agreement is not being renewed by the Company and Employee's employment is terminating on the Last Date of Employment. The Last Date of Employment will be processed as the effective date of Employee's termination for all purposes.

2. The Employee will receive, regardless of whether Employee signs this Agreement: (a) all base salary earned through the Last Date of Employment, less all applicable taxes and deductions, (b) all earned and accrued but unused vacation (that being 97 hours paid in the gross amount of $13,990.00, less applicable taxes and withholdings); and (c) payment for unreimbursed, covered business expenses incurred up to the Last Date of Employment in accordance with Company policy, all of which payments shall be made on the next regularly scheduled payroll date after the Last Date of Employment. Except for amounts and benefits set forth above, the Employee confirms that Employee has been paid in full for all wages, bonuses, commissions, severance, accrued vacation/PTO, reimbursable expenses and any other amounts or benefits due or owing to the Employee and that no further payment shall become due or owing to the Employee except as set forth in this Agreement.

3. Employee confirms by the signature below that the Employee has returned all property of the Company to the Company as of the Last Date of Employment, including, without limitation, all reports, files, memoranda, records, computer hardware and software, laptop computers and accessories, credit cards, telephone calling cards, card-key passes, identification badges, door, file, vehicle and other keys, computer access codes, disks and instructional manuals, calculators, cellular telephones, and other physical or personal property which have been provided for Employee's use in connection with employment with the Company. Notwithstanding anything to the contrary, the Company's obligation to provide Employee with the consideration specified in this Agreement shall be contingent upon Employee returning all Company property on or before the above date.

4. **Severance Benefits Offered by the Company.** Provided that the Employee first signs and does not revoke this Agreement, and subject to the Employee's continued compliance with the terms and conditions of the Agreement, in consideration of Employee's promises and releases contained in this Agreement, the Company agrees to provide the Employee with the following consideration and/or benefits (collectively, the "**Severance**"):

a. payment in an amount equal to twelve (12) months of Employee's current base pay in the gross amount of $300,000.00, less all applicable taxes and withholdings, to be paid in accordance with the Company's regularly scheduled payroll schedule with payment to begin on the Company's first payroll date that is operationally feasible after the Effective Date, as that term is defined in Section 23 below;

____ Employee Initials

payment to Employee of Employee's annual bonus, in the gross amount of $89,250.00, less applicable taxes and withholdings. Such bonus would be paid in 2020 at the typical time of annual bonus payouts; and

allow each Equity Award (to include Options and Restricted Stock Units) held by Employee to immediately vest and be exercisable to the extent such Equity Awards would have vested had Employee remained employed by the Company for a period of 12 months from the date of his termination. More specifically, the Equity Awards that will immediately vest and be exercisable consist of 45,833 Options at a strike price of $1.24; 40,000 Options at a strike price of $6.23; 56,666 Options at a strike price of $6.23; and 50,000 Restricted Stock Units. Employee can exercise the aforementioned Options on or before June 30, 2020 per the applicable Equity Incentive Plan(s).

