**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, 2023**

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter) based on the closing sale price of $1.12 as reported on the Nasdaq Global Market on that date was approximately $64,000,000.

As of March 5, 2024, the registrant had 74,721,139 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 (no later than 120 days after December 31, 2023) pursuant to Regulation 14A under the Securities Exchange Act of 1934, for its 2024 Annual Meeting of Stockholders are incorporated by reference into 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 ability to obtain funding for our future operations;
- our estimates regarding future revenue, expenses and needs for additional financing;
- our future capital requirements and sources and uses of cash;
- our expectations regarding the commercialization of XIPERE by our licensing partners;
- 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;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the timing and amount of milestone and royalty payments we are required to make or that we may receive under our license agreements;
- the clinical utility of our product candidates;
- our or our partners' ability to obtain and maintain regulatory approval of our product candidates in any of the indications for which we or our partners plan to develop them, and any related restrictions, limitations or warnings in the label of an approved product;
- 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;
- our ability to maintain compliance with the continued listing standards of the Nasdaq Global Market;
- the duration, severity and impact on our operations and clinical trials of geopolitical and macroeconomic events; and
- our estimates regarding our cash resources, our 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, 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.

**Risk Factors Summary**

The risk factors summarized below could materially harm our business, operating results, and/or financial condition, impair our future prospects and/or cause the price of our common stock to decline. These risks are discussed more fully in the section titled "Risk Factors." Material risks that may affect our business, financial condition, results of operations, and trading price of our common stock include the following:

- 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 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.
- 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, or SCS. Suprachoroidal injection is a novel approach and may fail to achieve and sustain market acceptance.
- If we are unable to obtain regulatory approval for, and commercialize either on our own or with a third party, CLS-AX or our other product candidates, or if we experience significant delays in doing so, our business may be harmed.
- 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.
- We have entered into, and intend to continue to enter into, collaborations with third parties for the development and commercialization of XIPERE. In addition, we may seek commercialization partners for our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of XIPERE and our product candidates.
- 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.

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**PART I**

## ITEM 1. BUSINESS

### Overview

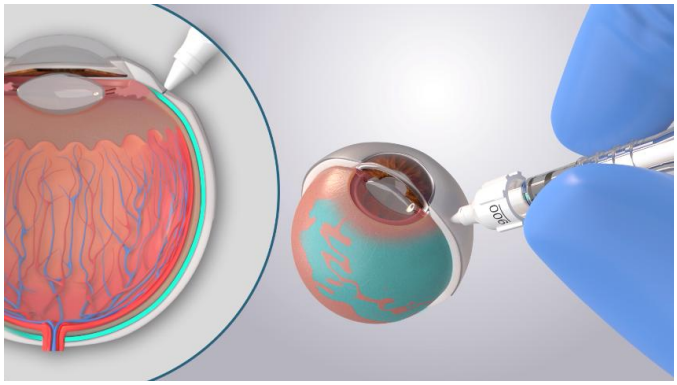
We are a biopharmaceutical company focused on revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space, or SCS. Our novel SCS injection platform, utilizing our proprietary SCS Microinjector, enables an in-office, repeatable, non-surgical procedure for the targeted and compartmentalized delivery of a wide variety of therapies to the macula, retina or choroid to potentially preserve and improve vision in patients with sight-threatening eye diseases. Our SCS injection platform can be used in conjunction with existing drugs designed for delivery to the SCS, novel therapies and future therapeutic innovations. We believe our proprietary suprachoroidal administration platform has the potential to become a standard for delivery of therapies intended to treat chorioretinal diseases.

We are leveraging our SCS injection platform by building an internal research and development pipeline targeting retinal diseases and by creating external collaborations with other companies. We are developing our own pipeline of small molecule product candidates for administration via our SCS Microinjector, and we also strategically partner with companies developing other ophthalmic therapeutic innovations to be administered using our SCS injection technology. Our first product, XIPERE (triamcinolone acetonide injectable suspension) for suprachoroidal use, was approved by the U.S. Food and Drug Administration, or the FDA, in October 2021. Approval of XIPERE was a significant milestone for us as it is the first approved therapeutic delivered into the SCS, the first commercial product developed by us and the first therapy for macular edema associated with uveitis.

We believe that we are creating a broad therapeutic platform for developing product candidates to treat serious eye diseases.

#### *Our Suprachoroidal Space (SCS) Injection Platform*

Our suprachoroidal injection platform is a novel, patented approach for delivering pharmacotherapy to the back of the eye via the 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 SCS microinjector is able to precisely administer drugs into the SCS utilizing a needle that is approximately one millimeter in length. This non-surgical method of administration facilitates more targeted delivery of therapeutic agents to chorioretinal structures and can be accomplished in an in-office setting. The suprachoroidal injection procedure is depicted in the picture below.



With suprachoroidal injections, product candidates are more directly administered to the retina and choroid, limiting exposure to non-target tissues as compared to other ocular drug administration techniques. Furthermore, a natural pressure gradient between the intraocular pressure, or IOP, and the SCS pressure drives suprachoroidal injectates posteriorly towards the macula, which facilitates treatment of macular disorders with this office-based approach, without the need for an intraocular catheter or other surgical techniques. In contrast, intravitreal injections, the current standard for delivery of many drugs for eye diseases, rely on diffusion of drug outward from the vitreous, a jelly-like substance that occupies the central portion of the eye, 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 may provide a number of benefits, including a non-surgical procedure, lower frequency of administration, limited exposure to non-targeted tissues, faster onset of therapeutic effect and an improved safety profile.

On January 1, 2024, a permanent Category 1 Current Procedural Terminology, or CPT, code was granted for the suprachoroidal injection of pharmacologic agents. We believe the Category 1 code may facilitate better access, insurance coverage and adoption of the suprachoroidal injection procedure.

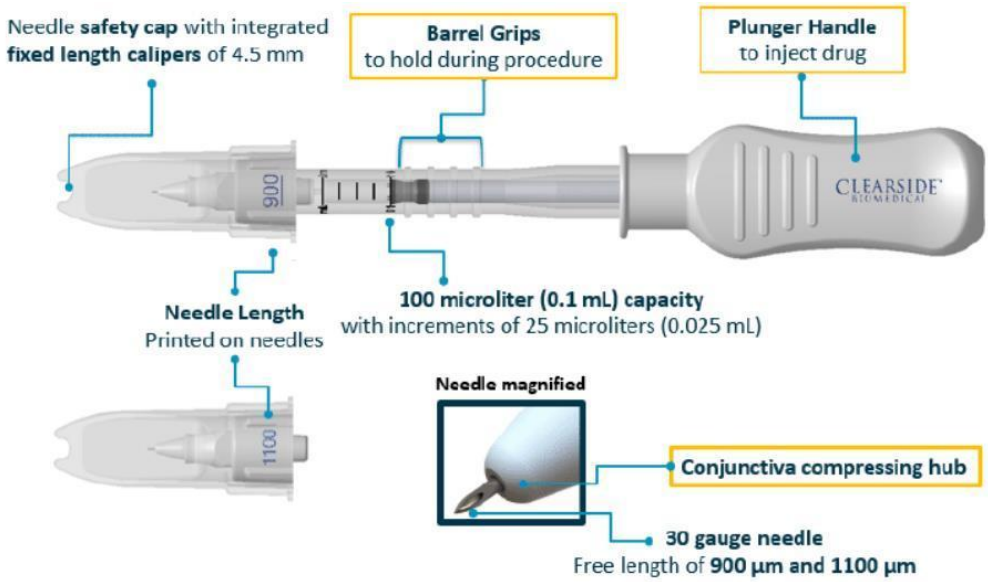
Our extensive patent portfolio provides us with the right to develop and commercialize pharmacological agents for treatment of eye diseases via suprachoroidal injection. We believe this proprietary method of administration has the potential to become the standard for the delivery of therapies intended to treat retinal and choroidal diseases. Our intellectual property portfolio consists of 28 issued U.S. patents and more than 80 European and international patents broadly directed to the use of the SCS Microinjector, administration of any drug into the SCS by injection, as well as XIPERE and our product candidates.

***Our SCS Microinjector***

Our proprietary SCS Microinjector can be used to inject a wide variety of therapies into the SCS, including our internally developed and our collaborators' drug candidates. Our SCS Microinjector provides targeted delivery to potentially improve efficacy and compartmentalization of medication to reduce or eliminate toxic effects on non-diseased cells. Suprachoroidal injection enables the rapid dispersion of medicine to the back of the eye, offering the potential for the medicine to act longer and minimize harm to the surrounding healthy parts of the eye.

Our SCS Microinjector has been used in thousands of suprachoroidal injections in our clinical trials and the clinical trials of our partners. It has been commercially accepted by retinal physicians following the launch of XIPERE in the United States by Bausch + Lomb with over 1,200 retinal physicians trained to date. Suprachoroidal injections using our SCS Microinjector have demonstrated a clinical safety profile comparable to intravitreal injections.

The SCS Microinjector, shown in the picture below, is composed of a syringe and two 30-gauge hollow microneedles of varying lengths, each approximately one millimeter, 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. Intravitreal injections are typically performed using a needle that is approximately five millimeters in length, or five 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.

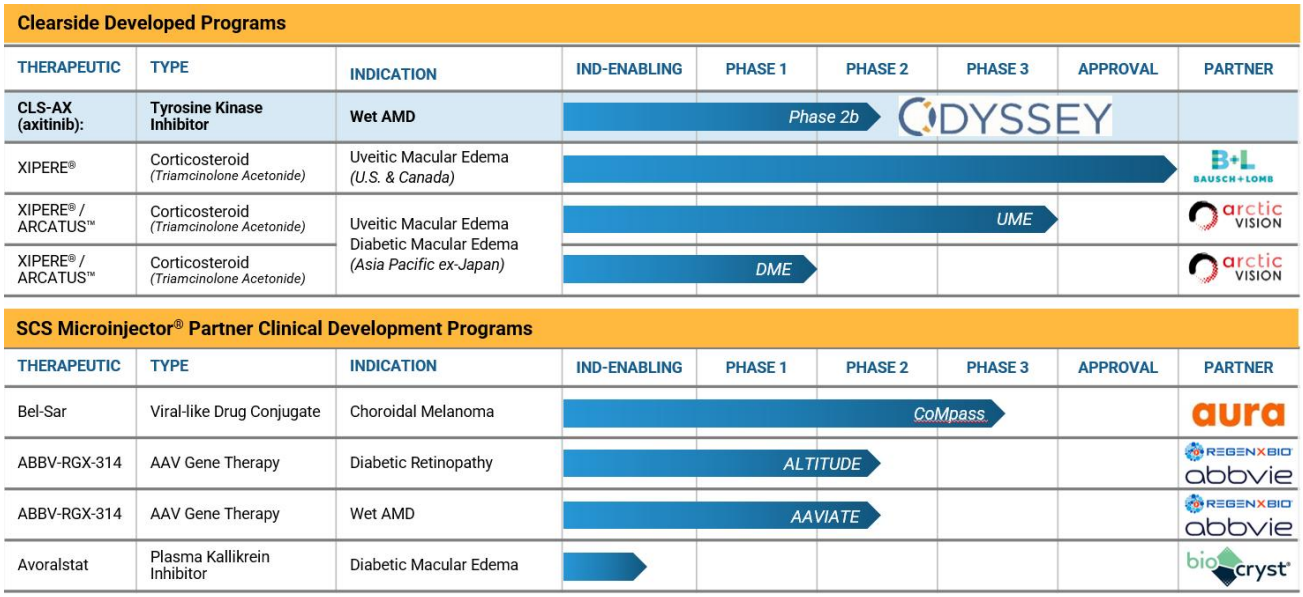
By contrast, our SCS Microinjector is designed to inject drug into the SCS. This suprachoroidal injection is designed to be carried out under local anesthesia, perpendicular to the sclera, at a site similar to an intravitreal injection. Once the microneedle

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 to the back of the eye, due to a natural pressure gradient between the IOP and the SCS pressure, precisely targeting the cells of interest without the need for intraocular catheters or other surgical techniques.

***Our Pipeline***

We have research capabilities focused on developing proprietary therapeutic formulations to utilize with our SCS Microinjector. Our current internal research and development initiatives are focused on small molecules to address serious diseases that affect the back of the eye. In addition to growing our internal pipeline, we are also focused on strategically collaborating with other companies to provide access to the suprachoroidal space through the use of our SCS Microinjector.

The current development status of our pipeline of internal product candidates and external collaborations is summarized in the chart below:




**Clinical Development Pipeline**

We are building a clinical development pipeline focused on small molecules. Our first product, XIPERE, was approved by the FDA in October 2021. The XIPERE approval supports our approach both clinically and preclinically to advance small molecule suspensions delivered into the SCS.

Our most advanced clinical development product candidate is a proprietary suspension of axitinib, a tyrosine kinase inhibitor, or TKI, for suprachoroidal injection, which we refer to as CLS-AX. We have completed OASIS, a Phase 1/2a clinical trial in patients with neovascular age-related macular degeneration, commonly referred to as wet AMD. In December 2023, we completed the randomization of participants for ODYSSEY, our Phase 2b clinical trial of CLS-AX. We expect to report topline data from the ODYSSEY trial in the third quarter of 2024.

***CLS-AX (axitinib injectable suspension)***

CLS-AX, our most advanced product candidate, is our proprietary suspension of the TKI axitinib for suprachoroidal injection delivered via our SCS Microinjector. CLS-AX is an inhibitor of vascular endothelial growth factor receptor-1, -2 and -3 that we believe may benefit patients as a potential longer duration maintenance therapy alongside other anti-VEGF therapies. We are developing CLS-AX for administration to the SCS as a long-acting therapy for wet AMD, a retinal degenerative disease that causes a progressive loss of central vision.

AMD is the leading cause of irreversible blindness in adults over 55 years old in developed countries. Approximately 11 million individuals in the United States are affected with AMD, with a global prevalence of 170 million. Aging is the greatest risk factor;

therefore, the United States prevalence of AMD is anticipated to increase to 22 million by 2050, while the global prevalence is expected to increase to 288 million by 2040. An estimated 10% to 15% of people with AMD will develop the wet form, which refers to the advanced neovascular stage of the disease in which blood vessels leak blood and fluid into the macula and damage photoreceptor cells. Wet AMD often progresses rapidly and causes substantial loss of central vision if left untreated. Current wet AMD therapy has a ceiling of efficacy as increased dosage or more intense regimens yield limited or no additional visual benefit and require adherence to a regimen of frequent injections. 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. The current anti-VEGF market for the treatment of retinal diseases consists of several drugs that generated aggregate 2020 sales of approximately $14.3 billion globally.

Axitinib is currently approved to treat renal cell cancer. Because it is a well-characterized small molecule instead of a novel complex biologic, we believe there is potential for less immune response and inflammation compared to some new, contemporary biologic agents. Also, compared to other TKIs, axitinib has shown better biocompatibility with ocular cells, including retinal pigment epithelial cells, which may potentially translate to safety benefits. Other TKIs have shown biologic effect in wet AMD clinical trials when delivered systemically, topically and intravitreally. However, each of these routes of administration have been associated with off-target effects. Consequently, a limitation of TKIs may be associated with the delivery of the drug and not a result of the mechanism of action. Importantly, we believe that administration of CLS-AX to the SCS using our SCS Microinjector, may minimize the occurrence of related adverse events, such as vitreous floaters, "snow globe" effect or corneal off-target effects seen with other TKI administration techniques.

With its broad VEGF blockade, we believe axitinib 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 preclinical studies, axitinib was observed to be greater than ten times more potent than other TKIs. In multiple preclinical animal studies conducted by independent investigators, axitinib has inhibited corneal, retinal and choroidal angiogenesis. In addition, in preclinical models, axitinib more effectively inhibited and regressed experimental corneal neovascularization than other TKIs.

In our internal preclinical studies, CLS-AX delivered through suprachoroidal injection was well tolerated and showed durability over several months. This could lead to a longer lasting, highly effective treatment that may reduce the number of treatments and visits required for wet AMD patients to achieve optimal results. These studies have also demonstrated up to eleven times higher drug levels in affected tissues versus intravitreal administration of the same dose of axitinib. Therefore, suprachoroidal delivery of CLS-AX has the potential to compartmentalize therapy away from unaffected tissues for potential safety benefits and target the affected chorioretinal tissue layers for potential efficacy benefits.

In August 2020, we announced that the FDA had accepted our Investigational New Drug application, or IND, for CLS-AX. In January 2021, we announced the enrollment of our first participant in OASIS, a Phase 1/2a clinical trial of CLS-AX in participants with wet AMD. OASIS was an open-label, dose-escalation clinical trial to assess the safety and tolerability of single doses of CLS-AX administered through suprachoroidal injection following two or more prior treatments with aflibercept, an intravitreal anti-VEGF agent, dosed at screening. All participants were highly treatment-experienced wet AMD participants with active disease at screening. The primary endpoint for the trial assessed the safety and tolerability of CLS-AX for the three months following the administration of CLS-AX, and secondary endpoints evaluated the pharmacokinetics, visual function, ocular anatomy and the need for additional treatment with intravitreal aflibercept during the three- and six-month periods.

Participant inclusion criteria for enrollment in OASIS included: active subfoveal choroidal neovascularization secondary to AMD; two or more anti-VEGF treatments with a meaningful response in the four months preceding the screening visit; and a best corrected visual acuity, or BCVA, score of $\geq$ 20 letters (20/400) and $\leq$ 75 letters (20/32) with < 5 letters change between screening and baseline to ensure patient stability after anti-VEGF treatment. Participants were assessed at weeks four, eight and twelve. Participants were assessed for additional therapy if they experienced any of the following: (1) loss of 10 or more letters in BCVA compared to the best prior study-assessed BCVA in the study eye that is attributed to intra- or sub-retinal fluid observed by the investigator; (2) increase in central subfield retinal thickness greater than 75 microns from baseline at visit 2 in the study eye; or (3) presence of vision-threatening hemorrhage due to AMD in the study eye. The trial consisted of four cohorts at the following doses of CLS-AX delivered via suprachoroidal injection: Cohort 1 at 0.03 mg; Cohort 2 at 0.1 mg; Cohort 3 at 0.5 mg; Cohort 4 at 1.0 mg. In January 2021, we announced that the first participants had been enrolled in OASIS. In December 2021, we announced that the primary endpoints were met in Cohorts 1 and 2. CLS-AX was well tolerated with no serious adverse events; there were no treatment emergent adverse events related to aflibercept, CLS-AX or the suprachoroidal injection procedure, no dispersion of drug into the vitreous, and no adverse events related to IOP, inflammation or vasculitis. In July 2022, we completed patient enrollment of OASIS and also completed dosing in Cohort 3 in which each patient received a dose of 0.5 mg, and in Cohort 4 in which each patient received a dose of 1.0 mg.

In the four OASIS cohorts we enrolled a total of 27 participants. All participants were highly treatment-experienced wet AMD participants with active disease at screening. These four cohorts allowed us to collect more CLS-AX patient data to help guide our selection of the most appropriate dosing protocol for ODYSSEY, our Phase 2b clinical trial of CLS-AX for the treatment of wet AMD.

Participants in Cohorts 2, 3, and 4 who elected to participate in an extension study were followed for an additional 3 months. In November 2022, we reported positive results that included final three-month data from Cohorts 3 and 4, and interim data from the extension study. CLS-AX demonstrated a positive safety profile in all four cohorts. There were no serious adverse events and no treatment emergent adverse events related to aflibercept, CLS-AX, or the suprachoroidal injection procedure. There were also no dose limiting toxicities. There were no adverse events related to inflammation, vasculitis or vascular occlusion, and there were no vitreous "floaters" or dispersion of CLS-AX into the vitreous.

In Cohorts 3 and 4, the data showed favorable durability with a meaningful reduction in treatment burden at the 3-month endpoint and to date in the extension study. Of the 16 participants in Cohorts 3 and 4, at the 3-month endpoint, 69% did not receive additional therapy, 92% did not receive additional therapy per protocol criteria, and there was at least a 73% reduction in treatment burden from the average monthly injections in the three months before CLS-AX administration. Of the 12 participants in the extension study, based on interim data as of October 27, 2022, 88% (7/8) of participants did not receive additional therapy to the 5-month endpoint and 75% (3/4) of participants did not receive additional therapy to the 6-month endpoint. Further, in the extension study, there was at least a 90% reduction in treatment burden from the average monthly injections in the six months before CLS-AX administration. In Cohorts 3 and 4, CLS-AX also showed an observable biologic effect with stable mean BCVA, stable mean central subfield thickness, or CST, and anatomical signs of TKI biologic effect observed on Optical Coherence Tomography, or OCT, images.

On February 2, 2023, we announced positive results from the completed OASIS extension study.

CLS-AX was well-tolerated and demonstrated a favorable safety profile across all cohorts in both the three-month dose-escalation portion (n=27) and the extension study (n=14). No serious adverse events, treatment emergent adverse events related to study or dose limiting toxicities were observed. In addition, there were no adverse events related to inflammation, vasculitis or vascular occlusion, no vitreous "floaters" or dispersion of CLS-AX into the vitreous and no retinal detachments, endophthalmitis or adverse events related to IOP.

The full extension data for Cohorts 3 and 4 (n=12) showed promising durability, with a 77% - 85% reduction in treatment burden observed compared to the average monthly injections in the six months before CLS-AX administration. The table below details the length of time the participants went without additional therapy:

| Duration Without Additional Therapy | Number of Participants (n=12) |
|---|---|
| ≥ 3 Months | 11/12 (92%) |
| ≥ 4 Months | 10/12 (83%) |
| ≥ 6 Months | 8/12 (67%) |
| > 6 Months | 6/12 (50%) |

In Cohorts 3 and 4 of the extension study, CLS-AX showed signs of biologic effect with stable mean BCVA and stable mean CST to the six-month timepoint. On OCT images, anatomical signs of TKI biologic effect were observed in anti-VEGF treatment experienced sub-responders.

*ODYSSEY Phase 2b Clinical Trial*

Based on the results from the OASIS trial, we are conducting a randomized, controlled, double-masked, Phase 2b clinical trial of CLS-AX for the treatment of wet AMD, which we refer to as ODYSSEY. ODYSSEY will compare CLS-AX suprachoroidal injection and aflibercept intravitreal injection over 36 weeks and is expected to have 60 total participants with a 2:1 randomization. The primary outcome measure is a mean change in best corrected visual acuity from baseline to week 36. The secondary outcome measures are changes in visual function and ocular anatomy, need for supplemental treatment and treatment burden as measured by total injections over the trial duration. We began enrolling participants in May 2023 and randomized our first participants in July 2023. In October 2023 we completed the recruitment of participants. The final participant was randomized to the CLS-AX treatment of the aflibercept comparator arm in December 2023. We expect to report topline data in the third quarter of 2024.

*Preclinical*

We have an experienced team of scientists and researchers evaluating small molecules that may be utilized as potential treatment options for back of the eye diseases. This work often entails developing a suspension formulation for delivery into the suprachoroidal space via our SCS Microinjector. Suprachoroidal delivery of a new suspension could provide targeting, compartmentalization and durability advantages over topical or intravitreal delivery, similar to what we have observed with XIPERE and CLS-AX. Once a formulation is confirmed, we proceed with conducting non-human studies until enough data is collected to warrant submitting an IND for such a product candidate.