5. In consideration of the Severance set forth in Section 4 above, the receipt and sufficiency of which is hereby acknowledged, Employee, on behalf of the Employee and the Employee's executors, heirs, administrators, assigns, and anyone claiming by, through, or under them, hereby irrevocably (except as specifically set forth below) and unconditionally releases and forever discharges the Company, its current, former and future parents, subsidiaries, affiliated companies, related entities, direct and/or indirect owners, stockholders, investors, employee benefit plans, or TriNet HR Corporation, and each of its and their current, former and future fiduciaries, predecessors, successors, officers, directors, managers, direct and/or indirect owners, stockholders, debt holders, agents, representatives, employees and assigns (collectively, the "**Releasees**") from any and all claims, causes of action, and liabilities as to any matter whatsoever up through the moment of the Employee's execution of this Agreement. The claims subject to this release include, but are not limited to, those relating to the Employee's employment with the Company and the termination of such employment. All such claims (including related attorneys' fees and costs) are barred without regard to whether those claims are based on any alleged breach of a duty arising in statute, contract or tort. This expressly includes the waiver and release of the rights and claims arising under any applicable laws, rules, regulations, and ordinances, including, but not limited to: the Age Discrimination in Employment Act, 29 U.S.C. §§ 621, *et seq.*, and/or the Older Workers' Benefit Protection Act of 1990, 29 U.S.C. § 626(f), *et seq.*; the Americans with Disabilities Act, 42 U.S.C. §§ 12101, *et seq.*; California laws regarding AIDS protection, including San Francisco Ordinance No. 160289 and Sacramento Ordinance No. 499-85 and/or California's Pregnancy Disability Leave Law, as amended, Cal. Govt. Code § 12945; California's Confidentiality of Medical Information Act, Cal. Civ. Code §§ 56 *et seq.;* the Rehabilitation Act of 1973, 29 U.S.C. §§ 701, *et seq.;* Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e, as amended; the California Fair Employment and Housing Act, Cal. Gov't. Code, §§ 12900 *et seq.*, as amended, California's Unruh Civil Rights Act, Cal. Civil Code, §§ 51 *et seq.*, as amended; California's Ralph Civil Rights Act, Cal. Civil Code §§ 51.7 *et seq.* and California laws pertaining to discrimination in public works codified at Cal. Labor Code, §§ 1735 and 1777.6, as amended by Ch. 913, L. 1992; the Equal Pay Act of 1963, 29 U.S.C. §§ 206, *et seq.* and/or the California Equal Pay Law, Cal. Labor Code, §§ 1197.5 *et seq.*; the Employee Retirement Income Security Act, 29 U.S.C. §§ 1001, *et seq.*; the National Labor Relations Act, 29 U.S.C. §§ 151, *et seq.* and Cal. Lab. Code § 98.6; the Fair Labor Standards Act; Cal. Lab. Code §§ 200 *et seq.*, § 2751 (laws regarding commissioned employees) and § 2802; the Worker Adjustment and Retraining Notification Act and/or California Labor Code §§ 1400 *et. seq.*; the Family and Medical Leave Act, the Moore-Brown-Roberti Family Rights Act/California Family Care and Medical Leave Law, Cal. Gov't. Code, §§ 12945.1 *et seq.* and 19702.3, the California Parental Leave Law, Cal. Lab. Code, §§ 230.7 *et seq.*, California's Paid Sick Leave Law, Cal. Lab. Code, §§ 233 and 234 and/or any local family leave laws or local Paid Sick Leave Ordinances; the California Labor Code, including, but not limited to Cal. Lab. Code §§ 98.6, 200 to 270 (salary, commission, compensation, leave, benefits and other matters), 432.5, 510, 558, 970 et seq., 980, 1041, 1101 et. seq., 1194, 1400 et. seq. (i.e. Cal. WARN), 1198, 1198.5, 1508 et. seq., 2698 et seq. (i.e. the Private Attorney General Act), 2750.5, 2751 et seq., 2802, 2810.3, 2810.5, 2814 and/or any applicable California Industrial Welfare Commission order, California Bus. & Prof. Code § 17200 et seq. (i.e., the Unfair Business Practices Act) and/or California Bus. & Prof. Code § 17500 et seq.; the San Francisco Health Care Security Ordinance, the San Francisco Family Friendly

Workplace Ordinance, the San Francisco Fair Chance Ordinance and/or the San Francisco Formula Retail Employee Rights Ordinances; Cal. Lab. Code § 432.7 (regarding arrest and/or conviction records); Cal. Lab. Code § 980 (social media privacy); Cal. Lab. Code §§ 1101-06 (political activities) and Cal. Lab. Code §§ 1508 *et seq.* (Michelle Maykin Memorial Donation Protection Act); Cal. Lab. Code § 230 (anti-retaliation against jurors/witnesses); California's Employee Literacy Education Assistance Act, Cal. Lab. Code § 1041; Cal. Lab. Code § 1198.5 (requiring employee access to personnel records); Cal. Lab. Code § 2810.3; California public policy including, but not limited to any policies articulated in Cal. Labor Code §§ 43 *et seq.* and/or 923 *et seq.*; *provided*, however, this release does not extend to, and has no effect upon: (i) any benefits that have accrued, and to which the Employee has become vested, under any employee benefit plan; (ii) the Employee's right to enforce the terms and conditions of this Agreement; (iii) any rights the Employee may have to indemnification pursuant to law or a contractual agreement with the Company; (iv) any right to file an administrative charge or complaint with the Equal Employment Opportunity Commission or any other federal, state or local governmental agency or commission ("Government Agencies"), although the Employee waives any right to monetary relief related to such a charge or administrative complaint; and (v) claims which cannot be waived by law, such as claims for unemployment benefit rights and workers' compensation.

6. Employee further understands and agrees that as a condition of this Agreement, in connection with the general release set forth above in Section 5, Employee waives any rights he may have under Section 1542 of the Civil Code of the State of California. That Section reads as follows:

> "§ 1542. [Certain claims not affected by general release.] A general release does not extend to claims which the creditor does not know or suspect to exist in her or his favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."

Notwithstanding the provision of Section 1542, and for the purpose of implementing a full and complete release and discharge of the Releasees, and each of them, Employee expressly acknowledges that this Agreement is intended to include and does include in its effect, without limitation, all claims which Employee does not know or suspect to exist in his favor against any of the Releasees at the time of his execution hereof, and that this Agreement expressly contemplates the extinguishment of all such claims.

____Employee Initials

7. Employee hereby represents and warrants to the Company that Employee is the sole and exclusive owner of the claims or causes of action being released by this Agreement, that Employee has not conveyed or assigned any interest in such claims or causes of action to any person or entity, and that such claims and causes of action have been fully and effectively released for all purposes. Employee further represents and warrants that Employee has no claims, lawsuits or actions pending in Employee's own name or on behalf of any other person or entity against any of the Releasees and does not intend to bring any claims on behalf of the Employee or any other person against any of the Releasees. Employee further represents and warrants that Employee will not participate or provide assistance to any person or entity who files a claim or intends to file a claim against the Company, unless ordered to do so by a court of competent jurisdiction or otherwise allowed by law.

8. Employee understands that this Agreement does not limit Employee's ability to communicate or share information with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agencies. However, based on the release of claims set forth in Section 5 of this Agreement, Employee acknowledges and agrees that Employee is releasing all claims and causes of action that Employee might personally pursue or that might be pursued in Employee's name and, to the extent permitted by applicable law, Employee's right to recover monetary damages or obtain injunctive relief that is personal to Employee in connection with such claims

_BR_ Employee Initials

and causes of action. Notwithstanding any other provision contained herein, nothing in this Agreement shall be construed as a waiver of any right which, by law, cannot be waived.

9. Employee acknowledges that Employee has read this Agreement and fully understands its meaning and intent, and has executed this Agreement knowingly and voluntarily, as a free and voluntary act, without duress, coercion, or undue influence exerted by or on behalf of any person or entity.

10. Neither the Company nor Employee shall be regarded as a prevailing party for any purpose, including, but not limited to, determining responsibility for or entitlement to attorneys' fees or costs under any statute or otherwise. The Company and Employee expressly waive, as to each other, any and all claims for attorneys' fees or costs.

11. This Agreement will not be used or construed by any person or entity as an admission of liability or finding or admission that any party's rights were in any way violated by any other party and this Agreement may not be offered or received in evidence in any action or proceeding as an admission or concession of liability or wrongdoing on the part of any party.

12. Each of the Company and Employee will keep the terms of this Agreement strictly confidential and shall not disclose any information concerning the terms of this Agreement or provide a copy of the same to anyone except the party's spouse (if applicable), legal or tax advisor, unless otherwise required by a court of competent jurisdiction. If required by law to produce a copy or to make such disclosure, Employee will give the Company reasonable advance notice prior to such production or disclosure.

13. Except as required or permitted by law, Employee will not do or say anything that a reasonable person would expect at the time would have the effect of diminishing or constraining the goodwill and good reputation of the Company or the Releasees or the Company's business, products or services. This obligation will include, but shall not be limited to refraining from making negative statements about the Releasees or the Company's methods of doing business, the effectiveness of its business policies, or the quality of any of its services or personnel; *provided*, however, that nothing herein is meant to limit any of Employee's rights under the National Labor Relations Act or meant to prohibit or restrain Employee from providing truthful testimony in response to a subpoena or a court order, or from providing truthful information to Government Agencies. This is a continuing obligation that shall survive this Agreement.

14. In further consideration of this Agreement and the commitments set forth in Section 4 hereinabove, Employee does hereby agree and acknowledge that the Releasees have no duty or obligation to hire Employee in the future nor shall Employee file any type of legal action or claim against Releasees for not reemploying Employee following Employee's cessation of employment with the Company. This Agreement will not, however, prevent Releasees from unilaterally offering Employee re-employment at their sole discretion.