**XIPERE (triamcinolone acetonide injectable suspension) for suprachoroidal use**

Our first product, XIPERE, formerly known as CLS-TA, is a proprietary, preservative-free suspension of the corticosteroid triamcinolone acetonide, or TA, for suprachoroidal use. 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 IOP, which can lead to glaucoma.

XIPERE was approved 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.

We are evaluating options for potential submissions to regulatory agencies in additional territories not currently licensed for the treatment of patients with macular edema associated with uveitis.

**External Collaborations Pipeline**

In order to expand the global reach of our suprachoroidal injection platform, we have strategically partnered some of our assets for development and/or commercialization and intend to continue partnering our assets. By entering into these partnerships, we have been able to expand the use of our suprachoroidal injection platform to other indications and geographies globally. We currently have collaborations with Bausch + Lomb, Arctic Vision, REGENXBIO, Inc., Aura Biosciences, Inc. and BioCryst Pharmaceuticals, Inc. As discussed below in "—Royalty Purchase and Sale Agreement", we are obligated to pay HealthCare Royalty Management, LLC, or HCR, any such royalties or milestone payments until we have satisfied our obligations under the Purchase and Sale Agreement.

***License agreement for commercialization of XIPERE in United States and Canada***

On October 22, 2019, we entered into a License Agreement with Bausch + Lomb or, as amended, the Bausch License Agreement. Pursuant to the Bausch License Agreement, we granted an exclusive license to Bausch to develop, manufacture, distribute, promote, market and commercialize XIPERE using our SCS Microinjector, as well as specified other steroids, corticosteroids and NSAIDs in combination with the SCS Microinjector, or together with XIPERE, the Products, subject to specified exceptions, in the United States and Canada, or the Territory, for the treatment of ophthalmology indications, including non-infectious uveitis.

Pursuant to the Bausch License Agreement, Bausch paid us an upfront payment of $5.0 million in October 2019. In October 2021, the FDA approved XIPERE, and we received $5.0 million from Bausch as a result of the approval. In January 2022, we received an additional payment of $10.0 million related to the completion of pre-launch activities for XIPERE. In addition, Bausch agreed to pay up to an aggregate of $55.0 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 Bausch License Agreement). 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 Territory, as well as a lower royalty on annual net sales of other products, in each case subject to reductions in specified circumstances. However, we will not receive any royalties on the first $45.0 million of cumulative net sales of all products in the Territory. Bausch launched XIPERE in the United States in the first quarter of 2022. Our rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described below in "—Royalty Purchase and Sale Agreement."

The Bausch License Agreement will expire upon expiration of the royalty terms for all Products and countries in the Territory, with each royalty term for a given Product and country ending on the latest of (i) the date of expiration of the last-to-expire valid claim

of any licensed patent rights covering such Product in such country in the Territory, (ii) the date of the loss of regulatory exclusivity for such Product in such country in the Territory, or (iii) ten years from the later of the first sale of such Product in such country in the Territory. Bausch may also terminate the Bausch License Agreement for convenience upon 180 days' written notice. In addition, we can terminate the Bausch License Agreement if Bausch commences a legal action challenging the validity, enforceability or scope of any of the licensed patents. Both parties may terminate the Bausch License Agreement (i) upon a material breach of the Bausch License Agreement, subject to a specified cure period and specified exceptions, or (ii) if the other party encounters bankruptcy or insolvency.

***License agreement for commercialization of XIPERE in China, Hong Kong, Macau, Taiwan and South Korea, India, ASEAN Countries, Australia and New Zealand***

On March 10, 2020, we entered into a license agreement, or the Arctic Vision License Agreement, with Arctic Vision (Hong Kong) Limited, or Arctic Vision. Pursuant to the Arctic Vision License Agreement, we granted an exclusive license to Arctic Vision to develop, distribute, promote, market and commercialize XIPERE, subject to specified exceptions, in China, Hong Kong, Macau, Taiwan and South Korea, or the Arctic Territory. Under the terms of the Arctic Vision License Agreement, neither party may commercialize XIPERE in the other party's territory. Arctic Vision has agreed to use commercially reasonably efforts to pursue development and commercialization of XIPERE for indications associated with uveitis in the Arctic Territory. In addition, with our consent, Arctic Vision will have the right, but not the obligation, to develop and commercialize XIPERE for additional indications in the Arctic Territory.

In March 2022, Arctic Vision announced dosing of the first patient in a Phase 1 clinical trial of ARVN011 in China for the treatment of diabetic macular edema. In July 2023, Arctic Vision announced the formal acceptance in Australia of its new drug application for suprachoroidal use of ARVN001 for the treatment of uveitic macular edema. In October 2023, Arctic Vision completed enrollment in its Phase 3 randomized, double-blind, placebo-controlled clinical trial in China for suprachoroidal use of ARVN001 for the treatment of uveitic macular edema. Arctic Vision has branded ARVN001 as Arcatus.

Pursuant to the Arctic Vision License Agreement, Arctic Vision paid us an upfront payment of $4.0 million in March 2020. In December 2021, we received a milestone payment of $4.0 million following receipt of FDA approval of XIPERE in the United States. In addition, Arctic Vision agreed to pay us up to a total of $22.5 million in development and sales milestone payments. Further, during the applicable royalty term, we are also entitled to receive tiered royalties of 10% to 12% of net sales based on achieving certain annual net sales thresholds in the Arctic Territory, subject to customary reductions, payable on a product-by-product and country-by-country basis, commencing at launch in such country and lasting until the latest of (i) the date that all valid claims within the licensed patent rights covering XIPERE have expired, (ii) the date of the loss of marketing or regulatory exclusivity of XIPERE in a given country or (iii) ten years from the first commercial sale of XIPERE in a given country. Our rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described below in "—Royalty Purchase and Sale Agreement."

The Arctic Vision License Agreement will expire upon the expiration of the last-to-expire royalty term. Arctic Vision may terminate the Arctic Vision License Agreement for convenience upon 45 days' notice if before regulatory approval in the Arctic Territory or 90 days' notice if after regulatory approval in the Arctic Territory. In addition, we can terminate the Arctic Vision License Agreement if Arctic Vision commences a legal action challenging the validity, enforceability or scope of the licensed patents. Both parties may terminate the Arctic Vision License Agreement (i) upon a material breach of the Arctic Vision License Agreement, subject to a specified cure period, or (ii) if the other party enters bankruptcy. Upon termination, all licenses and other rights granted to Arctic Vision pursuant to the Arctic Vision License Agreement would revert to us. If Arctic Vision exercises its termination right for convenience or if the Arctic Vision License Agreement terminates as a result of Arctic Vision's material breach or bankruptcy, Arctic Vision will assign and transfer all regulatory approvals, related documents and trademarks (with respect to trademarks, only those specific to) pertaining to XIPERE in the Arctic Territory to us. If Arctic Vision terminates the Arctic Vision License Agreement as a result of material breach by us or our bankruptcy after regulatory approval of XIPERE in the Arctic Territory, we are obligated to pay Arctic Vision royalties equal to a low-single digit percentage of net sales of XIPERE in the Arctic Territory.

In August 2021, we entered into an amendment to the Arctic Vision License Agreement to expand the territories covered by the license to include India and the ASEAN Countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam). In September 2021, we entered into a second amendment to the Arctic Vision License Agreement to expand the Arctic Territory to include Australia and New Zealand. We received an aggregate of $3.0 million in consideration for the expansion of the Arctic Territory.

***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 adeno-associated virus, or 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 diseased 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.

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 and 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. In preclinical studies 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. To expand our overall development pipeline, we are looking to selectively partner our proprietary technology for use with novel gene therapies.

*REGENXBIO, Inc.*

We have expanded the reach of our SCS Microinjector technology in AAV-based gene therapy through a development and commercial partner.

In August 2019, we entered into an option and license agreement, or the REGENXBIO Option and License Agreement, with REGENXBIO Inc., or 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 in-office 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.

In October 2019, REGENXBIO exercised the Option 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 paid us $3.0 million in connection with a development milestone and agreed to additional payments to us of up to an aggregate of $31.0 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. Our rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described below in "—Royalty Purchase and Sale Agreement."

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.

REGENXBIO is currently conducting two multi-center, open-label, randomized, controlled, dose-escalation Phase 2 clinical trials evaluating the efficacy, safety and tolerability of suprachoroidal delivery of ABBV-RGX-314 using our SCS Microinjector technology: (1) a Phase 2 trial entitled AAVIATE for the treatment of wet AMD; and (2) a second Phase 2 trial entitled ALTITUDE for the treatment of diabetic retinopathy, or DR. In November 2023, REGENXBIO presented data from the ALTITUDE trial showing that, at one year, dose level 2 in non-proliferative DR patients prevented disease progression as measured by the Early Treatment Diabetic Retinopathy Study-Diabetic Retinopathy Severity Scale. In January 2024, REGENXBIO presented data from the AAVIATE trial demonstrating that, at six months, patients treated with ABBV-RGX-314 continue to demonstrate stable vision and retinal anatomy while a meaningful reduction in anti-VEGF treatment burden was observed. REGENXBIO expects to provide program updates for the ALTITUDE trial in the second quarter of this year and for the AAVIATE trial in mid-2024.

***Ocular Oncology***

Ocular cancers are a group of rare, life-threatening conditions that affect one or both eyes. The main indications include choroidal melanoma, choroidal metastases, cancers of the ocular surface and retinoblastoma, among others. Diagnosing and treating these cancers early is important because they have the potential to spread both within the eye and to other organs. The risk for ocular cancer increases with age and increases significantly after the age of 50. For cancers that occur inside the eye (e.g., choroidal melanoma), the typical treatment is radiotherapy in the form of plaque brachytherapy and proton beam therapy, but these treatments are highly invasive and result in major vision loss and other comorbidities for many patients.

Choroidal melanoma is the most common intraocular cancer in adults, with an incidence of approximately 11,000 patients per year in the United States and Europe. This comprises approximately 90% of all cases of uveal melanoma, consisting of melanomas in the choroid, ciliary body and iris, which are collectively referred to as the uvea. It is estimated that 96% of patients are diagnosed early without clinical evidence of metastatic disease. There are approximately 2,000 new cases treated each year in the United States and 1,600 new cases treated each year in Europe. However, despite the current treatments with radiotherapy, the long-term prognosis is poor with death occurring in more than 50% of cases. There are no FDA-approved therapies for choroidal melanoma. There is a need for treatment of early-stage disease which includes small melanomas and indeterminate lesions representing approximately 9,000 patients in the United States and Europe.

*Aura Biosciences, Inc.*

On July 9, 2019, we entered into a worldwide licensing agreement with Aura Biosciences, Inc., or 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. Our SCS Microinjector may offer a non-surgical alternative to intravitreal delivery of Aura's oncology drug candidates, and we believe suprachoroidal administration may further enhance the value proposition of choroidal melanoma by potentially improving safety and expanding access. Pursuant to the licensing agreement, we have received an aggregate of $1.6 million in connection with upfront license fees and development milestones. We are eligible to receive up to an additional $19.5 million in payments related to pre-specified development and regulatory milestones, as well as low to mid-single digit royalties on net sales that utilize the SCS Microinjector. Our rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described below in "—Royalty Purchase and Sale Agreement."

Aura is utilizing our SCS Microinjector to deliver their viral like drug conjugate, bel-sar, for the treatment of choroidal melanoma. In November 2023, Aura reported positive clinical safety and efficacy updates from its ongoing Phase 2 clinical trial with suprachoroidal administration. The results, with 90% of patients at twelve months of follow-up who received three cycles of therapy in Cohorts 5 and 6 and who match the criteria for the planned global Phase 3 trial, showed a tumor control rate of 80% and the visual acuity preservation rate was 90%. In December 2023, Aura announced the first patient dosed in CoMpass, their global Phase 3 clinical trial.

*BioCryst Pharmaceuticals, Inc.*

On November 1, 2023, we entered into a license agreement, or the BioCryst License Agreement, with BioCryst Pharmaceuticals, Inc., or BioCryst, pursuant to which we granted BioCryst an exclusive, worldwide and sublicensable license to our SCS Microinjector for the delivery of BioCryst's proprietary plasma kallikrein inhibitor known as avoralstat for the treatment and prevention of diabetic macular edema, or DME.

We received an upfront license fee payment of $5.0 million in connection with signing of the BioCryst License Agreement. In addition, we are eligible to receive up to an additional $30.0 million in clinical and regulatory milestone payments, and up to a total of $47.5 million in a series of post-approval sales-based milestone payments based on the achievement of annual global net product sales milestones up to $2.0 billion. Further, during the royalty term, BioCryst has also agreed to pay us tiered mid-single digit royalties on annual global net product sales, with the highest royalty rate applied to sales over $1.5 billion, subject to reductions in specified circumstances. Our rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described below in "—Royalty Purchase and Sale Agreement."

BioCryst will be responsible for all development, regulatory and commercialization activities for avoralstat. We are responsible for supplying SCS Microinjectors to meet BioCryst's reasonable needs.

The BioCryst License Agreement, unless earlier terminated, will expire (a) on a country-by-country basis upon the expiration of the royalty term in such country or (b) in its entirety upon the expiration of all payment obligations of BioCryst under the BioCryst License Agreement in all countries pursuant to clause (a). Each party has the right terminate the BioCryst License Agreement (i) upon a material breach of the BioCryst License Agreement by the other party, subject to a specified cure period and specified exceptions, or (ii) if the other party encounters bankruptcy or insolvency. We may terminate the BioCryst License Agreement if BioCryst or any of its sublicensees, or a Sublicensee commences a legal action challenging the validity, enforceability or scope of any of the licensed patents, provided that with respect to any such action initiated by a Sublicensee, or Sublicensee Action, we may terminate the BioCryst License Agreement if the Sublicensee Action is not terminated within a specified period of time following BioCryst's receipt of written notice from us or if BioCryst does not terminate the applicable sublicense, in each case within a specified period of time. BioCryst may terminate the BioCryst License Agreement (i) immediately upon written notice to us if, after exercising commercially reasonable efforts, BioCryst determines in good faith that it is not advisable to continue development or commercialization of avoralstat as a result of a material safety issue and (ii) in its entirety or in part on a country-by-country basis, for any or no reason, upon prior written notice to us, provided that in the event of such a termination, BioCryst shall not, for a period of two years from the date of such a termination, initiate in the territory subject to the termination a Phase 3 clinical trial in which avoralstat is administered to the suprachoroidal space using a device other than the SCS Microinjector.

**Royalty Purchase and Sale Agreement**

On August 8, 2022, or the Closing Date, we, through our wholly-owned subsidiary Clearside Royalty LLC, a Delaware limited liability company, or Royalty Sub, entered into a Purchase and Sale Agreement, or the Purchase and Sale Agreement, with entities managed by HealthCare Royalty Management, LLC, or HCR, pursuant to which Royalty Sub sold to HCR certain of its rights to receive royalty and milestone payments payable to Royalty Sub under the Arctic Vision License Agreement, the Bausch License Agreement, that certain License Agreement, effective as of July 3, 2019, by and between us and Aura Biosciences, Inc., or the Aura License Agreement, the REGENXBIO Option and License Agreement and any and all out-license agreements following the Closing Date for, or related to XIPERE or the SCS Microinjector technology (to be used in connection with compounds or products of any third parties delivered, in whole or in part, by means of the SCS Microinjector technology), excluding, for the avoidance of doubt, any in-licensed or internally developed therapies following the Closing Date, or the Royalties, in exchange for up to $65 million. In connection with this transaction, we assigned the Arctic Vision License Agreement, Bausch License Agreement, Aura License Agreement, REGENXBIO Option and License Agreement, our license agreement with Emory University and The Georgia Tech Research Corporation and related intellectual property rights to Royalty Sub.

Under the terms of the Purchase and Sale Agreement, Royalty Sub received an initial payment of $32.1 million, representing the $32.5 million to which we were entitled, net of certain of HCR's transaction-related expenses which we agreed to reimburse. An additional $12.5 million was deposited by HCR in an escrow account which, was released to HCR pursuant to the Letter Agreement described below. The terms of the Purchase and Sale Agreement also provide for an additional $20 million milestone payment to Royalty Sub upon attainment of a second pre-specified sales milestone related to 2024 XIPERE sales, or the Second Milestone Event.

The Purchase and Sale Agreement will automatically expire, and the payment of Royalties from the Royalty Sub to HCR will cease, when HCR has received payments of the Royalties equal to 2.5 times the aggregate amount of payments made by HCR under the Agreement if the Second Milestone Event is achieved on or prior to December 31, 2024, or the Initial Cap. If the Second Milestone Event is not achieved on or prior to December 31, 2024, payment of Royalties from Royalty Sub to HCR will cease when HCR has received Royalties payments equal to 3.4 times the aggregate amount of payments under the Purchase and Sale Agreement, or the Alternative Cap. In the event of a change in control, acquiror will have the option to make a payment to HCR of the Initial Cap or the Alternative Cap, depending on which is then in effect, less the aggregate amount of Royalty payments made by Royalty Sub to HCR under the Purchase and Sale Agreement as a one-time payment at which time, payment of Royalties to HCR will cease. Alternatively, in the event of a change in control, the acquiror will have the option to make an initial payment of 1.0 times the aggregate amount of payments made by HCR under the Purchase and Sale Agreement as of the date of such change in control, then in that event, payment of Royalties from Royalty Sub to HCR will cease when HCR has received total Royalties payments (including the

initial payment) equal to the Alternative Cap. After the Purchase and Sale Agreement expires, all rights to receive the Royalties return to Royalty Sub.

On December 22, 2023, we, through Royalty Sub, entered into a letter agreement, or the Letter Agreement, with HCR and HCR Clearside SPV, LLC (as assignee of HCR Collateral Management, LLC), or Agent, amending the Purchase and Sale Agreement. Pursuant to the terms of the Letter Agreement, Royalty Sub and Agent mutually agreed that Royalty Sub waived any and all rights to the $12.5 million milestone payment which was deposited in an escrow account, or the First Milestone Payment, in connection with the closing of the transactions contemplated by the Purchase and Sale Agreement and agreed to the release of the First Milestone Payment to Agent.

**Manufacturing**

We do not own any manufacturing facilities. We utilize contract manufacturing organizations, or CMOs, to formulate and produce our drug candidates and to produce our SCS Microinjector. We procure active pharmaceutical ingredients for our drugs from third-party suppliers. We expect to continue to utilize third-party manufacturers to produce quantities of our drug candidates and the SCS Microinjector.

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, regulations promulgated by the FDA, confidentiality and other customary matters for an agreement of this nature. We may enter into commercial supply agreements with our other suppliers.

**Commercialization**

We have entered into exclusive license agreements for the commercialization and development of XIPERE with Bausch + Lomb in the United States and Canada and with Arctic Vision in China, Hong Kong, Macau, Taiwan, South Korea, India, the ASEAN Countries, Australia and New Zealand. We may enter into distribution or licensing arrangements for commercialization rights for other regions. We have also entered into an exclusive license agreement for the use of our SCS Microinjector with BioCryst. If any of our future product candidates, including CLS-AX, are approved by the applicable regulatory authorities, 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 companies, specialty pharmaceutical and biotechnology companies, government agencies and public, and private research and academic 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, although none are approved for the indication of macular edema associated with uveitis. Bristol-Myers Squibb markets TA, under the brand name Kenalog, for which a number of generic equivalents are currently available. Kenalog is indicated only for intramuscular or intraarticular injection; however, it is used off-label for intraocular inflammation using intravitreal and periocular administration. In addition, Alcon’s injectable TA, Triesence, is approved in the United States for the treatment of uveitis and other ocular inflammatory conditions unresponsive to topical corticosteroids, but it is not indicated for the treatment of macular edema associated with uveitis. Ozurdex, marketed by Allergan, is a bio-erodible, extended-release implant that delivers the corticosteroid and dexamethasone, and is approved for the treatment of non-infectious uveitis affecting the posterior segment of the eye and for macular edema due to retinal vein occlusion, or RVO, in both the United States and in the European Union. Ozurdex is also approved in the United States for the treatment of diabetic macular edema, or DME. Retisert and Yutiq, both intravitreal implants of fluocinolone acetonide, are marketed by Bausch and Alimera, respectively, and are approved in the United States for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. In addition, Oxular is developing OXU-001 which is dexamethasone delivered via the Oxulumis suprachoroidal device for the treatment of DME. It is possible physicians may use OXU-001 off label to treat macular edema associated with uveitis once approved.

CLS-AX faces competition with anti-VEGF drugs, the current standard of care for RVO and wet AMD, as well as other drug candidates in development for ocular use for the treatment of wet AMD, such as other TKI's. Axitinib, also known by its brand name Inlyta, is not currently approved for an ocular indication but is approved by the FDA and marketed by Pfizer for the treatment of advanced renal cell carcinoma. Genentech has several products which serve as competitors in this space, including anti-VEGF agents Lucentis, Avastin, and Susvimo. 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 routinely 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. Susvimo, an ocular implant that releases ranibizumab over time, received approval from the FDA in October 2021 for the treatment of wet AMD in patients who have previously responded to anti-VEGF therapy. Additionally, Genentech's product, Vabysmo (faricimab-svoa), an intravitreal injection which blocks two disease pathways, including (Ang-2) and vascular endothelial growth factor-A (VEGF-A), received approval in January 2022 for the treatment of wet AMD and diabetic macular edema.

In addition to Genentech's products, Regeneron's anti-VEGF product, Eylea 2 mg and 8 mg and Novartis' product, Beovu, also present potential competition for CLS-AX in both the United States and Europe. Eylea is approved for the treatment of wet AMD, macular edema following RVO and diabetic retinopathy and DME in the United States and for the treatment of wet AMD, RVO and DME in the European Union.

Additional future competition may emerge from biosimilar anti-VEGF products as they are approved and enter the market.

Ocular drug candidates being investigated for treatment of wet AMD may also represent potential competition for CLS-AX. Ocular Therapeutics and Eyepoint are companies currently investigating TKIs for ocular use in late-stage clinical trials. We expect other established companies will seek to develop new products in the ocular space with the goal of superior efficacy and duration over the current standard of care.

REGENXBIO, Adverum, and 4D Molecular Therapeutics are currently conducting mid to late-stage clinical trials with various ocular gene therapies for the treatment of wet AMD. These gene-based treatments could potentially compete with CLS-AX due to their potential to be long-acting treatments.

The SCS Microinjector faces competition from other devices being developed to access ocular posterior tissues via the SCS. Oxular Limited and Everads both have developed competing products and are in various stages of early-stage clinical development.

Both large and established companies, as well as smaller or early-stage companies could represent challenges in the competitive space. Larger established companies may have greater resources such as greater financial resources, deeper expertise and personnel in nonclinical development, clinical development, manufacturing and regulatory sectors. Smaller or early-stage companies could pose a challenge competitively through collaborative arrangements with large and established companies. Lastly, both small and large companies will compete in areas such as recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient recruitment for competing clinical trials.

Several key competitive factors affecting the potential success of our product candidates are likely to be the efficacy, safety, method of administration, convenience, price and the availability of coverage and reimbursement from government and other third-party payors. Additionally, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, more convenient or are less expensive than any drugs we develop. The timing of competitors' regulatory approval and patent protection could also impact commercial opportunities. Competitors receiving approval prior to us could result in stronger market positioning and/or obtaining FDA market exclusivity. Competitors' patent protection could potentially delay FDA approval of our product candidates for up to 30 months, as well as subject us to potential patent litigation that might arise beyond the 30 months.

**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 28 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 21 patent applications pending in the United States, 88 issued foreign patents, 2 pending international PCT applications and 39 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 8 issued U.S. patents, 4 pending U.S. applications, and 23 of the issued foreign patents in major international markets, each relating to devices or 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, if issued, between 2027 and 2042, 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 Abbreviated New Drug Application, or 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, or the Georgia Tech License Agreement, with Emory University, or Emory, and the Georgia Tech Research Corporation, or GTRC and together with Emory, the Licensor, 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, we made a $75,000 payment related to a milestone that was achieved in December 2021 for 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. Additionally, we are currently paying 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.

On January 31, 2024, or the Amendment Execution Date, we and the Licensor entered into an amendment, or the Amendment, to the Georgia Tech License Agreement.

Pursuant to the Amendment, the parties agreed to reduce the Sublicense Percentage (as defined in the Georgia Tech License Agreement) from a low double digit percentage to a high single digit percentage that we will pay the Licensor applicable to any fees or payments paid to us by any Sublicensee (as defined in the Georgia Tech License Agreement) of the Licensed Patents and/or Licensed Technology (each as defined in the Georgia Tech License Agreement), on or after July 1, 2023, excluding (i) amounts paid to us by a Sublicensee to reimburse us for certain research and development costs pursuant to a written agreement between us and such Sublicensee, (ii) the value of intellectual property transferred or granted to us if necessary or helpful to the development or commercialization of Licensed Products (as defined in the License Agreement) and (iii) amounts paid for shares of our stock. The payment to Licensor of any such Sublicense Percentage is due within 30 days of receipt by us of a qualifying payment from a Sublicensee, provided however, with respect to any qualifying payments received by us from a Sublicensee after July 1, 2023 but prior to January 1, 2025, the payment to Licensor of any such Sublicensee Percentage is due to Licensor by March 31, 2025.

In addition, the parties agreed to a revised annual license maintenance fee due each year, or the Maintenance Fee, starting in 2023 through 2028, as follows: $250,000 for 2023 through 2025, $350,000 for 2026, $400,000 for 2027 and $500,000 for 2028. We paid the Maintenance Fee for 2023 in February 2024. The remaining annual Maintenance Fee payments are due on October 1st of each year.

The remaining terms of the Georgia Tech License Agreement, including the low single digit royalty rate paid to the Licensor by us on sales of Licensed Products, were unchanged by the Amendment.

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, the Georgia Tech License Agreement will expire upon the expiration of the last to expire of the licensed patents. We have the right to terminate the Georgia Tech License Agreement at any time upon 60 days' written notice to Emory and GTRC. Emory and GTRC may also terminate the Georgia Tech License Agreement in the event of a material breach by us. The Georgia Tech 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 trademarks in Russia, two registered trademarks in Singapore, six registered trademarks in Brazil, five registered and one pending application in Canada, five registered trademarks, one pending and one unfiled trademarks in China, six registered trademarks in the European Union, two registered trademarks in each of India and New Zealand, one registered trademarks in Japan, three registered, one pending and two unfiled applications in Israel, eight registered trademarks and one pending in Mexico, four registered and three pending applications in South Africa, six registered trademarks and four pending applications in the United States and six registered trademarks in the United Kingdom. We also have three international registrations: the first with registered protection in the European Union, India, Japan, New Zealand, Korea and Singapore; the second with registered protection in Australia, China, European Union, India, Israel, Japan, Korea, Mexico, New Zealand, Russia, and Singapore; and the third with extensions of protection pending in Australia, Brazil, Canada, Japan and Mexico.

***Government regulation***

In the United States, the FDA regulates drug and device products under the Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations. This includes combination products where a drug and a device are used together.

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, has primary jurisdiction over the premarket development, review and approval of our product candidates.

***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 good laboratory practice;
- 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 independent institutional review board, or 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 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 boxed 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. The FDA will issue either an approval of the NDA or a complete response letter, or 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. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. 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***

One of our regulatory strategies 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 may seek orphan drug designation for 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 and their subcontractors that use, disclose, access, or otherwise process protected health information. 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.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, impose strict requirements for processing personal data. Under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, the Personal Information Protection and Electronic Documents Act and various related provincial laws, as well as Canada's Anti-Spam Legislation, may, in the future, apply to our operations.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

Additionally, California has 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 applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the California Privacy Rights Act of 2020, or CPRA, expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia, Colorado, Utah, and Connecticut have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely.

With the GDPR, CCPA, CPRA, and other state and Federal laws, regulations and other obligations relating to privacy and data protection imposing new and relatively burdensome obligations, and with substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices, and may incur significant costs and expenses in an effort to do so. Additionally, if third parties we work with, such as vendors or service providers, violate applicable laws or regulations or our policies, such violations may also put our or our customers' data at risk and could in turn have an adverse effect on our business.

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 (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), 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 XIPERE and our other 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. In November 2023, AMA assigned XIPERE the Category 1 CPT code 67516. We believe the Category 1 code may facilitate better access and adoption of XIPERE and the suprachoroidal injection method.

Our strategy will include efforts to engage third-party payors to establish coverage, coding and reimbursement that will facilitate access to XIPERE and 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 XIPERE and 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 XIPERE and our product candidates or for XIPERE and 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 XIPERE and 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. Under both Advanced Alternative Payment Models, or APMs, and Merit-based Incentive Payment System, or MIPS, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments. In addition, beginning on January 1, 2023, certain

manufacturers will be required to pay quarterly refunds to CMS for discarded amounts of single-dose container and single-use package drugs covered under Medicare Part B. Refunds will be based on the discarded volume above 10% of the total allowed amount, except in unique circumstances as determined by CMS. 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 have been judicial and Congressional challenges to certain aspects 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. Further, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear any additional healthcare reform measures of the Biden administration 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. 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 subsequent amendments, will remain in effect until 2032. 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, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B

or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. It is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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 and Human Capital Resources**

We strive to recruit people who share our vision to develop technology that provides a ground-breaking impact to medicine and superior care to patients. We are proud of what we do and believe we create an excellent working environment that is inclusive and diverse with meaningful compensation, benefits and wellness programs that continue to facilitate the attraction, retention and motivation of talented employees.

As of December 31, 2023, we had 30 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 30005. 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 a net loss of $32.5 million and $32.9 million, respectively, in 2023 and 2022. We expect to incur significant expenses and operating losses over the next several years. Our financial results may fluctuate significantly from quarter to quarter and year to year.

We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. 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;
- establish additional partnerships for the development and commercialization of our assets;
- 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.

***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 third quarter of 2025. However, we will need to obtain substantial additional funding in connection with our continuing operations beyond the third quarter of 2025, including additional funding to complete clinical development of CLS-AX. 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, for any of our product candidates for which we receive marketing approval and intend to commercialize ourselves;
- the amount of revenue, if any, received pursuant to our license and collaboration agreements;
- the amount of revenue, if any, received from commercial sales of any 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 of our product candidates and achieve product sales. In addition, XIPERE and our other product candidates, if approved, may not achieve commercial success. 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. For example, in February 2024, we completed a registered direct offering of 11,111,111 shares of common stock and accompanying warrants to purchase 11,111,111 shares of common stock for gross proceeds of approximately $15.0 million, before deducting placement agent fees and estimated offering expenses. We do not currently have any committed external source of funds, 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 grant licenses on terms that may not be favorable to or relinquish valuable rights to our technologies, research programs, product candidates or future revenue streams. For example, we, through our wholly-owned subsidiary, sold our rights to receive certain royalty and milestone payments under the Arctic Vision License Agreement, Bausch License Agreement, the Aura License Agreement, the REGENXBIO Option and License Agreement and any out-license agreements for, or related to, XIPERE or our SCS Microinjector technology to be used in connection with compounds or products of any third parties in exchange for up to $65 million. 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 agreements with HCR contain various covenants and other provisions, which, if violated, could materially adversely affect our financial condition.***

In August 2022, we, through Royalty Sub, entered into the Purchase and Sale Agreement, with HCR pursuant to which we sold our rights to royalty and milestone payments due to us from XIPERE and certain license agreements related to our SCS Microinjector, or the Royalties, subject to a cap of 2.5 times the total purchase price paid by HCR under the Purchase and Sale Agreement, which cap can be increased to 3.4 times under certain circumstances. Under the terms of the Purchase and Sale Agreement, Royalty Sub received an initial payment of $32.5 million, less certain expenses. The terms of the Purchase and Sale Agreement also provide for an additional $20 million milestone payment to Royalty Sub upon attainment of a second pre-specified sales milestone related to 2024 XIPERE sales.

In connection with the Purchase and Sale Agreement, we entered into a Contribution and Servicing Agreement with Royalty Sub, pursuant to which we assigned the Arctic Vision License Agreement, Bausch License Agreement, Aura License Agreement, REGENXBIO Option and License Agreement, our license agreement with Emory University and The Georgia Tech Research Corporation and related intellectual property rights, or collectively the Contributed Assets, to Royalty Sub. The Contribution and Servicing Agreement contains various representations and warranties, covenants, indemnification obligations and other provisions related to the contribution of the Contributed Assets and our maintenance and servicing obligations with respect to the same.

In connection with the Purchase and Sale Agreement, we also entered into a Pledge and Security Agreement with HCR. The Pledge and Security Agreement contains various representations, warranties and covenants, and includes a limited recourse guaranty of Royalty Sub's obligations under the Purchase and Sale Agreement which is secured by the pledge in favor of HCR all of the capital stock of Royalty Sub. HCR is entitled to foreclose on the capital stock of Royalty Sub following the occurrence of certain remedies events, including, without limitation, a bankruptcy of us, our failure of to perform our obligations under the Contribution and Servicing Agreement or in the event of a change of control of us, any failure to make the payment required under Section 2.3 of the Purchase and Sale Agreement within the time period required thereunder. Such foreclosure, if it were to occur, could have a material adverse effect on our financial condition as HCR, by virtue of owning Royalty Sub, would own the Royalties and the Contributed Assets.

***Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, such as the conflicts in Ukraine and the Middle East, or other macroeconomic conditions.***

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability. In 2023, the Federal Reserve raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military hostilities in Russia, Ukraine and the Middle East have created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our or our partners' business. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly or more dilutive or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including clinical trials costs and labor and employee benefit costs.

***Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.***

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems.

Our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity.

**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 SCS. 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 third parties to deliver their proprietary drug candidates into the SCS for the potential treatment of certain ocular indications.

Although the FDA approved XIPERE for suprachoroidal use for the treatment of macular edema associated with uveitis, we cannot guarantee that suprachoroidal injection of other 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 other drugs will achieve regulatory approval, even if the clinical trials are successful.

In addition, 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 drugs 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 drugs. Additionally, in some cases, drugs 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 SCS. 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 after we have satisfied our obligations under the Purchase and Sale Agreement, which could significantly harm our financial position.

***If we are unable to obtain regulatory approval for, and commercialize either on our own or with a third party, CLS-AX or our other product candidates, or if we experience significant delays in doing so, our business may be harmed.***

Given our 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 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 trials. 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 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 CLS-AX or 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.

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.

For example, our ODYSSEY trial was delayed due to the issuance by FDA of draft guidance, requiring us to reassess our original protocol design and we subsequently decided to amend the protocol to have aflibercept as the comparator drug.

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 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.

***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. After we have satisfied our obligations under the Purchase and Sale Agreement, if we are unable to maintain our partnership with Bausch, or if Bausch fails to successfully commercialize XIPERE, our business and prospects will be materially harmed.***

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. We will not retain these royalties and milestone payments until our obligations under the Purchase and Sale Agreement described above in "Business—Royalty Purchase and Sale Agreement" are satisfied. The successful or timely achievement of many of these milestones is outside of our control because the relevant activities will be conducted by Bausch or third parties engaged by Bausch, including manufacturers and suppliers. We expect to depend to a large degree on the payments from Bausch after we have satisfied our obligations under the Purchase and Sale Agreement as well as payments from 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 have entered into, and intend to continue to enter into, collaborations with third parties for the development and commercialization of XIPERE. In addition, we may seek commercialization partners for our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of XIPERE and our product candidates.***

We have entered into, and intend to continue to enter into, agreements with third-party collaborators for the development and commercialization of XIPERE and 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 XIPERE and 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;
- our collaborators' regulatory submissions may be denied by the applicable regulatory authorities;
- 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 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 our 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 do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of our current product candidates and our SCS Microinjector. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug products and 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 of our product candidates 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, for any of our product candidates that receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug products 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. In addition, 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 subject to 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. 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.

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/or our commercialization partner's 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.

***XIPERE and any of our product candidates that receive marketing approval, 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.***

XIPERE and any of our product candidates that receive marketing approval 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 XIPERE or 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 XIPERE and 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 products 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. We also are aware of companies that are developing suprachoroidal injectors which may compete with our SCS Microinjector.

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, for which a number of generic equivalents are currently available. Kenalog is indicated only for intramuscular or intraarticular injection; however, it is commonly used off-label for intraocular inflammation using intravitreal and periocular administration. In addition, Alcon's injectable TA, Triesence, is approved in the United States for the treatment of uveitis and other ocular inflammatory conditions unresponsive to topical corticosteroids, although it is not indicated for the treatment of macular edema associated with uveitis. 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. Ozurdex is also approved in the United States for the treatment of DME. Retisert and Yutiq, both intravitreal implants of fluocinolone acetonide, are marketed by Bausch and Alimera, respectively, and are approved in the United Sates for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

CLS-AX faces competition with anti-VEGF drugs, the current standard of care for RVO and wet AMD, as well as other drug candidates in development for ocular use for the treatment of wet AMD, such as other TKI's. Axitinib, also known by its brand name Inlyta, is not currently approved for an ocular indication but is approved by the FDA and marketed by Pfizer for the treatment of advanced renal cell carcinoma. Genentech has several products which serve as competitors in this space, including anti-VEGF agents Lucentis, Avastin, and Susvimo. 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 routinely 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. Susvimo, an ocular implant that releases ranibizumab over time, received approval from the FDA in October 2021 for the treatment of wet AMD in patients who have previously responded to anti-VEGF therapy. Additionally, Genentech's product, Vabysmo (faricimab-svoa), an intravitreal injection which blocks two disease pathways, including (Ang-2) and vascular endothelial growth factor-A (VEGF-A), received approval in January 2022 for the treatment of wet AMD and diabetic macular edema. In addition to Genentech's products, Regeneron's anti-VEGF product, Eylea 2 mg and 8 mg and Novartis' product, Beovu, also present potential competition for CLS-AX in both the United States and Europe. Eylea is approved for the treatment of wet AMD, macular edema following RVO and diabetic retinopathy and DME in the United States and for the treatment of wet AMD, RVO and DME in the European Union. Novartis' Beovu was approved in 2019 for the treatment of wet AMD in the United States and in 2020 in Europe.

Ocular drug candidates being investigated for treatment of wet AMD may also represent potential competition for CLS-AX. Ocular Therapeutics and Eyepoint are companies currently investigating TKIs for ocular use in late-stage clinical trials. We expect other established companies will seek to develop new products in the ocular space with the goal of superior efficacy and duration over the current standard of care.

REGENXBIO, Adverum, and 4D Molecular Therapeutics are currently conducting mid to late-stage clinical trials with various ocular gene therapies for the treatment of wet AMD. These gene-based treatments could potentially compete with CLS-AX due to their potential to be long acting treatments.

The SCS Microinjector faces competition from other devices being developed to access ocular posterior tissues via the SCS. Oxular Limited and Everads both have developed competing products and are in various stages of early-stage clinical development

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.

***XIPERE and 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 XIPERE and any of our product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for XIPERE and 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 XIPERE and any other 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 XIPERE and our other 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 XIPERE and our other 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. Under both APMs and MIPS, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments. 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 XIPERE and our other 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. In November 2023, AMA assigned XIPERE the Category 1 CPT code 67516. We believe the Category 1 code may facilitate better access and adoption of XIPERE and the suprachoroidal injection method. 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. Additionally, coverage policies and reimbursement rates may change at any time. For example, beginning on January 1, 2023, certain manufacturers will be required to pay quarterly refunds to CMS for discarded amounts of single-dose container and single-use package drugs covered under Medicare Part B. Refunds will be based on the discarded volume above 10% of the total allowed amount, except in unique circumstances, as determined by CMS. 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. Further, 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.

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 XIPERE and one or more product candidates, even if our other product candidates obtain marketing approval.

There can be no assurance that XIPERE and our other 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 XIPERE and our other 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 sale of XIPERE as well as the testing of our product candidates in human clinical trials. 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.

**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.

***Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment, or PTA, for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in future and whether patent expiration dates may be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system will likely be introduced by the end of 2023, which would significantly impact European patents, including

those granted before the introduction of such a system. Under the unitary patent system, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

***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. If 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**

***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 expect to rely on third-party CROs to assist us in preparing some or all aspects of the applications necessary to gain marketing approvals. 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 a product candidate satisfies 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 in this pathway 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 believe that certain of 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 for a product candidate 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-device combination product.***

Our product candidates require coordination within the FDA and similar foreign regulatory agencies for review of the drug along with the SCS Microinjector. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination 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. Additionally, other jurisdictions may have additional requirements for any drug and device combination, which may cause delays in product approval.

***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.

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money

laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

***Any product 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. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. 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, including 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 research, 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 (including privacy and cybersecurity laws and regulations) 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;
- the Health Insurance Portability and Accountability Act, or 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 the Health Information Technology for Economic and Clinical Health Act of 2019, or 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 and their subcontractors that use, disclose, access, or otherwise process individually identifiable health information, 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, 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 (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), 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;

- U.S. data privacy regulations, such as the CCPA, which creates new individual privacy rights for consumers and places increased privacy and security obligations on entities handling personal data of consumers or households. 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;
- new U.S. data privacy regulations, such as the California Privacy Rights Act of 2020, or CPRA, which establishes a new California Privacy Protection Agency to implement and enforce the CPRA. Other states, such as Virginia, Colorado, Utah, and Connecticut have also passed comprehensive privacy laws that have or will go into effect during 2023, and similar laws are being considered in several other states, as well as at the federal and local levels. While these new state laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors);
- foreign data privacy regulations, such as the General Data Protection Regulation (2016/679), or GDPR, which 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, including a private right of action. Also under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions. Other such foreign data privacy obligations include the EU GDPR as it forms part of United Kingdom, or UK, law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or UK GDPR; and
- In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

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.

The Affordable Care Act among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) 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; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented 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 expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been judicial and congressional challenges to certain aspects of the Affordable Care Act. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. The Affordable Care Act may be subject to additional judicial or Congressional challenges in the future. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how any additional healthcare reform measures of the Biden administration 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 subsequent legislative amendments, will stay in effect through 2032, unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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.

**Risks Related to Ownership of Our Common Stock**

***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. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated or disproportionate to the operating performance of particular companies. Broad market and industry factors, including potentially worsening economic conditions, inflation and other adverse effects or developments may negatively affect the market price of our common stock, regardless of our actual operating performance. 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;
- sales of our common stock, including sales by our directors and officers or specific stockholders; and
- general political and economic conditions.

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 and other equity-linked securities in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.***

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. For example, we, among other things, issued warrants to purchase 11,111,111 shares of common stock to certain investors in a registered direct offering. As of March 5, 2024, we had outstanding warrants to purchase an aggregate of 11,111,111 shares of common stock. The exercise of our outstanding warrants could result in significant dilution to existing stockholders, adversely affect

the market price of our common shares and impair our ability to raise capital through the sale of additional equity securities. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

***If we fail to meet all applicable requirements of Nasdaq and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.***

On September 27, 2023, we received a letter from Nasdaq, notifying us that, for the previous 30 consecutive business day periods prior to the date of the letter, the closing bid price for our common stock was below $1.00. In accordance with Nasdaq Listing Rule 5810(c)(3)(A) we were provided an initial period of 180 calendar days, or until March 25, 2024, to regain compliance with Nasdaq's bid price requirement. On December 12, 2023, as a result of our common stock trading over $1.00 for 10 consecutive business days, we received a notice from the Nasdaq Listing Qualifications Office indicating that we regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5450(a)(1).

There can be no assurance that we will maintain compliance with the requirements for listing our common stock on Nasdaq. If we are unable to satisfy the Nasdaq criteria for continued listing, our common stock would be subject to delisting. A delisting of our common stock could negatively impact us by, among other things, reducing the liquidity and market price of our common stock; reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; decreasing the amount of news and analyst coverage of us; and limiting our ability to issue additional securities or obtain additional financing in the future. In addition, delisting from Nasdaq may negatively impact our reputation and, consequently, our business.

***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.

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. However, this exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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

We are a "smaller reporting company," meaning that the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We will continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and we have reduced disclosure obligations regarding executive compensation. In addition, as a smaller reporting company and non-accelerated filer, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

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

We have broad discretion over the use of our cash and cash equivalents. Investors may not agree with our decisions, and our use of our cash may not yield any return on investment. Our failure to apply our resources effectively could compromise our ability to pursue our growth strategy. Investors 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 the sole source of gains and investors may never receive a return on their investment.***

Investors 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 prior loan agreement prohibited us from paying dividends without the consent of the lenders under the agreement, and we expect that the terms of any future debt agreements would likewise preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be investors' sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

**General Risk Factors**

***If our information technology systems or those third parties upon which we rely or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.***

In the ordinary course of our business, we and the third parties upon which we rely, process, collect, receive, store, process, generate, use, transfer, disclose, and share proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets.

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. Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect and threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. These threats come from a variety of sources. In addition to traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors now engage in attacks. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective.

Any of the foregoing 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, or any personal data for which we are responsible, 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. Our contracts may not contain limitations

of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

***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, as modified by the CARES Act, the Inflation Reduction Act, 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, or the Code. In March 2020, the Tax Act was modified in certain respects by the Coronavirus Aid, Relief, and Economic Security (CARES) Act. More recently, the Inflation Reduction Inflation of 2022, or the IRA, was enacted which includes provisions that impact the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to the Tax Act, as modified by the CARES Act, and the IRA, may affect us, and certain aspects of the Tax Act, CARES Act and IRA 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, the CARES Act, the IRA, 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, the CARES Act, the IRA, 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 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, 2023, we had approximately $225.9 million of federal and $89.3 million of state net operating loss, or NOL, carryforwards. If not utilized, the portion of these federal NOL carryforwards arising in tax years beginning before 2018 will

begin to expire at various dates beginning in 2034, and these state NOL carryforwards will begin to expire at various dates beginning in 2027. Under the Tax Act, as modified by the CARES Act, federal NOLs incurred in taxable years beginning in 2018 and in later years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited for taxable years beginning after 2020 to 80% of taxable income. Certain states have conformed to the federal NOL rules included in the Tax Act and CARES Act. However, under Section 382 of the Code of 1986, 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 ownership changes. The completion of our IPO, follow-on public offerings, private placements and other transactions that have occurred, and future offerings of our securities have triggered, and may in the future trigger additional, ownership changes. We have determined that three such ownership changes have occurred in the past. We have determined that $38,000 and $2,000 of our deferred tax assets related to federal NOL and R&D credits, respectively, will expire due to Section 382.

In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo ownership changes in the future. Any such additional limitations 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 limitations. At the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

***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. Because we are a smaller reporting company and a non-accelerated filer, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. However, 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 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 if we cease to be a smaller reporting 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.