15. Except as required or permitted by law, Employee will keep strictly confidential and not use for personal benefit or disclose to others any confidential or proprietary business or financial information or trade secrets of the Company, or other technical, business, or financial information, the use or disclosure of which may be contrary to the Company's interests. This obligation shall remain in effect as to any confidential business or financial information or trade secrets of the Company for so long as such confidential business or financial information or such trade secrets shall remain confidential and protected information of the Company under applicable law. Without limiting the generality of the foregoing, Employee hereby acknowledges and agrees that Employee will continue to be bound by the terms of the Proprietary Information and Inventions Agreement and the Insider Trading and Window Period Policy between Employee and the Company, which terms are in full force and effect and will survive Employee's termination of employment with the Company.

16. Employee agrees upon request to cooperate with and provide reasonable assistance to the Company and the Releasees and their legal counsel in connection with any litigation (including without limitation arbitration or administrative hearings) or investigations affecting the Company or the Releasees, in which Employee's assistance or cooperation is needed as determined by the Company or its legal counsel. Employee further agrees that, in the event Employee is subpoenaed by any person or entity to give testimony which in any way relates to Employee's employment by the Company or with respect to any relationship with the Releasees, Employee will give prompt notice of such request to the Company and will make no disclosure until the Company has had a reasonable opportunity to contest the right of the requesting person or entity to such disclosure. Notwithstanding the foregoing, nothing in this Section is intended to limit the rights detailed in Section 8 above.

17. This Agreement shall be binding upon and inure to the benefit of each of the Company and Employee and their respective predecessors, successors, assigns, heirs, executors, and administrators. Employee shall not assign this Agreement or delegate Employee's obligations hereunder without the prior written consent of the Company.

18. The Company and Employee acknowledge that this Agreement is intended to be a binding contract between them and shall not be modified except by writing signed by each of the Company and Employee. Employee acknowledges that Employee has not relied on any representation or statement by any of the Releasees or by any of the Releasees' agents, representatives or attorneys regarding the subject matter, basis or effect of this Agreement. The Company and Employee acknowledge that this Agreement, together with the Proprietary Information and Inventions Agreement, the Insider Trading and Window Period Policy and any Equity Incentive Plan(s), contain and comprise the entire agreement and understanding of the Parties with respect to the subject matter hereof and supersedes any and all prior oral and written agreements (including, but not limited to, superseding the February 20, 2018 Executive Employment Agreement) and understandings, and that there are no agreements or understandings other than those contained herein.

19. Each of the Parties acknowledges and recognizes that a violation of this Agreement and its covenants will cause irreparable damage to the other party and that the other party will have no adequate remedy at law for such violation. Accordingly, each of the Parties agrees that the other party will be entitled, as a matter of right, to seek an injunction from any court of competent jurisdiction restraining any further violation of the Agreement or covenant. This right to injunctive relief will be cumulative and in addition to whatever remedies the Parties may otherwise have at law.

20. The Parties agree that the Company's past, present, and future officers, directors, agents, stockholders, debt holders, employees, and representatives are each beneficiaries of this Agreement, and may rely on it directly for enforcement of the release set forth herein and the other benefits contained herein.

21. If one or more of the provisions, or portions thereof, of this Agreement are determined to be illegal or unenforceable, such provision, or portion thereof, shall be modified to the extent necessary to be valid or enforceable. Such modification shall not affect the enforceability of any remaining provisions. To the extent that it is determined that the provisions, or portions thereof, cannot be modified, the Agreement will be read as though the same were deleted, the remainder of this Agreement will not be affected by that determination and each remaining provision, or portion thereof, will continue to be valid and effective and will be enforceable to the fullest extent permitted by law.

22. This Agreement is made and entered into in the State of California and shall be governed by and construed in accordance with the laws of the State of California, except with regard to the conflict of laws rules of such State.

23. Employee is advised and understands that Employee has the right to consult with an attorney prior to executing this Agreement. Employee acknowledges that he was given at least forty-five

(45) days to consider this Agreement prior to signing, and that he has seven (7) days after execution to revoke his agreement to its terms. In the event Employee decides to waive the forty-five (45) day time period in which to consider this Agreement and decides to sign this Agreement immediately, he agrees to execute the Waiver attached hereto as Exhibit A. This Agreement and the offer of Severance made hereunder will no longer be available for acceptance after the forty-five (45) day consideration period detailed herein. This Agreement shall become effective and enforceable on the 8th day after Employee has signed the Agreement, provided that Employee has timely returned and not revoked the Agreement before such date (the "**Effective Date**"). If Employee chooses to revoke Employee's execution of the Agreement, written notice must be provided within the seven (7) day period to Dawn Botteron, Director of Human Resources, at Dawn.Botteron@clearsidebio.com.