***Climate change, extreme weather events, earthquakes and other natural disasters could adversely affect our business.***

In recent years, extreme weather events and changing weather patterns such as storms, flooding, droughts, fires and temperature changes have become more common. As a result, we are potentially exposed to varying natural disaster or extreme weather risks such as hurricanes, tornadoes, fires, droughts or floods, or other events that may result from the impact of climate change on the environment, such as sea level rise. The potential impacts of climate change may also include increased operating costs associated with additional regulatory requirements and investments in reducing energy, water use and greenhouse gas emissions.

***Adverse global economic conditions and geopolitical tensions could have a negative effect on our business, results of operations and financial condition and liquidity.***

In recent years, concerns about the global economic outlook have adversely affected market and business conditions in general. Macroeconomic weakness and uncertainty could make it more difficult for us or the licensing partners on whom we depend to commercialize XIPERE to manage our respective operations. Geopolitical tensions, such as Russia's recent incursion into Ukraine, ongoing conflicts between the United States and China, tariff and trade policy changes, economic sanctions and increasing potential of conflict involving countries in Asia, including countries that are part of the Arctic Territory under our license agreement with Arctic Vision, create uncertainty for us and for global commerce generally. Sustained or worsening of global economic conditions and increasing geopolitical tensions may increase our cost of doing business, limit our ability to access capital, disrupt our supply chain operations or the supply chain operations of our licensing partners and intensify pricing pressures. Any or all of these factors could negatively affect our business, financial condition and result of operations.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 1C. CYBERSECURITY

***Risk management and strategy***

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and trade secrets, data we may collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information, or collectively Information Systems and Data.

Our cybersecurity function, which comprises, in part, our information technology team, helps identify, assess and manage our cybersecurity threats and risks. Our cybersecurity function identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, manual tools, internal or external audits, automated tools, subscribing to and analyzing reports and services that identify cybersecurity threats and threat actors, conducting threat assessments for internal and external threats, conducting scans of the threat environment, evaluating our (and our industry's) risk profile, using external intelligence feeds, conducting vulnerability assessments to identify vulnerabilities, and evaluating threats reported to us. Depending on the environment, we implement and maintain various technical, physical, and organizational measures and processes designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response, an incident response plan, a vendor risk management program, employee training, data encryption, access controls, physical security, network security controls, systems monitoring, cyber insurance, and asset management, tracking, and disposal.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, the cybersecurity function works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example professional services firms (including legal counsel), threat intel service providers, and cybersecurity software providers. We also use third-party service providers to perform a variety of functions throughout our business, such as hosting companies, application providers, contract research organizations, supply chain resources, and contract manufacturing organizations. We manage cybersecurity risks associated with our use of these providers by conducting audits and risk assessments on certain vendors, requesting and analyzing responses on a security questionnaire, and reviewing relevant reports.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "—If our information technology systems or those third parties upon which we rely or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.".

***Governance***

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The audit committee is responsible for overseeing Company's cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of management, including our Senior Director of Information Technology, who has over 23-years of experience in IT management (including cybersecurity) and a degree in Computer Information Systems.

Our Senior Director of IT, as part of our overall cybersecurity function, is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. Our Chief Financial Officer, or CFO, is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other significant security-related incidents.

Our response process to cybersecurity incidents is designed to escalate certain incidents to members of management depending on the circumstances, including the CFO. Our CFO and Senior Director of IT work with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response policy includes reporting to the board of directors committee responsible for certain cybersecurity incidents.

The audit committee receives an annual update from our cybersecurity function concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. In addition, they receive timely notifications of significant cybersecurity incidences based on our cybersecurity response plan. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

## ITEM 2. PROPERTIES

Our principal offices occupy approximately 14,000 square feet of office space in Alpharetta, Georgia under a lease with an initial term until November 2026, with a renewal option for one additional three-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.

### Stockholders

As of March 5, 2024, we had 74,721,139 shares of common stock outstanding held by 7 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. [Reserved].

## 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 focused on revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space, or SCS. Our SCS injection platform, utilizing our proprietary SCS Microinjector, enables an in-office, repeatable, non-surgical procedure for the targeted and compartmentalized delivery of a wide variety of therapies to the macula, retina or choroid to potentially preserve and improve vision in patients with sight-threatening eye diseases. Our suprachoroidal injection technology can be used in conjunction with existing drugs designed for delivery to the SCS, novel therapies, and future therapeutic innovations. We believe our proprietary suprachoroidal administration platform has the potential to become a standard for delivery of therapies intended to treat chorioretinal diseases.

We are leveraging our SCS injection platform by building an internal research and development pipeline targeting retinal diseases and by creating external collaborations with other companies. We are developing our own pipeline of small molecule product candidates for administration via our SCS Microinjector, and we also strategically partner with companies developing other ophthalmic therapeutic innovations to be administered using our SCS injection platform. Our first product, XIPERE (triamcinolone acetonide injectable suspension) for suprachoroidal use, was approved by the U.S. Food and Drug Administration, or the FDA, in October 2021. Approval of XIPERE was a significant milestone for us as it is the first approved therapeutic delivered into the SCS, the first commercial product developed by us, and the first therapy for macular edema associated with uveitis.

Our operations to date have been limited to organizing and staffing our company, raising capital, conducting preclinical studies and clinical trials and undertaking other research and development initiatives. To date, we have only generated revenue through upfront payments and milestone payments related to license agreements and other revenue generated from collaboration agreements. 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, 2023, we had an accumulated deficit of $320.9 million. We recorded net losses of $32.5 million and $32.9 million for the years ended December 31, 2023 and 2022, respectively, and net income of $0.4 million for the year ended December 31, 2021. 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 therapeutics 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 XIPERE is successfully commercialized by its licensees or until we successfully complete development of, obtain regulatory approval for and commercialize additional product candidates, either on our own or together with a third party. Our financial results 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. We expect clinical trial expenses to increase in 2024 as a result of our ongoing Phase 2b clinical trial of CLS-AX as well as continuing our pipeline development. We also 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. Based on our current research and development plans, we expect to have sufficient resources to fund our planned operations into the third quarter of 2025. We will require additional capital in order to complete clinical development of CLS-AX.

### Macroeconomic Considerations

Unfavorable conditions in the economy in the United States and abroad may negatively affect the growth of our business and our results of operations. For example, macroeconomic events, rising inflation, the U.S. Federal Reserve raising interest rates, and conflicts in Ukraine, Russia and the Middle East have led to economic uncertainty globally. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed. For further discussion of the potential impacts of macroeconomic events on our business, financial condition, and operating results, see the section titled "Risk Factors."

**Components of Operating Results**

***Revenue***

We have not generated any revenue from the sale of XIPERE and we do not expect to generate any other product revenue unless or until we obtain regulatory approval of and commercialize our other product candidates, either on our own or with a third party. The revenue received under the Bausch license agreement, as well as other certain payments from our licensees, will be recorded as non-cash revenue until we have fulfilled our obligations under the Purchase and Sale Agreement. Our revenue in recent years has been generated primarily from our license agreements. We continue to seek 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 activities and clinical trials;
- 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, 2023, 2022 and 2021.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| | | (in thousands) | |
| XIPERE (uveitis program) | $ 132 | $ 339 | $ 2,612 |
| CLS-AX (wet AMD program) | 9,170 | 5,449 | 4,515 |
| Total program expense | 9,302 | 5,788 | 7,127 |
| Unallocated | 11,544 | 13,842 | 11,410 |
| Total research and development expense | $ 20,846 | $ 19,630 | $ 18,537 |

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.

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 our product candidates including the SCS Microinjector for clinical trials and for requirements associated with regulatory filings;
- 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***

Other income consists of the gain on the extinguishment of the Paycheck Protection Program, or PPP, Loan and accrued interest and interest income earned on our cash and cash equivalents. Interest income is not currently significant to our financial statements.

***Non-cash Interest Expense on Liability Related to the Sales of Future Royalties***

Non-cash interest expense on liability related to the sales of future royalties consists of imputed interest on the carrying value of the liability and the amortization of the related issuance costs.

**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 consolidated 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 consolidated 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 royalty financing obligation, 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, in accordance with U.S. GAAP, as those 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***

We recognize revenue from our contracts with customers under Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, or ASC 606. 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. The arrangements may also include assistance and oversight of the customer's use of the drug substance or drug product. 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 consolidated 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.

***Share-based compensation***

Compensation cost related to share-based awards granted to employees, directors and consultants 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. 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 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 estimate 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.* 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 the historical volatility of our common stock.
- *Expected term.* In the years ended December 31, 2023 and 2022, we used historical data to calculate the expected term. In the year ended December 31, 2021, we used the simplified method as prescribed by the SEC Staff Accounting Bulletin

No. 107, *Share-Based Payment*, as we did 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 $4.2 million, $4.9 million and $5.1 million for the years ended December 31, 2023, 2022 and 2021, respectively.

***Liabilities Related to the Sales of Royalties and Non-Cash Interest Expense***

In connection with the Purchase and Sale Agreement, we recognized a liability related to the sales of future royalties under ASC 470-10 Debt and ASC 835-30 Interest - Imputation of Interest. The initial funds received by us pursuant to the terms of the Purchase and Sale Agreement were recorded as a liability and are accreted under the effective interest method up to the estimated amount of future royalties and milestone payments to be made under the Purchase and Sale Agreement. The issuance costs were recorded as a direct deduction to the carrying amount of the liability and are being amortized under the effective interest method over the estimated period the liability will be repaid. We estimate the total amount of future royalty revenue and milestone payments to be generated over the life of the Purchase and Sale Agreement, and a significant increase or decrease in these estimates could materially impact the liability balance and the related interest expense. If the timing of the receipt of royalty payments or milestones is materially different from the original estimates, we will prospectively adjust the effective interest and the related amortization of the liability and related issuance costs.

***Tax valuation allowance***

We recorded aggregate deferred tax assets of $47.4 million, primarily related to our net operating losses, as of December 31, 2023, 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, 2023. We incurred a net loss for tax purposes of $7.8 million for the year ended December 31, 2023. 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, 2023, we had federal NOL carryforwards of $225.9 million and state NOL carryforwards of $89.3 million available to reduce future taxable income, if any. These federal NOL carryforwards will begin to expire at various dates starting in 2034. 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. The completion of our IPO, follow-on public offerings, private placements and other transactions that have occurred, and future offerings of our securities have triggered, and may in the future trigger additional, ownership changes. We have determined that three such ownership changes have occurred in the past. We have determined that $38,000 and $2,000 of our deferred tax assets related to federal NOL and R&D credits, respectively, will expire due to Section 382. In addition, 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, 2023 and 2022**

The following table sets forth our results of operations for the years ended December 31, 2023 and 2022.

| | Year Ended December 31, | | Period-to-Period Change |
|---|---|---|---|
| | 2023 | 2022 | |
| | | (in thousands) | |
| License and other revenue | $ 8,226 | $ 1,327 | $ 6,899 |
| Operating expenses: | | | |
| Cost of goods sold | 355 | 204 | 151 |
| Research and development | 20,846 | 19,630 | 1,216 |
| General and administrative | 11,869 | 11,770 | 99 |
| Total operating expenses | 33,070 | 31,604 | 1,466 |
| Loss from operations | (24,844) | (30,277) | 5,433 |
| Other income | 1,719 | 669 | 1,050 |
| Non-cash interest expense on liability related to the sales of future royalties | (9,360) | (3,339) | (6,021) |
| Net loss | $ (32,485) | $ (32,947) | $ 462 |

*Revenue*. In the year ended December 31, 2023 and 2022, we recognized $8.2 million and $1.3 million of revenue associated with our license agreements. License revenue for the year ended December 31, 2023 was primarily a result of the upfront license fee payment of $5.0 million from BioCryst, $1.4 million of milestone payments from Aura and $1.0 million from providing training materials and clinical trial products to our licensees. License revenue for the year ended December 31, 2022 was primarily from providing training materials and clinical trial products to our licensees.

*Cost of Goods Sold*. In the years ended December 31, 2023 and 2022, we recognized $0.4 million and $0.2 million, respectively, in cost of goods sold related to the sales of our SCS Microinjector kits to our licensees.

*Research and development*. Research and development expense increased by $1.2 million, from $19.6 million for the year ended December 31, 2022 to $20.8 million for the year ended December 31, 2023. This increase was primarily due to a $6.8 million increase for the costs of ODYSSEY, a Phase 2b clinical trial of CLS-AX and related manufacturing costs for formulation and production. This was offset by a $2.2 million decrease in costs for OASIS, a Phase 1/2a clinical trial of CLS-AX and the OASIS extension study. Additionally, there was $1.4 million decrease in costs related to our other programs, a $0.2 million decrease in costs related to XIPERE, a $0.7 million decrease in employee related costs and $0.8 million in research and development tax credits received in the current year.

*General and administrative*. General and administrative expenses increased by $0.1 million for the years ended December 31, 2023 and 2022. This increase was primarily a result of a $0.7 million increase in professional fees, partially offset by a $0.2 million decrease in patent related expenses and a $0.3 million decrease for insurance costs.

*Other income.* Other income for the year ended December 31, 2023 and 2022 was primarily comprised of interest income from the cash and cash equivalents. The increase for the year ended December 31, 2023 was due to higher interest rates.

*Non-cash interest expense from liability related to the sales of future royalties*. Non-cash interest expense for the year ended December 31, 2023 and 2022 was comprised of imputed interest on the liability related to the sales of future royalties and the amortization of the associated issuance costs. The increase was due to a full year of interest expense for the year ended December 31, 2023 versus five months of interest expense for the year ended December 31, 2022.

**Results of Operations for the Years Ended December 31, 2022 and 2021**

The following table sets forth our results of operations for the years ended December 31, 2022 and 2021.

| | Year Ended December 31, | | Period-to-Period Change |
|---|---|---|---|
| | 2022 | 2021 | |
| | (in thousands) | | |
| License and other revenue | $ 1,327 | $ 29,575 | $ (28,248) |
| Operating expenses: | | | |
| Cost of goods sold | 204 | — | 204 |
| Research and development | 19,630 | 18,537 | 1,093 |
| General and administrative | 11,770 | 11,665 | 105 |
| Total operating expenses | 31,604 | 30,202 | 1,402 |
| Loss from operations | (30,277) | (627) | (29,650) |
| Other income | 669 | 1,003 | (334) |
| Non-cash interest expense on liability related to the sales of future royalties | (3,339) | — | (3,339) |
| Net (loss) income | $ (32,947) | $ 376 | $ (33,323) |

*Revenue*. In the year ended December 31, 2022 and 2021, we recognized $1.3 million and $29.6 million of revenue associated with our license agreements. License revenue for the year ended December 31, 2022 was primarily from providing training materials and clinical trial products to our licensees. License revenue for the year ended December 31, 2021 was primarily a result of (i) the milestone payments from Bausch that consisted of $5.0 million received upon FDA approval of XIPERE, the recognition of $5.0 million of deferred revenue for the upfront milestone payment and the recognition of a $10.0 million milestone for pre-launch activities and (ii) an aggregate of $8.0 million received from Arctic Vision for FDA approval of XIPERE, territory expansion and certain development milestones.

*Cost of Goods Sold*. In the year ended December 31, 2022, we recognized $0.2 million in cost of goods sold related to the sales of our SCS Microinjector kits to our licensees.

*Research and development*. Research and development expense increased by $1.1 million, from $18.5 million for the year ended December 31, 2021 to $19.6 million for the year ended December 31, 2022. This increase was primarily due to a $0.9 million increase in costs for the CLS-AX program, including costs for OASIS, a Phase 1/2a clinical trial of CLS-AX, the OASIS extension study and the preliminary startup costs of ODYSSEY, a Phase 2b clinical trial of CLS-AX. Additionally, there was a $1.2 million increase in costs related to our other programs and a $0.7 million increase in costs related to an increase in headcount. This is partially offset by a $2.3 million decrease in costs related to XIPERE.

*General and administrative*. General and administrative expenses increased by $0.1 million for the years ended December 31, 2022 and 2021. This increase was primarily a result of a $0.4 million increase in patent related expenses and a $0.5 million decrease in costs related to employee benefits.

*Other income.* Other income for the year ended December 31, 2022 was primarily comprised of interest income from the cash and cash equivalents. Other income for the year ended December 31, 2021 was primarily comprised of the gain on the extinguishment of debt from the forgiveness of the PPP Loan and accrued interest.

*Non-cash interest expense from liability related to the sales of future royalties*. Non-cash interest expense for the year ended December 31, 2022 was comprised of imputed interest on the liability related to the sales of future royalties and the amortization of the associated issuance costs.

**Liquidity and Capital Resources**

***Sources of Liquidity***

We have funded our operations primarily through the proceeds from public offerings of our common stock, sales of convertible preferred stock and the issuance of long-term debt. As of December 31, 2023, we had cash and cash equivalents of $28.9 million. We

invest any cash in excess of our immediate requirements primarily with a view to liquidity and capital preservation. As of December 31, 2023, our funds were held in cash and money market funds.

On February 6, 2024, we entered into a securities purchase agreement with institutional investors and an existing stockholder, pursuant to which we issued and sold, in a registered direct offering, or the Registered Direct Offering: (i) an aggregate of 11,111,111 shares of our common stock, or Shares; and (ii) warrants to purchase up to 11,111,111 shares of common stock, or Warrants.

The combined purchase price of each Share and accompanying Warrant was $1.35. The exercise price for the Warrants is $1.62 per share. The Warrants will be exercisable from August 9, 2024 and will expire on August 9, 2029. The net proceeds to us from the Registered Direct Offering were approximately $13.9 million.

On January 31, 2024, or the Amendment Effective Date, we entered into a fourth amendment to the license agreement, or the Emory License Agreement, with Emory University and Georgia Tech Research Corporation (collectively, the "Licensor") pursuant to which the parties agreed to reduce the Sublicense Percentage (as defined in the Emory License Agreement) from a low double digit percentage to a high single digit percentage that we will pay the Licensor applicable to any fees or payments paid to us by any Sublicensee (as defined in the Emory License Agreement) of the Licensed Patents and/or Licensed Technology (each as defined in the Emory License Agreement), on or after July 1, 2023, excluding (i) amounts paid to us by a Sublicensee to reimburse us for certain research and development costs pursuant to a written agreement between us and such Sublicensee, (ii) the value of intellectual property transferred or granted to us if necessary or helpful to the development or commercialization of Licensed Products (as defined in the Emory License Agreement) and (iii) amounts paid for shares of our stock. The payment to Licensor of any such Sublicense Percentage is due within 30 days of receipt by us of a qualifying payment from a Sublicensee, provided however, with respect to any qualifying payments received by us from a Sublicensee after July 1, 2023 but prior to January 1, 2025, the payment to Licensor of any such Sublicensee Percentage is due to Licensor by March 31, 2025. The parties also agreed to a revised annual license maintenance fee due each year, or the Maintenance Fee, starting in 2023 through 2028, as follows: $0.3 million for 2023 through 2025, $0.4 million for 2026, $400,000 for 2027 and $0.5 million for 2028. We paid the Maintenance Fee for 2023 in February 2024. The remaining annual Maintenance Fee payments are due on October 1st of each year.

On December 22, 2023, we, through our wholly owned subsidiary Royalty Sub, entered into a letter agreement, or the Letter Agreement, with HCR and HCR Clearside SPV, LLC (as assignee of HCR Collateral Management, LLC), or the Agent, amending that certain Purchase and Sale Agreement, dated as of August 8, 2022, by and among Royalty Sub, HCR and Agent. Pursuant to the terms of the Letter Agreement, Royalty Sub and Agent mutually agreed that Royalty Sub waived any and all rights to the $12.5 million milestone payment which was deposited in an escrow account, or the First Milestone Payment, in connection with the closing of the transactions contemplated by the Purchase and Sale Agreement and agreed to the release of the First Milestone Payment to Agent. The First Milestone Payment was to be released to Royalty Sub upon attainment of a pre-specified XIPERE sales milestone if such milestone was achieved by March 31, 2024, or the First Milestone Event, or, at Agent's option, in the event the First Milestone Event was not achieved.

On November 1, 2023, we**,** entered into a license agreement, or the BioCryst License Agreement, with BioCryst Pharmaceuticals, Inc., or BioCryst, pursuant to which we granted BioCryst an exclusive, worldwide and sublicensable license to our SCS Microinjector for the delivery of BioCryst's proprietary plasma kallikrein inhibitor known as avoralstat for the treatment and prevention of diabetic macular edema, or DME.

We received an upfront license fee payment of $5.0 million in connection with signing of the BioCryst License Agreement. In addition, we are eligible to receive up to an additional $30.0 million in clinical and regulatory milestone payments, and up to a total of $47.5 million in a series of post-approval sales-based milestone payments based on the achievement of annual global net product sales milestones up to $2.0 billion. Further, during the royalty term, BioCryst has also agreed to pay us tiered mid-single digit royalties on annual global net product sales, with the highest royalty rate applied to sales over $1.5 billion, subject to reductions in specified circumstances. Our rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described above in "Business—Royalty Purchase and Sale Agreement."

In May 2023, we terminated our at-the-market sales agreement with Cowen and Company, LLC, or the Prior ATM Agreement. We sold 515,959 shares of its common stock for net proceeds of $0.7 million under the Prior ATM Agreement with Cowen and Company, LLC during the six months ended June 30, 2023, prior to the termination of the Prior ATM Agreement. During the year ended December 31, 2022, we sold 425,460 shares of common stock for net proceeds of $0.6 million under the Prior ATM Agreement. During the year ended December 31, 2021, we sold 2.9 million shares of common stock for net proceeds of $12.2 million under the Prior ATM Agreement.

In May 2023, we entered into a Controlled Equity Offering[SM] Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor under which we may offer and sell, from time to time at its sole discretion, shares of its common stock, having an

aggregate offering price of up to $50.0 million through Cantor as our sales agent. During the year ended December 31, 2023, we sold 1,073,740 shares of our common stock for net proceeds of $1.1 million under the Sales Agreement. Subsequent to December 31, 2023, we sold an additional 339,912 shares of our common stock pursuant to the Sales Agreement for net proceeds of $0.5 million.

On August 8, 2022, or the Closing Date, we, through our wholly-owned subsidiary Clearside Royalty LLC, a Delaware limited liability company, or Royalty Sub, entered into a Purchase and Sale Agreement with entities managed by HealthCare Royalty Management, LLC, or HCR, pursuant to which Royalty Sub sold to HCR certain of its rights to receive royalty and milestone payments payable to Royalty Sub under the Arctic Vision License Agreement, Bausch License Agreement, that certain License Agreement, effective as of July 3, 2019, by and between us and Aura Biosciences, Inc., that certain Option and License Agreement, dated as of August 29, 2019, by and between REGENXBIO Inc. and us, and any and all out-license agreements following the Closing Date for, or related to XIPERE or the SCS Microinjector technology to be used in connection with compounds or products of any third parties delivered, in whole or in part, by means of the SCS Microinjector technology, excluding, for the avoidance of doubt, any in-licensed or internally developed therapies following the Closing Date, in exchange for up to $65 million. Under the terms of the Purchase and Sale Agreement, Royalty Sub received a payment of $32.1 million, representing the $32.5 million to which we were entitled less certain expenses. There were additional issuance costs of $1.5 million related to the Purchase and Sale Agreement resulting in net proceeds of $30.6 million. An additional $12.5 million was deposited in an escrow account, which was released to HCR pursuant to the Letter Agreement described above. The terms of the Purchase and Sale Agreement also provide for an additional $20 million milestone payment to Royalty Sub upon attainment of a second pre-specified sales milestone related to 2024 XIPERE sales.

On January 6, 2021, we entered into a securities purchase agreement with certain institutional purchasers pursuant to which we issued and sold 4.2 million shares of our common stock in a registered direct offering at a price of $2.851 per share. We raised net cash proceeds of $11.1 million after deducting offering expenses.

In April 2020, we entered into a loan agreement with Silicon Valley Bank under the terms of which Silicon Valley bank loaned us $1.0 million, or the PPP Loan, pursuant to the Paycheck Protection Program, or PPP, under the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act. In accordance with the requirements of the CARES Act, we used the proceeds primarily for payroll costs and other eligible expenses. The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. On January 11, 2021, we received notification from Silicon Valley Bank that the PPP Loan was forgiven in full, including approximately $7,000 of accrued interest.

Pursuant to the Arctic Vision License Agreement, Arctic Vision paid us an upfront payment of $4.0 million in March 2020. In December 2021, we received a milestone payment of $4.0 million following receipt of FDA approval of XIPERE in the United States. In addition, Arctic Vision has agreed to pay us up to a total of $22.5 million in development and sales milestone payments. Further, during the applicable royalty term, we will also be entitled to receive tiered royalties of 10-12% of net sales in the Arctic Territory, subject to customary reductions. In August 2021, we entered into an amendment to the Arctic Vision License Agreement to expand the territories covered by the license to include India and the ASEAN Countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam). In September 2021, we entered into a second amendment to the Arctic Vision License Agreement to expand the Arctic Territory to include Australia and New Zealand. We received an aggregate of $3.0 million in consideration for the expansion of the Arctic Territory.

In October 2019, we announced that Bausch acquired an exclusive license for the commercialization and development of XIPERE in the United States and Canada. On October 25, 2021, we announced that the FDA approved XIPERE for the treatment of macular edema associated with uveitis. We received a $5.0 million milestone payment from Bausch within 30 days of FDA approval. In December 2021, $10.0 million was recorded as revenue upon completion of pre-launch activities for XIPERE and the payment was received in January 2022. Bausch launched XIPERE in the United States in the first quarter of 2022.

***Funding Requirements***

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, research and development costs to build our product candidate pipeline, legal and other regulatory expenses and general overhead costs. In addition, we have certain contractual obligations for future payments. Refer to Footnote 12 to our financial statements included this Annual Report on Form 10-K.

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 CLS-AX 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. We expect that we will require additional capital to fund our ongoing operations. Additional funds may not be available to us on a timely basis, on commercially reasonable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and disruptions to, and volatility in, the credit and financial markets in the United States and worldwide and related macroeconomic changes, such as rising inflation. 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 of the territories in which we have previously licensed or granted options to license XIPERE, 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 generate significant milestone payments and royalties from XIPERE and other licensing arrangements or revenues from other product candidates. We will need additional financing to fund our operations. Our plans primarily consist of raising additional capital, potentially in a combination of equity or debt financings, monetizing royalties, 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 the filing date, March 12, 2024, will enable us to fund our planned operating expenses and capital expenditure requirements into the third quarter of 2025. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect. We will require additional capital in order to complete clinical development of CLS-AX.

***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, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| | | (in thousands) | |
| Net cash (used in) provided by: | | | |
| Operating activities | $ (18,135) | $ (13,365) | $ (10,733) |
| Investing activities | (1,777) | (246) | — |
| Financing activities | 414 | 31,333 | 23,782 |
| Net change in cash and cash equivalents | $ (19,498) | $ 17,722 | $ 13,049 |

During the years ended December 31, 2023, 2022 and 2021, our operating activities used net cash of $18.1 million, $13.4 million and $10.7 million, respectively. The net cash used in operating activities for the year ended December 31, 2023 as compared to the year ended December 31, 2022 was due to ongoing research and development expenses to develop our pipeline and ongoing costs for ODYSSEY, the Phase 2b clinical trial for CLS-AX, as well as the supporting general and administrative costs. This was partially offset by the receipt of research and development tax credits. The increase in cash used in operating activities for the year ended December 31, 2022 as compared to the year ended December 31, 2021 was primarily due to research and development expenses related to the preclinical and clinical programs offset by the receipt of the $10.0 million milestone payment received from Bausch in connection with pre-launch activities for XIPERE.

In the year ended December 31, 2023 and 2022, our investing activities used net cash of $1.8 million and $0.2 million, respectively, for the purchase of machinery and equipment.

During the years ended December 31, 2023, 2022 and 2021, our net cash provided by financing activities was $0.4 million, $31.3 million and $23.8 million, respectively. The cash provided by financing activities for the year ended December 31, 2023 consisted primarily of $1.7 million of net proceeds from the sale of shares of our common stock under the ATM Agreement and the Sales Agreement partially offset by a payment of $1.4 million related to the Purchase and Sale agreement. The net cash provided by financing activities for the year ended December 31, 2022 was primarily comprised of $30.6 million from the Purchase and Sale Agreement, net of issuance costs and $0.6 million of net proceeds from the sale of shares of our common stock under the ATM agreement. The net cash provided by financing activities for the year ended December 31, 2021 was primarily comprised of $11.1 million of net proceeds from the sale of shares of our common stock in a registered direct offering and $12.2 million of net proceeds from the sale of shares of our common stock under the ATM agreement.

**Cybersecurity**

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors and Item 1C. Cybersecurity in this Annual Report on Form 10-K, including "—If our information technology systems or those third parties upon which we rely or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences."

**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.

**Smaller Reporting Company Status**

We are a "smaller reporting company," meaning that the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We will continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and we have reduced disclosure obligations regarding executive compensation.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

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**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 consolidated balance sheets of Clearside Biomedical, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

**Basis for Opinion**

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

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

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

**Critical Audit Matter**

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

***Valuation of Liability Related to the Sales of Future Royalties, Net***

| | |
|---|---|
| *Description of the Matter* | As discussed in Note 5 to the consolidated financial statements, on August 8, 2022, the Company entered into a Royalty Purchase and Sale Agreement with a third party, pursuant to which the Company sold certain of its rights to receive royalty and milestone payments. The Company received proceeds of $32.1 million, representing the $32.5 million to which the Company was entitled, net of certain transaction related expenses. The Company will repay the lender at a multiple of the initial proceeds received, which may vary based on timing and amount of cash flows received from its licensing partners.<br><br>The Company records the financing as a Liability related to the sales of future royalties, net on the balance sheet at its carrying value of $42.0 million as of December 31, 2023. The Company imputes interest expense associated with this liability using the effective interest rate method. Such interest expense is recorded in the statement of operations for the year ended December 31, 2023 as Non-cash interest expense on liability related to the sales of future royalties. The effective interest rate is calculated based on the rate that would enable the estimated liability to be repaid in full over the anticipated life of the arrangement. The Company utilizes the prospective method to record interest expense by updating its estimate of the new effective interest rate each period, based on its current estimate of remaining cash flows under the arrangement. The Company estimates the amount and timing of expected payments based on historical experience and its expectations of future activities from its license partners, as well as current market conditions.<br><br>Auditing the liability related to the sales of future royalties, net was complex and highly judgmental due to the estimation uncertainty in determining the effective interest rate. The Company's effective interest rate model includes cash flow projections for future royalty and milestone payments, which are sensitive to certain assumptions that are forward looking and could be affected by future market conditions. |
| *How We Addressed the Matter in Our Audit* | To test the liability related to the sales of future royalties, net as of December 31, 2023, our audit procedures included, among others, assessing the underlying data and significant assumptions used by the Company in determining the timing and amount of future cash flows used within its effective interest rate model. We assessed the reasonableness of the significant assumptions used in the cash flow projections by inspecting third party evidence to support management's projections. We also performed a comparison of management's prior projections of cash flow activity to actual results, and assessed the reasonableness of future projections based on activity to date. We recalculated the current year interest expense and performed sensitivity analyses to evaluate the changes in the effective interest rate, and associated interest expense, that would result from changes in the assumptions. |

/s/ Ernst & Young LLP

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

Atlanta, Georgia
March 12, 2024

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

| | December 31, | |
|---|---|---|
| | 2023 | 2022 |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 28,920 | $ 48,258 |
| Accounts receivable | 170 | — |
| Prepaid expenses | 722 | 704 |
| Other current assets | 311 | 439 |
| Total current assets | 30,123 | 49,401 |
| Property and equipment, net | 2,996 | 755 |
| Operating lease right-of-use asset | 869 | 1,117 |
| Other assets | 30 | 30 |
| Total assets | $ 34,018 | $ 51,303 |
| **Liabilities and stockholders' (deficit) equity** | | |
| Current liabilities: | | |
| Accounts payable (includes $331 to a related party as of December 31, 2023) | $ 2,205 | $ 1,050 |
| Accrued liabilities (includes $215 to a related party as of December 31, 2023) | 4,169 | 4,179 |
| Current portion of operating lease liabilities | 364 | 349 |
| Deferred revenue | 75 | 205 |
| Total current liabilities | 6,813 | 5,783 |
| Liability related to the sales of future royalties, net | 41,988 | 33,977 |
| Operating lease liabilities | 649 | 936 |
| Other non-current liabilities | 480 | — |
| Total liabilities | 49,930 | 40,696 |
| Commitments and contingencies | | |
| Stockholders' (deficit) equity: | | |
| Preferred stock, $0.001 par value; 10,000,000 shares authorized and no shares issued at December 31, 2023 and 2022 | — | — |
| Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2023 and 2022, respectively; 62,850,841 and 60,639,827 shares issued and outstanding at December 31, 2023 and 2022, respectively | 63 | 61 |
| Additional paid-in capital | 304,948 | 298,984 |
| Accumulated deficit | (320,923) | (288,438) |
| Total stockholders' (deficit) equity | (15,912) | 10,607 |
| Total liabilities and stockholders' (deficit) equity | $ 34,018 | $ 51,303 |

*See accompanying notes to the financial statements*

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| License and other revenue (includes $5,050 from a related party for the year ended December 31, 2023) | $ 8,226 | $ 1,327 | $ 29,575 |
| Operating expenses: | | | |
| Cost of goods sold | 355 | 204 | — |
| Research and development (includes $1,109 to a related party for the year ended December 31, 2023) | 20,846 | 19,630 | 18,537 |
| General and administrative | 11,869 | 11,770 | 11,665 |
| Total operating expenses | 33,070 | 31,604 | 30,202 |
| Loss from operations | (24,844) | (30,277) | (627) |
| Other income | 1,719 | 669 | 1,003 |
| Non-cash interest expense on liability related to the sales of future royalties | (9,360) | (3,339) | — |
| Net (loss) income | $ (32,485) | $ (32,947) | $ 376 |
| | | | |
| Net (loss) income per share of common stock — basic and diluted | $ (0.53) | $ (0.55) | $ 0.01 |
| | | | |
| Weighted average shares outstanding — basic | 61,806,959 | 60,204,862 | 58,491,986 |
| Weighted average shares outstanding — diluted | 61,806,959 | 60,204,862 | 59,906,602 |

*See accompanying notes to the financial statements.*

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

| | Common Stock | | Additional Paid-In-Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|
| | Shares | Amount | | | |
| Balance at December 31, 2020 | 51,860,941 | $ 52 | $ 264,578 | $ (255,867) | $ 8,763 |
| Issuance of common shares under at-the-market sales agreement | 2,891,419 | 3 | 12,202 | — | 12,205 |
| Issuance of common shares under a direct registered offering | 4,209,050 | 4 | 11,074 | — | 11,078 |
| Issuance of common shares under employee stock purchase plan | 65,481 | — | 111 | — | 111 |
| Exercise of stock options | 280,771 | 1 | 387 | — | 388 |
| Vesting and settlement of restricted stock units | 415,268 | — | — | — | — |
| Share-based compensation expense | — | — | 5,054 | — | 5,054 |
| Net income | — | — | — | 376 | 376 |
| Balance at December 31, 2021 | 59,722,930 | 60 | 293,406 | (255,491) | 37,975 |
| Issuance of common shares under at-the-market sales agreement | 425,460 | 1 | 565 | — | 566 |
| Issuance of common shares under employee stock purchase plan | 66,919 | — | 112 | — | 112 |
| Exercise of stock options | 49,187 | — | 17 | — | 17 |
| Vesting and settlement of restricted stock units | 375,331 | — | — | — | — |
| Share-based compensation expense | — | — | 4,884 | — | 4,884 |
| Net loss | — | — | — | (32,947) | (32,947) |
| Balance at December 31, 2022 | 60,639,827 | 61 | 298,984 | (288,438) | 10,607 |
| Issuance of common shares under at-the-market sales agreement | 1,589,699 | 2 | 1,664 | — | 1,666 |
| Issuance of common shares under employee stock purchase plan | 68,109 | — | 65 | — | 65 |
| Exercise of stock options | 81,816 | — | 33 | — | 33 |
| Vesting and settlement of restricted stock units | 471,390 | — | — | — | — |
| Share-based compensation expense | — | — | 4,202 | — | 4,202 |
| Net loss | — | — | — | (32,485) | (32,485) |
| Balance at December 31, 2023 | 62,850,841 | $ 63 | $ 304,948 | $ (320,923) | $ (15,912) |

*See accompanying notes to the financial statements.*

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| **Operating activities** | | | |
| Net (loss) income | $ (32,485) | $ (32,947) | $ 376 |
| Adjustments to reconcile net (loss) income to net cash used in operating activities: | | | |
| Non-cash interest expense on liability related to the sales of future royalties, net of issuance costs accretion | 9,361 | 3,339 | — |
| Depreciation | 67 | 145 | 178 |
| Share-based compensation expense | 4,202 | 4,884 | 5,054 |
| Gain on termination of operating lease | — | (55) | — |
| Loss on disposal of fixed assets | — | 33 | — |
| Gain on extinguishment of debt | — | — | (998) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable, prepaid expenses and other current assets | (220) | 10,420 | (10,869) |
| Other assets and liabilities | 456 | (83) | (155) |
| Accounts payable and accrued liabilities (includes $82 to a related party for the year ended December 31, 2023) | 614 | 694 | 681 |
| Deferred revenue | (130) | 205 | (5,000) |
| Net cash used in operating activities | (18,135) | (13,365) | (10,733) |
| **Investing activities** | | | |
| Acquisition of property and equipment | (1,777) | (246) | — |
| Net cash used in investing activities | (1,777) | (246) | — |
| **Financing activities** | | | |
| Proceeds from royalty purchase and sale agreement, net of $1,862 of issuance costs | — | 30,638 | — |
| Payments on royalty purchase and sale agreement | (1,350) | — | — |
| Proceeds from at-the-market sales agreement, net of issuance costs | 1,666 | 566 | 12,205 |
| Proceeds from registered direct offering, net of issuance costs | — | — | 11,078 |
| Proceeds from shares issued under employee stock purchase plan | 65 | 112 | 111 |
| Proceeds from exercise of stock options | 33 | 17 | 388 |
| Net cash provided by financing activities | 414 | 31,333 | 23,782 |
| Net (decrease) increase in cash, cash equivalents and restricted cash | (19,498) | 17,722 | 13,049 |
| Cash, cash equivalents and restricted cash, beginning of period | 48,418 | 30,696 | 17,647 |
| Cash, cash equivalents and restricted cash, end of period | $ 28,920 | $ 48,418 | $ 30,696 |
| **Supplemental disclosure** | | | |
| Purchase of property and equipment in accounts payable and accrued liabilities | $ 531 | $ 282 | $ — |
| Forgiveness of PPP Loan and accrued interest | $ — | $ — | $ 998 |

**Reconciliation of cash, cash equivalents and restricted cash:**

| | December 31, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| Cash and cash equivalents | $ 28,920 | $ 48,258 | $ 30,436 |
| Restricted cash ($160 and $100 as of December 31, 2022 and 2021, respectively, is recorded in other current assets) | — | 160 | 260 |
| Cash, cash equivalents and restricted cash at end of period | $ 28,920 | $ 48,418 | $ 30,696 |

*See accompanying notes to the financial statements.*

**CLEARSIDE BIOMEDICAL, INC.**

**Notes to the Consolidated Financial Statements**

## 1. The Company

Clearside Biomedical, Inc. (the "Company") is a biopharmaceutical company focused on revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS). 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 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 $28.9 million as of December 31, 2023.

Historically, the Company has funded its operations primarily through the sale of common stock and convertible preferred stock, the issuance of long-term debt, and license agreements. On October 25, 2021, the Company announced that the U.S. Food and Drug Administration (the "FDA") approved XIPERE® (triamcinolone acetonide injectable suspension) for the treatment of macular edema associated with uveitis, a form of eye inflammation. In January 2022, the Company received $10.0 million from Bausch + Lomb, a division of Bausch Health Companies, Inc. ("Bausch"), upon completion of pre-launch activities for XIPERE pursuant to the license agreement granting Bausch an exclusive license to develop and commercialize XIPERE in the United States and Canada. Bausch launched XIPERE in the United States in the first quarter of 2022.

On February 6, 2024, the Company entered into a securities purchase agreement with institutional investors and an existing stockholder, pursuant to which the Company issued and sold, in a registered direct offering (the "Registered Direct Offering"): (i) an aggregate of 11,111,111 shares (the "Shares") of its common stock; and (ii) warrants to purchase up to 11,111,111 shares of common stock (the "Warrants").

The combined purchase price of each Share and accompanying Warrant was $1.35. The exercise price for the Warrants is $1.62 per share. The Warrants will be exercisable from August 9, 2024 and will expire on August 9, 2029. The net proceeds to the Company from the Registered Direct Offering were approximately $13.9 million.

On January 31, 2024 (the "Amendment Effective Date"), the Company entered into a fourth amendment to the license agreement (as amended, the "Emory License Agreement") with Emory University and Georgia Tech Research Corporation (collectively, the "Licensor") pursuant to which the parties agreed to reduce the Sublicense Percentage (as defined in the Emory License Agreement) from a low double digit percentage to a high single digit percentage that the Company will pay the Licensor applicable to any fees or payments paid to the Company by any Sublicensee (as defined in the Emory License Agreement) of the Licensed Patents and/or Licensed Technology (each as defined in the Emory License Agreement), on or after July 1, 2023, excluding (i) amounts paid to the Company by a Sublicensee to reimburse the Company for certain research and development costs pursuant to a written agreement between the Company and such Sublicensee, (ii) the value of intellectual property transferred or granted to the Company if necessary or helpful to the development or commercialization of Licensed Products (as defined in the Emory License Agreement) and (iii) amounts paid for shares of the Company's stock. The payment to Licensor of any such Sublicense Percentage is due within 30 days of receipt by the Company of a qualifying payment from a Sublicensee, provided however, with respect to any qualifying payments received by the Company from a Sublicensee after July 1, 2023 but prior to January 1, 2025, the payment to Licensor of any such Sublicensee Percentage is due to Licensor by March 31, 2025. The parties also agreed to a revised annual license maintenance fee due each year (the "Maintenance Fee") starting in 2023 through 2028, as follows: $250,000 for 2023 through 2025, $350,000 for 2026, $400,000 for 2027 and $500,000 for 2028. The Company paid the Maintenance Fee for 2023 in February 2024. The remaining annual Maintenance Fee payments are due on October 1st of each year.

On December 22, 2023, Clearside Biomedical, Inc., through its wholly owned subsidiary Royalty Sub, entered into a letter agreement (the "Letter Agreement") with HCR and HCR Clearside SPV, LLC (as assignee of HCR Collateral Management, LLC) ("Agent") amending that certain Purchase and Sale Agreement, dated as of August 8, 2022, by and among Royalty Sub, HCR and Agent. Pursuant to the terms of the Letter Agreement, Royalty Sub and Agent mutually agreed that Royalty Sub waived any and all

rights to the $12.5 million milestone payment which was deposited in an escrow account (“First Milestone Payment") in connection with the closing of the transactions contemplated by the Purchase and Sale Agreement and agreed to the release of the First Milestone Payment to Agent. The First Milestone Payment was to be released to Royalty Sub upon attainment of a pre-specified XIPERE sales milestone if such milestone was achieved by March 31, 2024 (“First Milestone Event”) or, at Agent’s option, in the event the First Milestone Event was not achieved.

On November 1, 2023, the Company**,** entered into a license agreement (the “BioCryst License Agreement”) with BioCryst Pharmaceuticals, Inc. (“BioCryst”) pursuant to which the Company granted BioCryst an exclusive, worldwide and sublicensable license to the Company’s SCS Microinjector for the delivery of BioCryst’s proprietary plasma kallikrein inhibitor known as avoralstat for the treatment and prevention of diabetic macular edema (“DME”).

The Company received an upfront license fee payment of $5.0 million in connection with signing of the BioCryst License Agreement. In addition, the Company is eligible to receive up to an additional $30.0 million in clinical and regulatory milestone payments, and up to a total of $47.5 million in a series of post-approval sales-based milestone payments based on the achievement of annual global net product sales milestones up to $2.0 billion. Further, during the royalty term, BioCryst has also agreed to pay the Company tiered mid-single digit royalties on annual global net product sales, with the highest royalty rate applied to sales over $1.5 billion, subject to reductions in specified circumstances. The Company’s rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described above in in Note 5 to the consolidated financial statements.

In May 2023, the Company terminated its at-the-market sales agreement with Cowen and Company, LLC (the "ATM Agreement"). The Company sold 515,959 shares of its common stock for net proceeds of $0.7 million under its ATM Agreement with Cowen and Company, LLC during the six months ended June 30, 2023, prior to the termination of the ATM Agreement. During the year ended December 31, 2022, the Company sold 425,460 shares of its common stock for net proceeds of $0.6 million under its ATM Agreement. During the year ended December 31, 2021, the Company sold 2.9 million shares of its common stock for net proceeds of $12.2 million under its ATM Agreement.

In May 2023, the Company entered into a Controlled Equity Offering$^{SM}$ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to $50.0 million through Cantor as its sales agent. During the year ended December 31, 2023, the Company sold 1,073,740 shares of its common stock for net proceeds of $1.1 million under the Sales Agreement. Subsequent to December 31, 2023, the Company sold an additional 339,912 shares of its common stock pursuant to the Sales Agreement for net proceeds of $0.5 million.

On August 8, 2022, the Company entered into a Purchase and Sale Agreement (the "Purchase and Sale Agreement") pursuant to which it sold its rights to receive royalty and milestone payments due to the Company from XIPERE and certain SCS Microinjector license agreements subject to a cap which may be increased under certain circumstances. The Company received a payment of $32.1 million in September 2022, representing the $32.5 million to which the Company was entitled, net of certain of HCR's transaction-related expenses which the Company agreed to reimburse. There were additional issuance costs of $1.5 million related to the Purchase and Sale Agreement resulting in net proceeds of $30.6 million.

On January 6, 2021, the Company entered into a securities purchase agreement with certain institutional purchasers that purchased 4.2 million shares of its common stock in a registered direct offering at a price of $2.851 per share. The Company raised net proceeds of $11.1 million after deducting offering expenses.

In August 2021, the Company entered into an amendment to the Arctic Vision License Agreement (as defined in Note 10 - License and Other Agreements) to expand the territories covered by the license to include India and the ASEAN Countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam). In September 2021, the Company entered into a second amendment to the Arctic Vision License Agreement to expand the territories covered by the license to include Australia and New Zealand. The Company received an aggregate of $3.0 million in consideration for the expansion of the licensed territory.