PLEASE READ CAREFULLY. THIS AGREEMENT INCLUDES A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS.

IN WITNESS WHEREOF, Employee and the Company, each having read this Release and Settlement Agreement, and voluntarily and knowingly accepting its terms intending to be legally bound hereby, have executed this Release and Settlement Agreement as of the date set forth below, to be effective as of the Effective Date.

EMPLOYEE:

. Raymond

Brion S. Raymond

, 2020

IOMEDICAL, INC.

Lasezkay
Lasezkay
ecutive Officer

Date: January 3, 2020

Exhibit A

WAIVER OF FORTY-FIVE (45) DAY CONSIDERATION PERIOD

I, Brion Raymond, understand and agree to the following:

1. In connection with the separation of my employment from Clearside Biomedical, Inc., I have been presented with a Release and Settlement Agreement (hereinafter "Agreement") that I have to sign in order to receive my severance package.

2. The Agreement provides that I have been given the opportunity to take forty-five (45) days to consider the Agreement before signing it.

3. I have reviewed the Agreement, and I understand it and am in agreement with its terms.

4. I would prefer to elect to receive my severance package without having to wait the entire forty-five (45) day consideration period. I understand that even if I decide to waive the forty-five (45) day consideration period, I still have seven (7) days within which to revoke the Agreement and the Company has a reasonable period of time within which to pay me my severance benefits.

5. In order to receive my severance package without having to wait the entire forty-five (45) day consideration period, I hereby waive my right to take forty-five (45) days to consider the Agreement before signing it, and instead choose to sign it at the same time as this Waiver.

BY SIGNING MY NAME BELOW, I HEREBY CERTIFY THAT I UNDERSTAND AND AGREE TO THE TERMS OF THIS WAIVER, AND THAT MY DECISION TO SIGN THIS WAIVER WAS ENTIRELY VOLUNTARY.

Dated: , 2019 Brion Raymond

HLG: 220448

CONSULTING AND INDEPENDENT CONTRACTOR AGREEMENT

THIS CONSULTING AND INDEPENDENT CONTRACTOR AGREEMENT ("Agreement") is made by and between Clearside Biomedical, Inc., a Delaware corporation (the "Company" or "Clearside"), and Brion Raymond ("Consultant") (hereinafter collectively "the parties") and entered into as of the date of execution by both parties (the "Effective Date").

WHEREAS, Consultant's employment with Clearside terminated effective December 30, 2019 (the "Separation Date");

WHEREAS, the parties have entered into a Release and Settlement Agreement (hereinafter "Release Agreement") and intend for all terms contained within the Release Agreement to remain in effect and binding;

WHEREAS, Clearside wishes to continue to affiliate with Consultant to obtain the consulting services described below; and

WHEREAS, Clearside wishes to maintain in confidence all trade secrets and confidential information of the Company for the purpose of the consulting services or arising from the consulting services.

NOW, THEREFORE, the Company and Consultant hereby agree:

1. **Scope of Engagement.** During the term of this Agreement, the Company hereby engages the Consultant as an independent contractor to provide consulting services to the Company (hereinafter "Consulting Services"). These Consulting Services shall consist of consulting on XIPERE related matters, certain non-XIPERE related matters and any and all other services as specifically authorized and directed by the Company to perform. If the nature of the Consulting Services does not require Consultant to be present at Clearside's business premises, Consultant will not be required to perform such Services at any particular location.

2. **Term.** The Consultant's engagement with the Company shall commence on January 2, 2020, and shall continue for a period of six (6) months, through and until June 30, 2020, after which it shall terminate (the "Term"). During the Term, Consultant agrees to provide Clearside with up to the equivalent of twelve (12) work days (that being ninety-six (96) hours) of consulting services on XIPERE related matters at no hourly fee. Consultant further agrees to provide Clearside with consulting services on non-XIPERE related matters, and XIPERE related matters beyond the twelve (12) work days referenced, on an hourly basis to be billed in accordance with Paragraph 3.1 below. The Term may be extended beyond June 30, 2020 with the mutual consent of both parties in writing. Any such extension of the Agreement shall be month to month and either party may terminate thereafter by giving written notice to the other party prior to the start of any subsequent month.