Based on its current plans and forecasted expenses, the Company expects that its cash and cash equivalents as of the filing date, March 12, 2024 will enable it to fund its planned operating expenses and capital expenditure requirements into the third quarter of 2025. The Company has based this estimate on assumptions that may prove to be wrong, and it could exhaust its capital resources sooner than expected. 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.

**2. Significant Accounting Policies**

***Basis of Presentation and Principles of Consolidation***

The Company's consolidated financial statements include the results of the financial operations of Clearside Biomedical, Inc. and its wholly-owned subsidiary, Clearside Royalty LLC. a Delaware limited liability company, which was formed for the purposes of the transactions contemplated by the Purchase and Sale Agreement described in Note 5. All intercompany balances and transactions have been eliminated.

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 consolidated 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 consolidated financial statements and reported amounts of income and expenses during the reporting periods. Significant items subject to such estimates and assumptions include the estimate of the total amount of future royalty revenue and milestone payments to be generated over the life of the Purchase and Sale Agreement, revenue recognition, the accounting for useful lives to calculate depreciation and amortization, clinical trial expense 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 Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*. 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.

In the year ended December 31, 2023, 2022, and 2021, the Company recognized $8.2 million, $1.3 million, and $29.6 million of revenue associated with its license agreements, respectively. License revenue for the year ended December 31, 2023 was primarily for a non-refundable $5.0 million upfront license fee payment from BioCryst and $1.4 million of milestone payments from Aura Biosciences, Inc. The $5.0 million non-refundable upfront payment was recognized upon transfer of control of the license to BioCryst. The $1.4 million in milestone payments from Aura were recognized upon satisfaction of the related performance obligations. Remaining revenues for the year ended December 31, 2023 were generated by providing training materials and clinical trial products to the Company's licensees. License revenue for the year ended December 31, 2022 was primarily from providing training materials and clinical trial products to the Company's licensees. License revenue for the year ended December 31, 2021 was primarily a result of (i) the milestone payments from Bausch that consisted of $5.0 million received upon FDA approval of XIPERE, the recognition of $5.0 million of deferred revenue for the upfront milestone payment and the recognition of a $10.0 million milestone for pre-launch activities and (ii) an aggregate of $8.0 million received from Arctic Vision for FDA approval of XIPERE, territory expansion and certain development milestones.

***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.

***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, 2023. 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.

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 estimating and measuring 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.

***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 preclinical studies and clinical trials;
- costs associated with preclinical and clinical 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 trial activities, are recognized based on an evaluation of the estimated total costs for the clinical trial, progress to completion of specific tasks, using data such as patient enrollment, pass through expenses, clinical site activations, data from the clinical sites 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 contracts and any subsequent amendments, which may differ from the patterns of costs incurred, and are reflected in the financial statements as prepaid or accrued expenses.

***Share-Based Compensation***

Compensation cost related to share-based awards granted to employees, directors and consultants is measured based on the estimated fair value of the award at the grant date. 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 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.

***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, 2022, the restricted cash balance was invested in a commercial money market account. The current portion of the restricted cash is recorded in other current assets and the long-term portion is recorded in restricted cash.

***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.

***Liability Related to the Sales of Future Royalties and Non-Cash Interest Expense***

In connection with the Purchase and Sale Agreement, the Company recognized a liability related to the sales of future royalties under ASC 470-10 Debt and ASC 835-30 Interest - Imputation of Interest. The initial funds received by the Company pursuant to the terms of the Purchase and Sale Agreement were recorded as a liability and are accreted under the effective interest method up to the estimated amount of future royalties and milestone payments to be made under the Purchase and Sale Agreement. The issuance costs were recorded as a direct deduction to the carrying amount of the liability and are being amortized under the effective interest method over the estimated period the liability will be repaid. The Company estimates the total amount of future royalty revenue and milestone payments to be generated over the life of the Purchase and Sale Agreement, and a significant increase or decrease in these estimates could materially impact the liability balance and the related interest expense. If the timing of the receipt of royalty payments or milestones is materially different from the original estimates, the Company will prospectively adjust the effective interest and the related amortization of the liability and related issuance costs.

**3. Property and Equipment, Net**

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

| | Estimated Useful Lives (Years) | December 31, 2023 | December 31, 2022 |
|---|---|---|---|
| Furniture and fixtures | 5 | $ 249 | $ 249 |
| Machinery and equipment | 5 | 581 | 343 |
| Computer equipment | 3 | 20 | 13 |
| Leasehold improvements | Lesser of useful life or remaining lease term | 476 | 476 |
| Work in process | | 2,590 | 527 |
| Total property and equipment | | 3,916 | 1,608 |
| Less: Accumulated depreciation | | (920) | (853) |
| Property and equipment, net | | $ 2,996 | $ 755 |

**4. Accrued Liabilities**

Accrued liabilities consisted of the following (in thousands):

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| Accrued research and development | $ 2,078 | $ 1,817 |
| Accrued employee costs | 1,862 | 1,837 |
| Accrued professional fees | 38 | 49 |
| Accrued expense | 191 | 476 |
| | $ 4,169 | $ 4,179 |

**5. Royalty Purchase and Sale Agreement**

On August 8, 2022 (the “Closing Date”), the Company, through its wholly-owned subsidiary Clearside Royalty LLC, a Delaware limited liability company (“Royalty Sub”), entered into a Purchase and Sale Agreement (the “Purchase and Sale Agreement”) with entities managed by HealthCare Royalty Management, LLC (“HCR”), pursuant to which Royalty Sub sold to HCR certain of its rights to receive royalty and milestone payments payable to Royalty Sub under the Arctic Vision License Agreement, the Bausch License Agreement, that certain License Agreement, effective as of July 3, 2019, by and between the Company and Aura Biosciences, Inc. (the “Aura License Agreement”), that certain Option and License Agreement, dated as of August 29, 2019, by and between REGENXBIO Inc. and the Company (the “REGENXBIO License Agreement”) and any and all out-license agreements following the Closing Date for, or related to XIPERE or the SCS Microinjector technology (to be used in connection with compounds or products of any third parties) delivered, in whole or in part, by means of the SCS Microinjector technology), excluding, for the avoidance of doubt, any in-licensed or internally developed therapies following the Closing Date (collectively, the “Royalties”), in exchange for up to $65 million. In connection with this transaction, the Company assigned the Arctic Vision License Agreement, Bausch License Agreement, Aura License Agreement, REGENXBIO License Agreement, the Company's license agreement with Emory University and The Georgia Tech Research Corporation and related intellectual property rights to Royalty Sub.

Under the terms of the Purchase and Sale Agreement, Royalty Sub received an initial payment of $32.1 million, representing the $32.5 million to which the Company was entitled, net of certain of HCR's transaction-related expenses which the Company agreed to reimburse. There were additional issuance costs of $1.5 million related to the Purchase and Sale Agreement resulting in net proceeds of $30.6 million. An additional $12.5 million (the "First Milestone Payment") was deposited by HCR in an escrow account which was released to HCR pursuant to the Letter Agreement described below. The terms of the Purchase and Sale Agreement also provide for an additional $20 million milestone payment to Royalty Sub upon attainment of a second pre-specified sales milestone related to 2024 XIPERE sales (the "Second Milestone Event").

The Purchase and Sale Agreement will automatically expire, and the payment of Royalties from the Royalty Sub to HCR will cease, when HCR has received payments of the Royalties equal to 2.5 times the aggregate amount of payments made by HCR under the Agreement if the Second Milestone Event is achieved on or prior to December 31, 2024 (the "Initial Cap"). If the Second Milestone Event is not achieved on or prior to December 31, 2024, payment of Royalties from Royalty Sub to HCR will cease when HCR has received Royalties payments equal to 3.4 times the aggregate amount of payments under the Purchase and Sale Agreement (the "Alternative Cap", and together with the Initial Cap, the "Cap Amount"). In the event of a change in control, acquiror will have the option to make a payment to HCR of the Cap Amount then in effect, less the aggregate amount of Royalty payments made by Royalty Sub to HCR under the Purchase and Sale Agreement as a one-time payment at which time, payment of Royalties to HCR will cease. Alternatively, in the event of a change in control, the acquiror will have the option to make an initial payment of 1.0 times the aggregate amount of payments made by HCR under the Purchase and Sale Agreement as of the date of such change in control, then in that event, payment of Royalties from Royalty Sub to HCR will cease when HCR has received total Royalties payments (including the initial payment) equal to the Alternative Cap. After the Purchase and Sale Agreement expires, all rights to receive the Royalties return to Royalty Sub.

On December 22, 2023, the Company, through its wholly owned subsidiary Royalty Sub, entered into the Letter Agreement with the Agent amending that certain Purchase and Sale Agreement, dated as of August 8, 2022, by and among Royalty Sub, HCR and Agent. Pursuant to the terms of the Letter Agreement, Royalty Sub and Agent mutually agreed that Royalty Sub waived any and all rights to the First Milestone Payment in connection with the closing of the transactions contemplated by the Purchase and Sale Agreement and agreed to the release of the First Milestone Payment to Agent.

Issuance costs pursuant to the Purchase and Sale Agreement consisting primarily of advisory and legal fees, totaled $1.9 million including the amount of HCR's transaction-related expenses that the Company reimbursed. The effective interest rate includes cash flow projections for future royalty and milestone payments that are forward looking and could be affected by future market conditions. The Company estimates the amount and timing of expected payments based on historical experience and its expectations of future activities from its license partners, as well as current market conditions.

The following table summarizes the activity of the Purchase and Sale Agreement (in thousands):

| | | |
|---|---|---|
| Balance at December 31, 2022 | $ | 33,977 |
| Payments | | (1,350) |
| Non-cash interest expense | | 9,361 |
| Balance at December 31, 2023 | $ | 41,988 |
| | | |
| Effective interest rate | | 23.3% |

6. **CARES Act Paycheck Protection Program Loan**

On April 20, 2020, the Company entered into a loan agreement with SVB (the "PPP Lender") under the terms of which the PPP Lender made a loan to the Company in an aggregate principal amount of $1.0 million (the "PPP Loan") pursuant to the Paycheck Protection Program (the "PPP") under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The PPP Loan was evidenced by a promissory note (the "Note") containing the terms and conditions for repayment of the PPP Loan.

Under the terms of the Note and the PPP Loan, interest accrued on the outstanding principal amount at the rate of 1.0% per annum. The term of the Note was until April 2022, with the Company obligated to make equal monthly payments of principal and interest, beginning in November 2020 and continuing until the maturity date.

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. On January 11, 2021, the Company was notified by the PPP Lender that the PPP Loan had been forgiven in full, including approximately $7,000 of accrued interest. In accordance with ASC 405-20, *Extinguishment of Liabilities*, the income from the forgiveness of the amount borrowed and the accrued interest was recognized in the statement of operations in other income as a gain on extinguishment of debt.

**7. 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, 2023 and 2022, there were 10,000,000 shares of preferred stock authorized, none of which were issued and outstanding.

At the Company's Annual Meeting of Stockholders held on June 22, 2022, the Company's stockholders approved an amendment to the amended and restated certificate of incorporation to increase the Company's authorized number of shares of common stock from 100,000,000 shares to 200,000,000 shares. As of December 31, 2023 the Company was authorized to issue 200,000,000 shares of $0.001 par value common stock. As of December 31, 2023 and 2022, there were 62,850,841 and 60,639,827 shares of common stock outstanding, respectively.

**8. Common Stock Warrants**

In September 2016, in connection with a 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 are fully exercisable and expire in September 2026, or earlier upon the occurrence of specified mergers or acquisitions of the Company. The warrants were recorded in equity at the time of issuance and had a remaining life of 2.75 years as of December 31, 2023.

On February 6, 2024, the Company entered into a securities purchase agreement with institutional investors and an existing stockholder, pursuant to which the Company issued and sold, in a registered direct offering (i) an aggregate of 11,111,111 shares (the "Shares") of its common stock; and (ii) warrants to purchase up to 11,111,111 shares of common stock (the "Warrants").

The combined purchase price of each Share and accompanying Warrant was $1.35. The exercise price for the Warrants is $1.62 per share. The Warrants will be exercisable from August 9, 2024 and will expire on August 9, 2029.

**9. 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, 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, 2023, under the 2016 Plan, options to purchase 9,638,424 shares of the Company's common stock were outstanding at a weighted average price of $2.79 per share and 570,024 shares remained available for future grant. As of January 1, 2024, the number of shares of common stock that may be issued under the 2016 Plan was automatically increased by 2,514,033 shares, representing 4% of the total number of shares of common stock outstanding on December 31, 2023, increasing the number of shares of common stock available for issuance under the 2016 Plan as of that date to 3,084,057 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, 2023, options to purchase 210,110 shares of the Company's common stock were outstanding under the 2011 Plan at a weighted average exercise price of $4.28 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 as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| Research and development | $ 1,200 | $ 1,616 | $ 1,570 |
| General and administrative | 1,758 | 1,785 | 1,985 |
| Total | $ 2,958 | $ 3,401 | $ 3,555 |

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, 2023, 2022 and 2021.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| Expected term (years) | 6.00 | 6.00 | 7.00 |
| Expected stock price volatility | 95.55% | 98.24% | 101.43% |
| Risk-free interest rate | 4.07% | 2.09% | 0.75% |
| Expected dividend yield | 0.00% | 0.00% | 0.00% |

*Expected term* (in years): In the years ended December 31, 2023 and 2022, the Company used historical data to calculate the expected term. In the year ended December 31, 2021, the Company utilized the simplified method as prescribed by ASC 718, as the Company did 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*: The Company calculates expected volatility based on the historical volatility of its common stock.

*Forfeitures:* The Company records forfeitures as they occur.

The following table summarizes the activity related to stock options during the year ended December 31, 2023:

| | Number of Shares | Weighted Average Exercise Price |
|---|---|---|
| Options outstanding at December 31, 2022 | 6,915,330 | $ 3.58 |
| Granted | 3,684,750 | 1.28 |
| Exercised | (81,816) | 0.40 |
| Forfeited or expired | (652,494) | 2.32 |
| Options outstanding at December 31, 2023 | 9,865,770 | 2.83 |
| Options exercisable at December 31, 2022 | 4,223,931 | 4.22 |
| Options exercisable at December 31, 2023 | 5,494,746 | 3.83 |

The following table provides additional information about the Company's stock options that were outstanding and exercisable at December 31, 2023 (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 | 6,879,914 | | | 7.64 | 2,836,713 | | | 5.73 |
| $3.00 - $6.99 | 2,364,770 | | | 5.11 | 2,036,947 | | | 4.79 |
| $7.00 - $8.99 | 419,308 | | | 3.18 | 419,308 | | | 3.18 |
| $9.00 - $20.84 | 201,778 | | | 3.76 | 201,778 | | | 3.76 |
| | 9,865,770 | $ 2.83 | $ 363 | 6.77 | 5,494,746 | $ 3.83 | $ 11 | 5.12 |

As of December 31, 2023, the Company had $4.1 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.3 years. The weighted average fair values of all stock options granted for the years ended December 31, 2023, 2022 and 2021 was $0.98 per share, $1.55 per share and $3.24 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 29, 2023 was $1.17, 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 four 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 total share-based compensation expense related to RSUs is reflected in the statements of operations as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| Research and development | $ 585 | $ 794 | $ 723 |
| General and administrative | 646 | 658 | 715 |
| Total | $ 1,231 | $ 1,452 | $ 1,438 |

The following table summarizes the activity related to RSUs during the year ended December 31, 2023:

| | Number of Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Non-vested RSUs outstanding at December 31, 2022 | 1,462,932 | $ 3.04 |
| Granted | — | — |
| Vested | (471,390) | 3.09 |
| Forfeited | (156,643) | 3.09 |
| Non-vested RSUs outstanding at December 31, 2023 | 834,899 | 3.01 |

As of December 31, 2023, the Company had $1.3 million of unrecognized compensation expense related to the RSUs, which amount is expected to be recognized over a weighted average period of 1.5 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 on January 1 of each year, 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, 2024. The number of shares of common stock available for issuance under the 2016 ESPP as of December 31, 2023 was 348,782 shares.

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, 2023, 2022 and 2021, the Company issued 68,109, 66,919 and 65,481 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, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| Research and development | $ 10 | $ 21 | $ 41 |
| General and administrative | 3 | 10 | 20 |
| Total | $ 13 | $ 31 | $ 61 |

**10. Income Taxes**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred income tax assets consist of the following (in thousands):

| | December 31, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| Deferred tax asset (liability): | | | |
| Net operating loss carryforwards | $ 52,657 | $ 50,267 | $ 53,966 |
| Non-deductible accrued expenses | 562 | 386 | 469 |
| Right-of-use asset | (210) | (238) | (96) |
| Lease liability | 246 | 274 | 176 |
| Stock compensation expense | 3,339 | 2,678 | 2,768 |
| Depreciation differences | (71) | (40) | (44) |
| Federal tax credits | 10,908 | 9,742 | 9,012 |
| State tax credits | 342 | 326 | 342 |
| Royalty purchase and sale agreement | 10,495 | 7,247 | — |
| Capitalized research and development expenses | 5,777 | 3,057 | — |
| Valuation allowance | (84,045) | (73,699) | (66,599) |
| Net deferred tax asset | $ — | $ — | $ (6) |

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| U.S. federal tax rate | 21.00% | 21.00% | 21.00% |
| State tax rate | 8.59 | (0.85) | (599.32) |
| Permanent difference | (1.44) | (1.34) | (3.15) |
| Tax credit | 3.64 | 2.18 | (253.97) |
| Valuation allowance | (31.85) | (21.57) | 847.82 |
| ASC 740-10 | — | — | (3.19) |
| Adjustment to prior year tax provision | — | 0.67 | (13) |
| Other | 0.06 | (0.09) | 3.97 |
| | 0.00% | 0.00% | 0.00% |

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, 2023, the Company had a valuation allowance of $84.0 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, 2023, the Company had income tax NOL carryforwards for federal and state purposes of $225.9 million and $89.3 million, respectively. The Company has recorded a deferred tax asset for both federal and state NOL carryforwards of $47.4 million and $5.6 million, respectively. If not utilized, the federal NOL carryforwards will begin to expire beginning in 2034, and the state NOL carryforwards will begin to expire at various dates beginning in 2027. Additionally, under the 2017 Tax Cuts and Jobs 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 beginning in 2021. Certain states have also adopted the indefinite carryforward period beginning with the 2018 tax year, but state conformity varies state by state.

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.

The following is a roll forward of the Company's uncertain tax positions (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Balance of uncertain tax positions at the beginning of the year | $ 7,520 | $ 7,520 |
| Gross decreases - tax positions in prior period | — | — |
| Gross decreases - settlements with taxing authorities | — | — |
| Balance of uncertain tax positions at the end of the year | $ 7,520 | $ 7,520 |

As of December 31, 2023 and 2022, there was $7.5 million in each period of unrecognized tax benefit that if recognized would be in the form of a net operating loss carryforward, which is expected to require a full valuation allowance based on present circumstances. The Company reversed $48,000 of previously recorded unrecognized tax expenses for the year 2021. The Company recognizes accrued interest related to unrecognized tax expenses and penalties as income tax expense. No significant amounts of interest or penalties have been recorded as of December 31, 2023.

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. In general, if the Company experiences a greater than 50% aggregate change in ownership over a 3-year period (a Section 382 ownership change), utilization of the Company's pre-change NOL carryforwards may be subject to limitation under the Code. The annual limitation generally is determined by multiplying the value of the Company's stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate for the month in which the ownership change occurred. Such limitation may result in expiration of a portion of the NOL carryforwards before utilization. The Company has completed an owner shift analysis to determine the dates in which the Company may have experienced a Section 382 ownership change, and determined that the Company experienced ownership changes for Section 382 purposes in January 2012, December 2013, and July 2016. Further, the Company has determined that $38,000 and $2,000 of its deferred tax asset related to Federal NOL and Federal R&D Credit, respectively, will expire due to Section 382.

The NOL DTA has a full valuation allowance as it is deemed that it is more likely than not to be utilized. The Company will continue to monitor equity movement and its impact on the utilization of the NOLs and credits. The Company's ability to use the remaining NOL carryforwards may be further limited if the Company experiences an additional Section 382 ownership change as a result of future changes in its stock ownership.

The Company is subject to taxation in the United States and certain state jurisdictions. As of December 31, 2023, the Company's tax returns for 2020, 2021 and 2022 are subject to full examination by the tax authorities. As of December 31, 2023, the Company is generally no longer subject to state or local examinations by tax authorities for years before 2020, except to the extent of NOLs generated in prior years claimed on a tax return.

**11. 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 2026. In November 2022, the Company singed an amended office lease agreement and decreased the square footage to approximately 14,000 square feet. The amended office lease agreement is for a four-year term with a renewal option for an additional thirty-eight months. Rental payments are $30,437 per month subject to an increase of 3% per year. Operating lease cost under this lease and the amendment is recognized on a straight-line basis over the term of the lease. In addition, the office lease agreement requires payment of the 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, 2023 |
|---|---|
| Operating lease right-of-use asset | $ 869 |
| | |
| Liabilities | |
| Current portion of operating lease liabilities | $ 364 |
| Operating lease liabilities | 649 |
| Total operating lease liabilities | $ 1,013 |

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 is not reasonably certain 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, 2023, the Company's incremental borrowing rate was 8.0% and the remaining lease term was 3.0 years. Cash payments included in operating activities on the consolidated statement of cash flows for operating lease liabilities were $362,000, $339,000 and $392,000 for the years ended December 31, 2023, 2022 and 2021, respectively.

Minimum lease payments were as follows at December 31, 2023 (in thousands):

| **Year ending December 31,** | |
|---|---|
| 2024 | $ 378 |
| 2025 | 389 |
| 2026 | 367 |
| Total minimum lease payments | 1,134 |
| Less imputed interest | (121) |
| Total operating lease liabilities | $ 1,013 |

Equipment leases with an initial term of 12 months or less are not recorded with operating lease liabilities. The Company recognizes expense for these leases on a straight-line basis over the lease term. The equipment leases were deemed to be immaterial.

Operating lease cost was $339,000, $262,000 and $247,000 for the years ended December 31, 2023, 2022 and 2021. Variable lease cost was $19,000, $87,000 and $95,000 for the years ended December 31, 2023, 2022 and 2021. Short-term lease cost was $93,000, $86,000 and $12,000 for the years ended December 31, 2023, 2022 and 2021, respectively.

***Georgia Tech License Agreement***

As described in Footnote 1, the Company entered into a fourth amendment to the Georgia Tech License Agreement pursuant to which the parties agreed to revised Maintenance Fee payments. The Company paid the Maintenance Fee for 2023 in February 2024. The remaining annual Maintenance Fee payments are due on October 1st of each year from 2024 through 2028, as show in the table below.

The annual Maintenance Fee will be paid as follows (in thousands):

| **Year Ending December 31,** | |
|---|---|
| 2024 | $ 250 |
| 2025 | 250 |
| 2026 | 350 |
| 2027 | 400 |
| 2028 | 500 |
| | $ 1,750 |

***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.

**12. License and Other Agreements**

*Bausch + Lomb*

On October 22, 2019, the Company entered into a License Agreement (as amended, the "Bausch License Agreement") with Bausch + Lomb, a division of Bausch Health Companies, Inc. ("Bausch"). Pursuant to the Bausch 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 SCS Microinjector (the "Device"), as well as specified other steroids, corticosteroids and NSAIDs in

combination with the Device (“Other Products,” and together with XIPERE, the “Products”), subject to specified exceptions, in the United States and Canada (the “Territory”) for the treatment of ophthalmology indications, including non-infectious uveitis.