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3. **Fees and Benefits.**

3.1 As full compensation for the Consulting Services, the Company will provide Consultant with the following compensation and/or benefits:

(a) Clearside will agree to accelerate the vesting of existing stock options for Consultant. More specifically, Clearside previously granted Consultant one or more options to purchase shares of the Company's common stock (the "Options") pursuant to the terms of the Company's 2016 Equity Incentive Plan (the "Plan"). Vesting of Consultant's outstanding Options ended on the Separation Date, at which time 77,500 shares subject to the Options remained unvested (the "Unvested Options"). Although the Company is not otherwise obligated to do so, if Consultant (i) continues to provide services to the Company under the terms of this Agreement through June 30, 2020, and (ii) timely signs, dates and returns this fully executed Agreement to the Company, subject to approval by the Company's Board of Directors, the Company will accelerate the vesting of 6,250 shares at a strike price of $1.24 subject to the Unvested Options on March 31, 2020 and 6,250 shares at a strike price of $1.24 subject to the Unvested Options on June 30, 2020. The exercise period for the aggregate of 12,500 shares referenced in the preceding sentence will be extended so that such shares will remain exercisable through September 30, 2020. Consultant and the Company hereby consent to the modification and amendment of the terms governing Consultant's Options and the option documents to conform to the provisions of this Agreement, and Consultant acknowledges and understands that the Options will no longer qualify as incentive stock options. Except as expressly set forth in this paragraph, Consultant's Options, including the terms and conditions of the Options and Consultant's rights and obligations with respect to the Options, will continue to be governed by the terms of Consultant's operative stock option grant notices and agreements with the Company and the Plan. With respect to the Options detailed in this subsection (a), each vesting shall be contingent on there being no uncured breach of the terms of this Agreement by Consultant on or prior to each vesting date.

(b) As it relates to the Consulting Services provided by Consultant on XIPERE related matters, Clearside will reimburse Consultant for pre-approved necessary and ordinary business-related expenses. Other than the Options detailed in subsection (a) above, Consultant will not be provided with additional compensation for the twelve (12) work days of XIPERE related Consulting Services provided pursuant to this Agreement. Should the Consulting Services on XIPERE related matters exceeds the twelve (12) work days contemplated in Paragraph 2 above, Consultant will be provided with his hourly rate referenced in 3.1(c) below.

(c) As it relates to the Consulting Services provided by Consultant on non-XIPERE related matters, Consultant will be paid his customary hourly rate of $400.00/hour (the "Consulting Fee"). For non-XIPERE related Consulting Services, Consultant will also be reimbursed for pre-approved necessary and ordinary business-related expenses.

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Consultant shall timely submit invoices detailing the Consulting Services rendered and the time spent on such Consulting Services pursuant to this Agreement and any approved business-related expenses incurred, along with supporting receipts and documentation. This invoicing requirement applies to both XIPERE related and non-XIPERE related Consulting Services so that Clearside can track the hours provided with respect to both XIPERE related and non-XIPERE related services. Any Consulting Fee due per subparagraphs (b) or (c) above and approved reimbursements shall be payable in a lump sum within thirty (30) days following the date the invoice for Consulting Services is submitted to the Company by Consultant. Consultant understands that he will receive an IRS Form 1099 or equivalent from the Company at year-end for the Consulting Fees, Options and reimbursements detailed herein. Consultant further acknowledges and agrees that he shall be solely responsible for all federal, state and local taxes related to the Consulting Fees and Options as detailed more fully in Section 4.2 below.

3.2 Consultant agrees that he is not entitled to any benefits that the Company provides to its employees, including but not limited to vacation, group medical or life insurance, disability, retirement benefits or any other benefit plans offered by the Company. Consultant expressly waives the right to participate in any such programs. Consultant also agrees that, consistent with his independent contractor status, Consultant will not apply for any government-sponsored benefits that are intended to apply to employees, including, but not limited to, unemployment benefits or workers' compensation benefits.

3.3 Except for pre-approved business-related expenses, Consultant is responsible for payment of all expenses incurred in performing the Consulting Services, including but not limited to expenses for Internet or phone service on mobile or other devices. Moreover, unless specifically authorized or otherwise addressed herein, Consultant shall furnish, at his own expense, the equipment, supplies, and other materials used to perform the Consulting Services. Consultant will be provided with access to the Company's premises and equipment to the extent necessary for the performance of the Consulting Services.