Pursuant to the Bausch License Agreement, Bausch paid the Company an upfront payment of $5.0 million (the “Upfront Payment”) in October 2019. In October 2021, the FDA approved XIPERE. The Company received $5.0 million from Bausch as a result of the approval. In December 2021, $10.0 million was recorded upon completion of pre-launch activities for XIPERE and payment was received in January 2022. In addition, Bausch has agreed to pay up to an aggregate of $55.0 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 Bausch 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 XIPERE achieving certain annual net sales thresholds in the Territory, in each case subject to reductions in specified circumstances; provided that the Company will not receive any royalties on the first $45.0 million of cumulative net sales of all products in the Territory. Bausch launched XIPERE in the United States in the first quarter of 2022. The Company's rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described in Note 5 to the consolidated financial statements.

The Company was responsible for all development expenses for XIPERE in the Territory until the Company's New Drug Application ("NDA") was approved by the FDA, subject to specified exceptions, as well as manufacturing costs in connection with the NDA. The Company was 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. Following FDA approval of XIPERE, Bausch is responsible for all such expenses.

Due to the refund provisions in the Bausch License Agreement, the Upfront Payment was included on the balance sheet as deferred revenue as of December 31, 2020. The refund provisions lapsed upon FDA approval of XIPERE and the $5.0 million was recognized as revenue in the fourth quarter of 2021.

*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 in October 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 $31.0 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. In September 2020, the Company received $3.0 million in milestone payments under the Option. The Company's rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described in Note 5 to the consolidated financial statements.

*Arctic Vision (Hong Kong) Limited*

On March 10, 2020, the Company entered into a License Agreement (the “Arctic Vision License Agreement”) with Arctic Vision (Hong Kong) Limited (“Arctic Vision”). Pursuant to the Arctic Vision License Agreement, the Company has granted an exclusive license to Arctic Vision to develop, distribute, promote, market and commercialize XIPERE, subject to specified exceptions in China, Hong Kong, Macau, Taiwan and South Korea (the “Arctic Territory”). Under the terms of the Arctic Vision License Agreement, neither party may commercialize XIPERE in the other party’s territory. Arctic Vision has agreed to use commercially reasonably efforts to pursue development and commercialization of XIPERE for indications associated with uveitis in the Arctic Territory. In addition, upon receipt of the Company’s consent, Arctic Vision will have the right, but not the obligation, to develop and commercialize XIPERE for additional indications in the Arctic Territory.

Pursuant to the Arctic Vision License Agreement, Arctic Vision paid the Company an upfront payment of $4.0 million in March 2020. In December 2021, the Company received a milestone payment of $4.0 million following the receipt of FDA approval of XIPERE in the United States. In addition, Arctic Vision has agreed to pay the Company up to $22.5 million in development and sales milestones. 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 Arctic Territory, subject to customary reductions, payable on a product-by-product and country-by-country basis, commencing at launch in such country and lasting until the latest of (i) the date that all valid claims within the licensed patent rights covering XIPERE have expired, (ii) the date of the loss of marketing or

regulatory exclusivity of XIPERE in a given country, or (iii) ten years from the first commercial sale of XIPERE in a given country. The Company's rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described in Note 5 to the consolidated financial statements.

In August 2021, the Company entered into an amendment to the Arctic Vision License Agreement to expand the territories covered by the license to include India and the ASEAN Countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam). In September 2021, the Company entered into a second amendment to the Arctic Vision License Agreement to expand the Arctic Territory to include Australia and New Zealand. The Company received an aggregate of $3.0 million in consideration for the expansion of the Arctic Territory.

*BioCryst Pharmaceuticals, Inc.*

On November 1, 2023, the Company**,** entered into the BioCryst License Agreement pursuant to which the Company granted BioCryst an exclusive, worldwide and sublicensable license to the Company's SCS Microinjector for the delivery of BioCryst's proprietary plasma kallikrein inhibitor known as avoralstat for the treatment and prevention of DME.

The Company received an upfront license fee payment of $5.0 million in connection with signing of the BioCryst License Agreement. In addition, the Company is eligible to receive up to an additional $30.0 million in clinical and regulatory milestone payments, and up to a total of $47.5 million in a series of post-approval sales-based milestone payments based on the achievement of annual global net product sales milestones up to $2.0 billion. Further, during the royalty term, BioCryst has also agreed to pay the Company tiered mid-single digit royalties on annual global net product sales, with the highest royalty rate applied to sales over $1.5 billion, subject to reductions in specified circumstances. The Company's rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described in Note 5 to the consolidated financial statements.

BioCryst will be responsible for all development, regulatory and commercialization activities for avoralstat. The Company is responsible for supplying SCS Microinjectors to meet BioCryst's reasonable needs.

The BioCryst License Agreement, unless earlier terminated, will expire (a) on a country-by-country basis upon the expiration of the royalty term in such country or (b) in its entirety upon the expiration of all payment obligations of BioCryst under the BioCryst License Agreement in all countries pursuant to clause (a). Each party has the right terminate the License Agreement (i) upon a material breach of the BioCryst License Agreement by the other party, subject to a specified cure period and specified exceptions, or (ii) if the other party encounters bankruptcy or insolvency. The Company may terminate the BioCryst License Agreement if BioCryst or any of its sublicensees (a "Sublicensee") commences a legal action challenging the validity, enforceability or scope of any of the licensed patents, provided that with respect to any such action initiated by a Sublicensee (a "Sublicensee Action), the Company may terminate the BioCryst License Agreement if the Sublicensee Action is not terminated within a specified period of time following BioCryst's receipt of written notice from the Company or if BioCryst does not terminate the applicable sublicense, in each case within a specified period of time. BioCryst may terminate the BioCryst License Agreement (i) immediately upon written notice to the Company if, after exercising commercially reasonable efforts, BioCryst determines in good faith that it is not advisable to continue development or commercialization of avoralstat as a result of a material safety issue and (ii) in its entirety or in part on a country-by-country basis, for any or no reason, upon prior written notice to the Company, provided that in the event of such a termination, BioCryst shall not, for a period of two years from the date of such a termination, initiate in the territory subject to the termination a Phase 3 clinical trial in which avoralstat is administered to the suprachoroidal space using a device other than the SCS Microinjector.

*Emory and Georgia Tech*

On January 31, 2024 (the "Amendment Execution Date"), the Company and the Licensor, entered into the Amendment to the Company's License Agreement with Licensor dated July 4, 2012 (as amended, the "License Agreement"), pursuant to which the Company received a worldwide exclusive license to specified patents relating to methods and devices for drug delivery using a microinjector.

Pursuant to the Amendment, the parties agreed to reduce the Sublicense Percentage (as defined in the License Agreement) from a low double digit percentage to a high single digit percentage that the Company will pay the Licensor applicable to any fees or payments paid to the Company by any Sublicensee (as defined in the License Agreement) of the Licensed Patents and/or Licensed Technology (each as defined in the License Agreement), on or after July 1, 2023, excluding (i) amounts paid to the Company by a Sublicensee to reimburse the Company for certain research and development costs pursuant to a written agreement between the Company and such Sublicensee, (ii) the value of intellectual property transferred or granted to the Company if necessary or helpful to the development or commercialization of Licensed Products (as defined in the License Agreement) and (iii) amounts paid for shares of the Company's stock. The payment to Licensor of any such Sublicense Percentage is due within 30 days of receipt by the Company of a qualifying payment from a Sublicensee, provided however, with respect to any qualifying payments received by the Company from

a Sublicensee after July 1, 2023 but prior to January 1, 2025, the payment to Licensor of any such Sublicensee Percentage is due to Licensor by March 31, 2025.

In addition, the parties agreed to a revised annual license maintenance fee due each year, or the Maintenance Fee, starting in 2023 through 2028, as follows: $250,000 for 2023 through 2025, $350,000 for 2026, $400,000 for 2027 and $500,000 for 2028. The Company paid the Maintenance Fee for 2023 in February 2024. The remaining annual Maintenance Fee payments are due on October 1st of each year.

*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 $50,000, $13,000 and $200,000 of revenue from these agreements during the years ended December 31, 2023, 2022 and 2021, respectively.

**13. Fair Value Measurements**

The Company's material financial instruments at December 31, 2023 and 2022, consisted primarily of cash and cash equivalents. The fair value of cash and cash equivalents, 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 liability related to the sales of future royalties approximates the carrying value.

There were no transfers between Levels 1, 2 and 3 during the years ended December 31, 2023 and 2022.

**14. Related Party Transactions**

During 2023, a member of the Company's Board of Directors took a position as Chief Executive Officer of a company that is a vendor of the Company. As of December 31, 2023, the Company has recorded $331,000 in accounts payable and $215,000 in accrued expense with this vendor in the consolidated balance sheets. For the year ended December 31, 2023, the Company has recorded $1.1 million of expense in the consolidated statements of operations.

The Chair of the Board of Directors of BioCryst also serves on the Company's Board of Directors. For the year ended December 31, 2023, there was $5.0 million related to the License Agreement recorded in license and other revenue in the consolidated statements of operations.

**15. Net (Loss) Income Per Share**

Basic net (loss) income per share is calculated by dividing the net (loss) income 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) income per share gives effect to all dilutive potential shares of common stock outstanding during this period.

For periods in which the Company incurred net losses, common stock equivalents were excluded which included 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.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| Net (loss) income - basic and diluted | $ (32,485) | $ (32,947) | $ 376 |
| | | | |
| Weighted average shares - basic | 61,806,959 | 60,204,862 | 58,491,986 |
| Effect of dilutive securities: | | | |
| Stock options | — | — | 1,058,134 |
| Restricted stock | — | — | 342,943 |
| ESPP | — | — | 13,539 |
| Weighted average shares - diluted | 61,806,959 | 60,204,862 | 59,906,602 |
| | | | |
| Net (loss) income per share - basic | $ (0.53) | $ (0.55) | $ 0.01 |
| Net (loss) income per share - diluted | $ (0.53) | $ (0.55) | $ 0.01 |

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2023 | 2022 | 2021 |
| Outstanding stock options | 9,865,770 | 6,915,330 | 4,704,194 |
| Non-vested restricted stock units | 834,899 | 1,462,932 | 974,404 |
| Stock purchase warrants | 29,796 | 29,796 | 29,796 |
| | 10,730,465 | 8,408,058 | 5,708,394 |

## 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, 2023. 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, 2023 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, 2023, 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 a non-accelerated filer and a smaller reporting company under SEC rules, management's report was not subject to attestation by our independent registered public accounting firm.

## ITEM 9B. OTHER INFORMATION

Not applicable.

## ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

## PART III

We will file a definitive Proxy Statement for our 2024 Annual Meeting of Stockholders (the "2024 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 2024 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 this item is hereby incorporated by reference to the 2024 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors," and "Information About Our Executive Officers."

**Code of Ethics**

We have adopted a Code of Business Conduct and Ethics (the "Code of Conduct") applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.clearsidebio.com. The Audit Committee is responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for executive officers and directors. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the amendment or waiver on our website.

### ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference to the sections of the 2024 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 2024 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 2024 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 2024 Proxy Statement under the caption "Ratification of Selection of Independent Auditors."

## PART IV

## ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) 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 | | Certificate of Amendment to 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 23, 2022). |
| 3.3 | | 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 | | 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). |
| 4.3 | | Form of Warrant to Purchase Common Stock issued to investors in February 2024 in connection with Securities Purchase 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 February 8, 2024). |
| 4.4 | | Description of Common Stock of Clearside Biomedical, Inc. (incorporated herein by reference to Exhibit 4.4 to the Registrant’s Annual Report on Form 10-K (File No. 001-37783), filed with the Commission on March 13, 2020). |
| 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). |
| 10.10 | | 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). |
| 10.11 | | 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). |
| 10.12 | + | 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). |
| 10.13 | + | Fourth Amended and Restated Non-Employee Director Compensation Policy (incorporated 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 12, 2022). |
| 10.14 | # | 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). |
| 10.15 | + | 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). |
| 10.16 | | 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). |
| 10.17 | ## | License Agreement, by and between the Registrant and Bausch Health Ireland Limited, dated as of October 22, 2019 (incorporated herein by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K (File No. 001-37783), filed with the Commission on March 13, 2020). |
| 10.18 | ## | First Amendment to License Agreement, by and between the Registrant and Bausch Health Ireland Limited, dated as of April 27, 2020. (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 10, 2020). |
| 10.19 | + | 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). |
| 10.20 | + | 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). |
| 10.21 | ##◆ | Option and License Agreement by and between the Registrant and REGENXBIO Inc., dated as of August 29, 2019 (incorporated herein by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K (File No. 001-37783), filed with the Commission on March 13, 2020). |
| 10.22 | ## | License Agreement by and between the Registrant and Arctic Vision (Hong Kong) Limited, dated as of March 20, 2020 (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 May 8, 2020). |
| 10.23 | + | Executive Employment Agreement, by and between the Registrant and Thomas Ciulla, dated as of June 24, 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 10, 2020). |
| 10.24 | ## | First Amendment to the License Agreement, by and between the Registrant and Arctic Vision (Hong Kong) Limited, dated as of August 15, 2021 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form-10 (File No. 001-37783), filed with the Commission on November 10, 2021. |
| 10.25 | ## | Second Amendment to the License Agreement, by and between the Registrant and Arctic Vision (Hong Kong) Limited, dated as of September 9, 2021 (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 10, 2021. |

| | | |
|---|---|---|
| 10.26 | | Second Amendment to the License Agreement, by and between the Registrant and Bausch + Lomb Ireland Limited (as assignee of Bausch Health Ireland Limited), dated as of September 27, 2021 (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 November 10, 2021. |
| 10.27 | ##◆ | Purchase and Sale Agreement, by and among Clearside Royalty LLC, Healthcare Royalty Partners IV, L.P. and HCR Collateral Management, LLC (in its capacity as agent for Purchaser), dated as of August 8, 2022 (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, 2022). |
| 10.28 | | First Amendment to Office Lease Agreement, by and between the Registrant and Radiant-North Point Properties, LLLP, dated as of November 1, 2022 (incorporated herein by reference to Exhibit 10.29 to the Registrant's Annual Report on Form 10-K (File No. 001-37783), filed with the Commission on March 14, 2023). |
| 10.29 | ## | First Amendment to Option and License Agreement, by and between the Registrant and REGENXBIO, Inc., dated as of January 14, 2023 (incorporated herein by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K (File No. 001-37783), filed with the Commission on March 14, 2023). |
| 10.30 | + | Consulting Agreement, by and between the Registrant and Thomas Ciulla, dated as of February 17, 2023 (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 February 21, 2023). |
| 10.31 | *##◆ | License Agreement, by and between the Registrant and BioCryst Pharmaceuticals, Inc., dated as of November 1, 2023. |
| 10.32 | | Letter Agreement, by and among Clearside Royalty LLC, Healthcare Royalty Partners IV, L.P. and HCR Clearside SPV, LLC (as assignee of HCR Collateral Management, LLC), dated as of December 22, 2023 (incorporated herein by reference to Exhibit 10.1 to the (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 December 28, 2023). |
| 10.33 | *## | Fourth Amendment to License Agreement, by and among the Registrant, Emory University and The Georgia Tech Research Corporation, dated January 31, 2024. |
| 10.34 | | Controlled Equity Offering℠ Sales Agreement, by and between the Registrant and Cantor Fitzgerald & Co., dated as of May 12, 2023 (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 12, 2023). |
| 10.35 | * | First Amendment to Consulting Agreement, by and between Registrant and Thomas Ciulla, dated as of February 17, 2024. |
| 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. |
| 97 | * | Clearside Biomedical, Inc. Clawback Policy. |
| 101.INS | | Inline XBRL Instance Document |
| 101.SCH | | Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents |
| 104 | | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101) |

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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 (indicated by asterisks) have been omitted because they are not material and are the type that the Registrant treats as private or confidential. The Registrant hereby agrees to furnish supplementally to the Securities and Exchange Commission, upon its request, an unredacted copy of this exhibit.

◆ Certain of the exhibits and schedules to this exhibit have been omitted in accordance with Regulation S-K Item 601. The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon request.

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**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 12, 2024

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints George Lasezkay and Charles A. Deignan, 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.*<br>George Lasezkay, Pharm.D., J.D. | President, Chief Executive Officer and Director<br>*(Principal Executive Officer)* | March 12, 2024 |
| */s/ Charles A. Deignan*<br>Charles A. Deignan | Chief Financial Officer<br>*(Principal Financial Officer and Principal Accounting Officer)* | March 12, 2024 |
| */s/ Clay B. Thorp*<br>Clay B. Thorp | Director | March 12, 2024 |
| */s/ Richard Croarkin*<br>Richard Croarkin | Director | March 12, 2024 |
| */s/ Jeffrey L. Edwards*<br>Jeffrey L. Edwards | Director | March 12, 2024 |
| */s/ William D. Humphries*<br>William D. Humphries | Director | March 12, 2024 |
| */s/ Nancy J. Hutson*<br>Nancy J. Hutson | Director | March 12, 2024 |
| */s/ Christy L. Shaffer, Ph.D.*<br>Christy L. Shaffer, Ph.D. | Director | March 12, 2024 |
| */s/Benjamin R. Yerxa*<br>Benjamin R. Yerxa | Director | March 12, 2024 |

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

**Exhibit 10.31**

# LICENSE AGREEMENT

**BY AND BETWEEN**

**BIOCRYST PHARMACEUTICALS, INC.**

**AND**

**CLEARSIDE BIOMEDICAL, INC.**

**November 1, 2023**

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

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**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

# LICENSE AGREEMENT

This License Agreement (the "**Agreement**") is entered into as of November 1, 2023 (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 BioCryst Pharmaceuticals, Inc., a Delaware corporation with a place of business at 4505 Emperor Blvd., Suite 200, Durham NC 27703 ("**BioCryst**"). Clearside and BioCryst may each be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, BioCryst is engaged in the research, development and commercialization of pharmaceutical products 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, a "**Clearside Device**");

WHEREAS, BioCryst and Clearside have entered into that certain Technology and Access Agreement dated as of August 11, 2022, as amended and restated by the Restated and Amended Technology Access Agreement dated as of July 12, 2023, pursuant to which Clearside has granted certain rights to BioCryst to evaluate the use of a Clearside Device in connection with BioCryst's products (the "**Technology Access Agreement**"); and

WHEREAS, as contemplated by the Technology Access Agreement, BioCryst and Clearside are entering into this Agreement to provide BioCryst 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:

## ARTICLE 1
## DEFINITIONS

When used in this Agreement, the following capitalized terms have the meanings set forth in this Article 1 (*Definitions*).

**1.1** "**AAA**" is defined in Section 11.11 (*Dispute Resolution*).

**1.2** "**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.

**1.3** "**Accounting Standards**" means, with respect to a Party, that such Party shall maintain records and books of accounts in accordance with (a) United States Generally Accepted

Accounting Principles, or (b) to the extent applicable, International Financial Reporting Standards as issued by the International Accounting Standards Board, in each case, consistently applied.

**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 for so long as such Person controls, is controlled by, or is under common control with such first Person. As used in this definition, 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 Manufacturer Election**" is defined in Section 4.2(e) (*Supply Failure*).

**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** "**Audit Arbitrator**" is defined in Section 5.11 (*Audit Dispute*).

**1.9** "**BioCryst**" is defined in the introduction to this Agreement.

**1.10** "**BioCryst Compound**" means BioCryst's proprietary plasma kallikrein inhibitor known as BCX-4161 or avoralstat, in any dosage strength, form or formulation thereof.

**1.11** "**BioCryst Indemnified Party**" is defined in Section 10.3 (*Indemnification by Clearside*).

**1.12** "**Breaching Party**" is defined in Section 9.2(a) (*Material Breach*).

**1.13** "**BioCryst Patent Application**" means [***] and any related Patent Rights.

**1.14** "**Business Day**" will mean any day other than a Saturday, Sunday, or United States federal holiday.

**1.15** "**Calendar Half**" means any of the respective periods of two (2) consecutive Calendar Quarters of any Calendar Year, except that the first Calendar Half of the Term will commence on the Effective Date and the last Calendar Half will end on the last day of the Term.

**1.16** "**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.

**1.17** "**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.

**1.18** "**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 (in one (1) transaction or a series of related transactions) of all or substantially all of such Party's business or assets to which this Agreement relates.

**1.19** "**Clearside**" is defined in the introduction to this Agreement.

**1.20** "**Clearside Device**" means a drug delivery device for delivery of therapeutic agents (including the BioCryst Compound) to the suprachoroidal space of the eye [***].

**1.21** "**Clearside Device Specifications**" is defined in Section 4.2(a)(i).

**1.22** "**Clearside DMF**" means Clearside's device master file number [***].

**1.23** "**Clearside Indemnified Party**" is defined in Section 10.2 (*Indemnification by BioCryst*).

**1.24** "**Clearside Inventions**" is defined in Section 6.5(b)(ii) (*Clearside Solely-Owned IP*).

**1.25** "**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 during the Term and (b) is necessary or useful for the Exploitation of a Clearside Device or administration of the BioCryst Compound using a Clearside Device. Without limiting the foregoing, Clearside Know-How includes Know-How relating to administration of any biological molecule, compound or other active ingredient or biologically active substance using a Clearside Device, and design of pre-clinical and clinical studies to test the safety and efficacy of a Clearside Device.

**1.26** "**Clearside Manufacturing Know-How**" has the meaning set forth in Section 2.5 (*Transfer of Know-How*).

**1.27** "**Clearside Patent Rights**" means (a) those Patent Rights Controlled by Clearside or any of its Affiliates as of the Effective Date and (b) any Patent Rights that become Controlled by Clearside or any of its Affiliates during the Term, in each case of (a) and (b), that Cover the Exploitation of the Covered Product. The Clearside Patent Rights existing as of the Effective Date include the Patent Rights identified in Exhibit 1.27 (CLEARSIDE PATENT RIGHTS).

**1.28** "**Clearside Technology**" means the Clearside Patent Rights and the Clearside Know-How.

**1.29** "**Continuation Notice**" is defined in Section 9.2(e)(i).

**1.30** "**Cost of Goods Sold**" or "**COGS**" means, with respect to a particular Clearside Device, the reasonable internal and Out-of-Pocket Costs of Clearside or any of its Affiliates incurred in Manufacturing such Clearside Device, including:

**(a)** to the extent that a Clearside Device is Manufactured by Clearside or any of its Affiliates, direct material and direct labor costs, logistics costs, plus manufacturing overhead directly attributable only to such Clearside Device (including quality assurance and quality control activities, sales, excise or other taxes imposed thereon, customs duties, import, export and other charges levied by Government Authorities, all costs of shipping and insuring such materials, facility start-up costs, directly incurred manufacturing variances, warehousing costs, costs to maintain inventory and a reasonable allocation of related manufacturing administrative and facilities costs (including depreciation)), all determined in accordance with the books and records of Clearside or its applicable Affiliate(s) maintained in accordance with Accounting Standards, consistently applied; and

**(b)** to the extent that a Clearside Device is Manufactured for Clearside by a Third Party manufacturer for provision by Clearside to BioCryst (or any of its Affiliates, subcontractors, or Sublicensees), the Out-of-Pocket Costs paid by Clearside or any of its Affiliates to the Third Party for the Manufacture of such Clearside Device, plus all reasonably allocated costs of Clearside and its Affiliates as described in the foregoing clause (a) incurred in managing or overseeing the sourcing of such Clearside Device from such Third Party, determined in accordance with the books and records of Clearside or its applicable Affiliate(s) maintained in accordance with Accounting Standards, consistently applied.