4. **Independent Contractor Status.**

4.1 Consultant understands and agrees that he is being engaged by the Company as an independent contractor. Nothing in this Agreement shall transform the Consultant into an employee, agent, or legal representative of the Company in any capacity whatsoever. Unless expressly authorized to do so, Consultant has no authority to bind or obligate the Company in any manner and shall not hold himself out to others as having any such authority. In addition, Consultant shall not make any agreements or representations on the Company's behalf without the Company's prior written consent. The Consultant shall be responsible for any and all of his acts or omissions. The Consultant agrees to indemnify and hold harmless the Company from all losses, liabilities, and costs incurred by the Company on account of any acts or omissions of the Consultant.

4.2 As an independent contractor, the Consultant understands and agrees that he will be responsible for obtaining his own valid workers' compensation insurance or any other

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required insurance. The Company shall not be responsible for any injuries sustained by Consultant while engaged with the Company. Consultant acknowledges and agrees that, due to the fact that Consultant is an independent contractor, the Company will not be responsible for withholding or paying any income, payroll, Social Security, or other federal, state, or local taxes, or making any insurance contributions. Consultant is responsible for, and shall indemnify the Company against, all such taxes or contributions, including any penalties and interest.

4.3 To the extent Consultant performs the Consulting Services on the Company's premises and/or utilizes the Company's equipment, he shall comply with all applicable policies of the Company relating to business and office conduct, health and safety, and use of the Company's facilities, supplies, information technology, equipment, networks and other resources.

5. **Confidentiality.**

In the course of Consultant providing Consulting Services, he will have access to and acquire knowledge of trade secrets and other confidential information as defined in Paragraph 15 of the Release Agreement and Clearside's Proprietary Information and Inventions Agreement concerning Clearside's operations, plans, products, finances, employees, and business methods, which information Consultant understands would be extremely damaging to Clearside if disclosed to a competitor or made available to any other person or corporation. Consultant promises that he will not disclose or reveal any trade secrets or confidential information to anyone, and will not use Clearside's trade secrets or confidential information for any personal or business purpose, unless necessary in the performance of the Consulting Services. The agreements set forth in this paragraph shall survive the termination of other arrangements contained in this Agreement and the duty imposed on Consultant hereunder shall remain effective for as long as the trade secrets and confidential information remain protected under state law. The parties agree and acknowledge that this non-disclosure provision is reasonable and breach of this provision would cause harm to Clearside.

6. **"Work Made for Hire" and Intellectual Property Developed by Consultant.**

6.1 The Company shall own all right, title and interest in any inventions or discoveries (e.g., compositions of matter, devices, processes, treatments, improvements, concepts, ideas and the like), whether or not patentable, developed or acquired by Consultant and/or the Company's employees as a result of the Consulting Services (hereinafter "Inventions").

6.2 Consultant will promptly, without royalty and at the Company's expense, (i) disclose to Company any Inventions that he develops or acquires, (ii) execute all applications, assignments and other instruments and do such other acts that the Company may deem necessary to obtain and maintain patent rights, copyrights and other similar intellectual property rights anywhere in the world and (iii) provide the Company assistance as needed in any legal proceedings regarding such intellectual property rights.

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6.3 Consultant will document, and provide such documentation at no extra charge to the Company, sufficient details of the work performed as such that the Company can verify the work done and u

7. **Consultant's Representation.** The Consultant represents and warrants to the Company that his acceptance of engagement by the Company hereunder does not violate and will not violate any contract or agreement to which the Consultant is a party and does not or will not result in a breach by the Consultant of any covenant of non-disclosure or any other covenant or agreements owed by the Consultant to any person, corporation or legal entity other than the Company. The Consultant shall indemnify and hold the Company harmless from any and all claims, suits, or causes of action arising from any contract, agreement, or covenant described herein to which the Consultant is a party. It is understood and agreed between the parties that the performance of Consulting Services as defined in this Agreement shall not be deemed to violate the applicable post-employment covenants contained within the Proprietary Information and Inventions Agreement executed by Consultant that remain in effect and binding as detailed in Paragraph 15 of the Release Agreement.

8. **Terms.**

8.1 **Waiver.** The waiver by the Company of a breach of any provision of this Agreement by Consultant shall not operate or be construed as a waiver of any subsequent breach by Consultant or any of the Company's rights hereunder.

8.2 **Entire Agreement.** This Agreement and the Release Agreement contain the entire agreement between the parties and supersede any prior or contemporaneous agreements between the parties. This Agreement may not be changed orally, but only by an agreement in writing, duly signed by the party against whom enforcement of any waiver, change, modification, extension, or discharge is sought.

8.3 **Severability.** In the event that any provisions of this Agreement shall be deemed void or invalid by a court of competent jurisdiction, the remaining provisions shall be and remain in full force and effect and Consultant hereby confers upon such court the power to replace such void or invalid provisions with such other enforceable and valid provisions as shall be as close to the original in form and effect.

8.4 **Governing Law.** This Agreement and all related disputes shall be governed by and construed in accordance with the laws of the State of Georgia, irrespective of the fact that either of the parties now is or may become a resident of a different state. Consultant acknowledges that Georgia has a substantial nexus with this Agreement.

8.5 **Forum Selection.** The parties hereto agree that all actions or proceedings arising in connection with this Agreement shall be tried and litigated exclusively in the state and federal courts located in Georgia. The aforementioned choice of venue is intended by the parties to be mandatory and not permissive in nature, thereby precluding the possibility of

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litigation between the parties with respect to or arising out of this Agreement in any jurisdiction other than that specified in this paragraph.

8.6 **Successors and Assigns.** The rights and obligations of the Company under this Agreement shall inure to the benefit of and shall be binding upon the successors and assigns of the Company. Consultant cannot assign any of his rights or obligations under this Agreement.

8.7 **Consultant Acknowledgement.** Consultant acknowledges that he has been advised by the Company to consult with independent counsel of his own choice, at his expense, concerning this Agreement, that he has had the opportunity to do so, and that he has taken advantage of that opportunity to the extent that he desires. Consultant further acknowledges that he has read and understands this Agreement, is fully aware of its legal effect, and has entered into it freely based on his own judgment.

8.8 **Counterparts.** This Agreement may be signed in counterparts, each of which shall be deemed an original and together shall constitute one executed Agreement. Scanned or facsimile signatures shall be deemed valid and the equivalent of originals unless there is an assertion that it is not genuine.

By:_/s/ Brion Raymond
Brion Raymond

Address: _____

_____

Date: January 3, 2020

By:/s/ George Lasezkay
On Behalf of Clearside Biomedical, Inc.

Address: _____

_____

Date: January 3, 2020

Exhibit 23.1

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. 333-212014) pertaining to the 2011 Stock Incentive Plan, as amended, Stock Option Awards, 2016 Equity Incentive Plan, and 2016 Employee Stock Purchase Plan of Clearside Biomedical, Inc.,

(2) Registration Statement (Form S-8 No. 333-216750) pertaining to the 2016 Equity Incentive Plan and 2016 Employee Stock Purchase Plan of Clearside Biomedical, Inc.,

(3) Registration Statement (Form S-3 No. 333-219132) of Clearside Biomedical, Inc.,

(4) Registration Statement (Form S-8 No. 333-224826) pertaining to the 2016 Equity Incentive Plan and 2016 Employee Stock Purchase Plan of Clearside Biomedical, Inc., and

(5) Registration Statement (Form S-8 No. 333-231383) pertaining to the 2016 Equity Incentive Plan of Clearside Biomedical, Inc.,

of our report dated March 13, 2020, with respect to the financial statements of Clearside Biomedical, Inc. included in this Annual Report (Form 10-K) of Clearside Biomedical, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Atlanta, Georgia
March 13, 2020

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, George Lasezkay, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2019 of Clearside Biomedical, Inc. (the "registrant");

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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2020

/s/ George Lasezkay, Pharm.D., J.D.
George Lasezkay, Pharm.D., J.D.
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles A. Deignan, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2019 of Clearside Biomedical, Inc. (the "registrant");

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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2020

/s/ Charles A. Deignan
Charles A. Deignan
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATIONS 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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), George Lasezkay, President and Chief Executive Officer of Clearside Biomedical, Inc. (the "Company"), and Charles A. Deignan, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2019, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 13th day of March, 2020.

/s/ George Lasezkay, Pharm.D., J.D.
George Lasezkay, Pharm.D., J.D.
President and Chief Executive Officer
(principal executive officer)

/s/ Charles A. Deignan
Charles A. Deignan
Chief Financial Officer
(principal financial officer)

* This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.