**1.31** "**Commercial Milestone"** is defined in Section 5.3 (*Commercial Milestones*).

**1.32** "**Commercial Milestone Payment**" is defined in Section 5.3 (*Commercial Milestones*).

**1.33** "**Commercial Supply Agreement**" is defined in Section 4.3 (*Commercial Manufacture and Supply of Clearside Devices*).

**1.34** "**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, detailing, distributing, importing and exporting 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.

**1.35** "**Commercially Reasonable Efforts**" means[***].

**1.36** "**Competing Activities**" means any activities that, if conducted by a Party or any of its Affiliates, would constitute a breach of Section 2.6(a)(i) (*Clearside Obligations*) or Section 2.6(b) (*BioCryst Obligations*), in each case, without consideration of Section 2.6(c) (*Exceptions*).

**1.37** [***]

**1.38** [***]

**1.39** "**Confidential Dispute Information**" is defined in Section 11.11 (*Dispute Resolution*).

**1.40** "**Confidential Information**" of a Party means all Know-How or other 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, Material Transfer Agreement or Technology Access Agreement, or after the Effective Date of this Agreement, and whether or not such Know-How or other non-public or confidential information is identified as confidential at the time of disclosure. "*Confidential Information*" does not include information that:

**(a)** was in the lawful knowledge and possession of the Receiving Party or its Affiliates prior to the time it was disclosed to the Receiving Party or its Affiliates, or was otherwise developed independently by the Receiving Party or its Affiliates, in each case, as evidenced by written records kept in the ordinary course of business, or other documentary proof of the Receiving Party or its Affiliates;

**(b)** was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party or its Affiliates;

**(c)** became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party or its Affiliates in breach of this Agreement; or

**(d)** was disclosed to the Receiving Party or its Affiliates, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party or its Affiliates not to disclose such information to others.

**1.41** "**Confidentiality Agreement**" means the Mutual Confidentiality Agreement, by and between Clearside and BioCryst, dated January 5, 2021.

**1.42** "**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. Notwithstanding anything to the contrary under this Agreement, with respect to any Third Party that becomes an Affiliate of Clearside after the Effective Date (including an Acquirer), no Intellectual Property of such Third Party owned or controlled by such Third Party immediately prior to the date such Third Party becoming an Affiliate of Clearside hereunder will be deemed Controlled by Clearside by virtue of such Third Party becoming an Affiliate of Clearside unless Clearside actually uses such Intellectual Property in the Exploitation of a Clearside Device during the Term.

**1.43** "**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, reproducing, creating of derivative works based upon, displaying, distributing, Developing, Commercializing or otherwise Exploiting of such product would, absent a license to such Intellectual Property, infringe, violate or misappropriate such Intellectual Property in the applicable country.

**1.44** "**Covered Product**" means the BioCryst Compound that is planned or anticipated to be administered using, or is actually administered using, a Clearside Device; *provided*, *however*, Covered Product excludes the BioCryst Compound if the BioCryst Compound is actually administered through a method other than a Clearside Device.

**1.45** [***].

**1.46** [***].

**1.47** "**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 (including through Phase IV Clinical Trials), 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.

**1.48** "**Development Milestone**" means the events that trigger Development Milestone Payments as described in Section 5.2 (*Development and Regulatory Milestone Payments*).

**1.49** "**Development Milestone Payment**" means the payments set forth in Section 5.2 (*Development and Regulatory Milestone Payments*).

**1.50** "**Development Order**" is defined in Section 4.2(a)(ii).

**1.51** "**Development Services**" is defined in Section 3.2(d) (*Development Services*).

**1.52** "**Disclosing Party**" is defined in Section 7.1 (*Protection of Confidential Information*).

**1.53** "**Distributor**" means any Person(s) appointed by BioCryst or any of its Affiliates or its or their Sublicensees to distribute, market and sell the Covered Product, with or without packaging rights[***].

**1.54** "**Dollars**" or "**$**" means United States Dollars.

**1.55** "**Drug Approval Application**" means an NDA, IND or other applications or dossier filed with a Regulatory Authority for the purpose of seeking Regulatory Approval, as applicable.

**1.56** "**Effective Date**" is defined in the introduction to this Agreement.

**1.57** "**EMA**" means the European Medicines Agency and any successor agency thereto.

**1.58** [***].

**1.59** [***]

**1.60** [***].

**1.61** "**European Major Market Countries**" means France, Germany, Italy, Spain and the United Kingdom.

**1.62** "**Existing Supplier**" is defined in Section 4.1(b) (*Existing Supply*).

**1.63** "**Existing Supply Agreements**" is defined in Section 4.1(b) (*Existing Supply*).

**1.64** "**Expert**" is defined in Section 9.2(e)(iii).

**1.65** "**Exploit**" means to make, have made, use, have used, sell, offer for sale, import and otherwise exploit, including to Develop, Commercialize, hold or keep (whether for disposal or otherwise), Manufacture, export, transport, distribute, conduct medical affairs activities with respect to, promote, and market. "**Exploitation**" means the act of Exploiting.

**1.66** "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

**1.67** "**Field**" means the treatment and prevention of diabetic macular edema.

**1.68** "**Firewall**" means reasonable and practical technical and administrative safeguards established by a Party that separate activities outside of this Agreement from activities under this Agreement, including to: (a) restrict access of personnel involved in performing activities outside of this Agreement to any Confidential Information of the other Party; and (b) restrict access of personnel involved in performing activities under this Agreement to non-public plans or non-public information relating to such activities; *provided*, that, in each case ((a) and (b)), senior management personnel may review and evaluate plans and information regarding such activities solely in connection with monitoring the progress of products, including portfolio decision-making among product opportunities. When used as a verb, "**Firewall**" means to establish a Firewall.

**1.69** "**First Commercial Sale**" means, with respect to the Covered Product and a country, the first sale for monetary value for use or consumption to the end user of the Covered Product in such country after Regulatory Approval for the Covered Product has been obtained in such country. Sales prior to receipt of Regulatory Approval for the 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.

**1.70** "**Forecast**" is defined in Section 4.2(a)(ii).

**1.71** "**Foreground IP**" is defined in Section 6.5(b)(i) (*BioCryst Solely-Owned IP*).

**1.72** "**Generic Product**" means, with respect to the Covered Product in a country, a pharmaceutical product delivered to the suprachoroidal space of the eye using a drug delivery device (other than the Covered Product) that (a) is sold by a Third Party other than a Distributor or Sublicensee under license from BioCryst in such country, (b) is authorized for use in such country in one or more of the indications for which the Covered Product has Regulatory Approval in such country; and (c) either (i) contains the same active pharmaceutical ingredient(s) as the Covered Product or (ii) is a product approved by way of an abbreviated regulatory mechanism by the Regulatory Authority in such country that, in each case, meets the equivalency determination by the applicable Regulatory Authority (including a determination that the product is "comparable", "interchangeable", "bioequivalent", "biosimilar" or other term of similar meaning, if applicable, with respect to the Covered Product).

**1.73** "**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.

**1.74** "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any nation, supranational body, state, county, city or other political subdivision.

**1.75** "**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.

**1.76** "**IND**" means (a) 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 and (b) all supplements and amendments that may be filed with respect to the foregoing.

**1.77** "**Indemnified Party**" is defined in Section 10.4(a) (*Notice*).

**1.78** "**Indemnifying Party**" is defined in Section 10.4(a) (*Notice*).

**1.79** "**Insolvency Proceedings**" is defined in Section 9.2(d) (*Termination for Insolvency*).

**1.80** "**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.

**1.81** "**Joint Inventions**" is defined in Section 6.5(b)(iii) (*Jointly-Owned IP*).

**1.82** "**Joint Patent Rights**" is defined in Section 6.1(c) (*Joint Patent Rights*).

**1.83** "**Know-How**" means any invention, trade secret, discovery, idea, data, information, process, method, technique, material, technology, result or other know-how, whether or not patentable.

**1.84** "**Knowledge**" or "**Knows**" means [***].

**1.85** "**Liability**" is defined in Section 10.2 (*Indemnification by BioCryst*).

**1.86** "**Major Market Countries**" means [***].

**1.87** [***].

**1.88** "**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. "**Manufactured**" shall have a corresponding meaning.

**1.89** "**Material Safety Issue**" means, with respect to a Clearside Device or the Covered Product, a Party's good faith belief that there is an unacceptable risk for harm in humans.

**1.90** "**Material Transfer Agreement**" means that certain Material Transfer Agreement dated as of March 30, 2018, as amended and restated by the Amended and Restated Material Transfer Agreement, effective as of March 30, 2018.

**1.91** "**MHRA**" means, in the United Kingdom, Medicines and Healthcare products Regulatory Agency, and any successor agency thereto.

**1.92** "**NDA**" means a New Drug Application, as defined in the U.S. Federal Food, Drug & Cosmetic Act, as amended, and applicable regulations promulgated thereunder by the FDA, or equivalent application for approval (but not including pricing and reimbursement approvals) to market a pharmaceutical product in a country or jurisdiction outside the United States.

**1.93** "**Net Sales**" means, with respect to the Covered Product for any period, [***]:

[***].

**1.94** "**Non-Breaching Party**" is defined in Section 9.2(a) (*Material Breach*).

**1.95** [***].

**1.96** "**Notice Period**" is defined in Section 9.2(a) (*Material Breach*).

**1.97** "**Out-of-Pocket Costs**" means amounts paid or payable by a Party or any of its Affiliates to a Third Party that are (a) accrued in accordance with Accounting Standards, and (b) directly incurred in the conduct of activities under this Agreement, but shall not include such Party's, or any of its Affiliates', internal or general overhead costs or expenses.

**1.98** [***]

**1.99** [***].

**1.100** [***].

**1.101** "**Party**" and "**Parties**" is defined in the introduction to this Agreement.

**1.102** "**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.

**1.103** "**Payment**" is defined in Section 5.8(a) (*Taxes—General*).

**1.104** "**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.

**1.105** "**Pharmacovigilance Agreement**" is defined in Section 3.2(c) (*Global Safety Database*).

**1.106** "**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.

**1.107** "**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.

**1.108** "**Phase IV Clinical Trial**" means clinical studies, other clinical activities or other activities that either Party is required by the applicable Regulatory Authority or otherwise commits to perform after obtaining Regulatory Approval for a pharmaceutical product in such country.

**1.109** "**Prosecution and Maintenance**" means, with respect to Patent Rights, the preparation, filing, prosecution, and maintenance of such Patent Rights, as well as re-examinations, reissues, appeals, and requests for patent term adjustments and patent term extensions with respect to such Patent Rights, together with the initiation or defense of interferences, oppositions, *inter partes* reviews, post-grant proceedings, and other similar proceedings (including any nullity, revocation, or compulsory license proceedings) with respect to such Patent Rights, and any appeals therefrom, but excluding, for clarity, any other enforcement actions taken with respect to such Patent Rights, and "**Prosecute and Maintain**" shall have a corresponding meaning.

**1.110** "**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 a Clearside Device.

**1.111** "**Receiving Party**" is defined in Section 7.1 (*Protection of Confidential Information*).

**1.112** "**Regulatory Approval**" means, with respect to a country in the Territory, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a pharmaceutical product in such country, including, where applicable, (a) pricing or reimbursement approval in such country [***].

**1.113** "**Regulatory Authority**" means any Governmental Authorities regulating or otherwise exercising authority with respect to the Exploitation of a product in the Territory, including, without limitation, the FDA in the United States, the MHRA in the United Kingdom, and the EMA in the other European Major Market Countries.

**1.114** "**Regulatory Documentation**" means: all (a) applications (including all Drug Approval Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals); (b) 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 (c) clinical and other data contained or relied upon in any of the foregoing; in each case ((a), (b), and (c)) relating to a pharmaceutical product.

**1.115** "**Representatives**" is defined in Section 7.2(a) (*Disclosure of Confidential Information*).

**1.116** "**Royalty Term**" means, with respect to the Covered Product and each country in the Territory, the period beginning on the date of the First Commercial Sale of the 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 or Covered Product Patent Right in such country that Covers the Covered Product or the administration thereof, or (b) [***] after the date of the First Commercial Sale in the applicable country.

**1.117** "**Rules**" is defined in Section 11.11 (*Dispute Resolution*).

**1.118** "**Safety Stock**" is defined in Section 4.2(d) (*Safety Stock*).

**1.119** "**Safety Stock Price**" is defined in Section 4.2(d) (*Safety Stock*).

**1.120** "**SEC**" means the United States Securities and Exchange Commission.

**1.121** "**Services Fee**" is defined in Section 3.2(d) (*Development Services*).

**1.122** "**Sublicense**" is defined in Section 2.3 (*Sublicenses*).

**1.123** "**Sublicensee**" means any Third Party (other than a Distributor) to whom BioCryst (or a Sublicensee or Affiliate of BioCryst) grants any rights under intellectual property rights Controlled by BioCryst to Develop, Manufacture, Commercialize or otherwise Exploit the Covered Product.

**1.124** "**Supply Failure**" is defined in Section 4.2(e) (*Supply Failure*).

**1.125** "**Supply Failure Notice**" is defined in Section 4.2(e) (*Supply Failure*).

**1.126** "**Technology Access Agreement**" is defined in the Recitals.

**1.127** "**Term**" is defined in Section 9.1 (*Term*).

**1.128** "**Terminated Territory**" means each country with respect to which this Agreement is terminated by BioCryst pursuant to Section 9.2(c) or, if this Agreement is terminated in its entirety, the entire Territory.

**1.129** "**Termination Notice**" is defined in Section 9.2(a) (*Material Breach*).

**1.130** "**Territory**" means the entire world, other than the Terminated Territory.

**1.131** "**Third Party**" means any Person other than BioCryst, Clearside or their respective Affiliates.

**1.132** "**Third Party Infringement Claim**" is defined in Section 6.3(a) (*Notice*).

**1.133** "**Third Party Claim**" is defined in Section 10.4(a) (*Notice*).

**1.134** "**Third Party Manufacturer**" is defined in Section 4.2(e) (*Supply Failure*).

**1.135** "**Transfer Price**" means the price at which Clearside will supply Clearside Devices to BioCryst (or its Affiliates, Distributors, subcontractors, or Sublicensees), which price will be, on a Clearside Device-by-Clearside Device basis: (a) for Clearside Devices supplied to BioCryst for Development activities conducted under this Agreement, [***] percent ([***]%) of COGS for such Clearside Device; and (b) for all other supply of Clearside Devices to BioCryst (including for BioCryst's Commercial activities, such as the sale of the Covered Product to Third Parties), [***] percent ([***]%) of COGS, subject to adjustments (up or down) to COGS for inflation and changes to device cost as further set forth in the Commercial Supply Agreement.

**1.136** "**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 [***] ([***]) 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.

## ARTICLE 2
## LICENSES AND RELATED GRANTS OF RIGHTS

**2.1 License Grant**. Clearside hereby grants to BioCryst and its Affiliates an exclusive (including with regard to Clearside and its Affiliates), nontransferable (except as set forth in Section 11.1 (*Assignment*)), sublicensable (as set forth in Section 2.3 (*Sublicenses*)), right and license under the Clearside Technology, all Patent Rights and Know-How Covering Joint Inventions[***] to Exploit the Clearside Devices for use in connection with the Covered Product in the Field in the Territory; *provided*, *however*, BioCryst covenants that it will not, and it will not permit Third Parties or its Affiliates, Distributors or Sublicensees to, Manufacture the Clearside Devices except as permitted pursuant to Section 4.2(e) (*Supply Failure*) or the Commercial Supply Agreement.

**2.2** [***]

**2.3 Sublicenses**. Clearside agrees that BioCryst has the right to grant sublicenses of the licenses set forth in Section 2.1 (*License Grant*) (each, a "**Sublicense**"), through multiple tiers of Sublicensees, Affiliates, or Distributors upon receipt of Clearside's prior written consent, not to be unreasonably withheld, conditioned or delayed; *provided* that any such Sublicenses will be subject to the terms and conditions of this Agreement. Notwithstanding the foregoing, BioCryst has the right to grant Sublicenses without such consent to its Affiliates, Distributors and to any contractors or commercial partners performing activities in furtherance of BioCryst's or its Affiliates' Exploitation of the Covered Product.

**2.4 Subcontracting**. Each Party will have the right to engage Affiliates and Third Party subcontractors to perform certain of its obligations under this Agreement as such Party deems appropriate, subject to the terms and conditions of this Agreement (including, for clarity, Section 4.2(e) (*Supply Failure*).

**2.5 Transfer of Know-How**. Clearside will provide BioCryst with all assistance reasonably required in order to transfer the Clearside Know-How to BioCryst, except that Clearside will not be required to transfer Clearside Know-How related to Manufacture of a Clearside Device ("**Clearside Manufacturing Know-How**") to BioCryst. The foregoing assistance will include Clearside making available to BioCryst, including at BioCryst's facilities or the facilities of BioCryst's Affiliates, those of Clearside's employees or contractors as BioCryst may reasonably request for purposes of transferring the Clearside KnowHow to BioCryst or for purposes of BioCryst acquiring expertise on the practical application of such Clearside Know-How. For any such assistance that BioCryst requests be provided on-site, such on-site support will be provided at such times as mutually agreed between the Parties. BioCryst will reimburse Clearside at a rate of [***] Dollars ($[***]) per Clearside employee or independent contractor per hour of on-site support provided following receipt of written invoices in reasonable detail; *provided*, *however*, that the first [***] ([***]) hours of support will be provided without charge; and *provided*, *further*, that BioCryst will reimburse Clearside for reasonable travel expenses in connection with providing such support.

**2.6 Exclusivity Covenants**.

**(a) Clearside Obligations**.

**(i)** During the Term, Clearside covenants that it and its Affiliates will not, alone, via an Affiliate, or through partnering with a Third Party, Exploit any kallikrein inhibitor delivered with a Clearside Device for use in ocular disease.

**(ii)** During the Term, Clearside covenants that it and its Affiliates will not, alone or via an Affiliate grant any license to any Third Party under the [***] to Exploit any kallikrein inhibitor delivered with a Clearside Device for use in ocular disease.

**(b) BioCryst Obligations**. During the Term, BioCryst covenants that it and its Affiliates will not, alone, via an Affiliate or through partnering with a Third Party, Exploit a product incorporating (i) the BioCryst Compound for use in ocular disease or (ii) another kallikrein inhibitor in the Field, in each case (i) and (ii), that is administered or delivered through the use of a device for delivery of therapeutic agents to the eye other than a Clearside Device.

**(c) Exceptions**.

**(i)** [***]

**(ii)** [***]

## ARTICLE 3
## DEVELOPMENT, COMMERCIALIZATION AND MANUFACTURE OF COVERED PRODUCT

**3.1 Diligence**. BioCryst will (itself or through its Affiliates or Sublicensees) use Commercially Reasonable Efforts to Develop, seek Regulatory Approval for and Commercialize the Covered Product in the Field in the Territory. Within [***] ([***]) days after the Effective Date, BioCryst will provide a non-binding written summary of BioCryst's planned Development and Commercialization activities for the Covered Product in the Field in the Territory for the subsequent [***] ([***]) month period. BioCryst shall provide Clearside with a non-binding update of such written summary within [***] ([***]) days after the end of each Calendar Year of the Royalty Term during which BioCryst did not provide a report pursuant to Section 3.6 (*Progress Reports*). All reports provided by BioCryst under this Section 3.1 (*Diligence*) will be BioCryst's Confidential Information, subject to the terms of Article 7 (*Confidentiality*).

**3.2 Development**. Subject to Section 3.1 (*Diligence*), BioCryst will have the sole right and responsibility, at its sole expense and in its sole discretion, for all aspects of the Development of the Covered Product. Without limiting the generality of the foregoing, BioCryst 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 the 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 the Covered Product sold by BioCryst, its Affiliates, Distributors, 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.

**(a) Regulatory Approvals**.

**(i)** As between the Parties, BioCryst 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 the Covered Product in the Field in the Territory. Clearside and its Affiliates will support BioCryst, as may be reasonably necessary and at BioCryst's expense, in obtaining Drug Approval Applications and Regulatory Approvals for the 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 BioCryst or any of its Affiliates or its or their Distributors and Sublicensees to obtain Regulatory Approvals for the Covered Product in the Field in the Territory. In particular: (A) Clearside will provide to BioCryst, 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 and any other relevant Regulatory Documentation in Clearside's possession as is required to enable BioCryst to make the relevant submission for each IND or any Regulatory Approval; (B) Clearside will provide all support reasonably useful or necessary to enable BioCryst to respond to any request of any Regulatory Authority in respect of any Drug Approval Application or Regulatory Approval; (C) Clearside will provide a letter of authorization granting BioCryst the right of reference to (x) the Clearside DMF and (y) any other relevant Regulatory Documentation, in each case ((x) and (y)), as is reasonably useful or necessary for the Covered Product in the Field in the Territory; and (D) Clearside will notify BioCryst of any amendments or supplemental filings relating to the Clearside DMF or any other relevant Regulatory Documentation provided under subclause (C) that would affect BioCryst's ability to Exploit the Covered Product.

**(ii)** Except to the extent prohibited by Applicable Law, all Regulatory Documentation (including all Regulatory Approvals) specifically relating to the Covered Product (excluding, for clarity, the Clearside DMF) or the BioCryst Compound in the Field with respect to the Territory created by BioCryst will be owned by and will be held in the name of, BioCryst or its designated Affiliate, Distributor, Sublicensee or designee.

**(iii)** BioCryst shall provide Clearside with copies of all material Regulatory Documentation to the extent making claims relating solely to a Clearside Device or containing statements relating to a Clearside Device that are not previously publicly available or previously approved by Clearside at least [***] ([***]) days prior to submission for review and comment by Clearside, and BioCryst shall consider in good faith any comments received from Clearside. Notwithstanding the foregoing, BioCryst shall notify Clearside of material correspondence received from any Regulatory Authority to the extent including information that

might reasonably affect any Regulatory Approval for a Clearside Device within [***] ([***]) Business Days.

**(iv)** BioCryst will inform Clearside of any safety related regulatory action related to a Clearside Device, queries or requests for inspection within the timelines outlined in the Pharmacovigilance Agreement and the Quality Agreement. BioCryst will provide Clearside the opportunity to review and comment on any response to any of the foregoing prior to finalization and submission thereof, and BioCryst shall consider in good faith any such comments received from Clearside.

**(b) Recalls, Suspensions or Withdrawals**.

**(i)** BioCryst will notify Clearside within [***] ([***]) Business Days following its determination that any event, incident or circumstance relating to the Covered Product has occurred that may result in the need for a recall, market suspension or market withdrawal of the Covered Product Exploited by BioCryst, its Affiliates, Distributors or Sublicensees in the Territory and will include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, BioCryst 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 the Covered Product Exploited by BioCryst, its Affiliates, Distributors, or Sublicensees is mandated by a Regulatory Authority in the Territory, as between the Parties, BioCryst 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 3.2(b)(i), as between the Parties, BioCryst will be solely responsible for the execution of such recalls, market suspensions or market withdrawals and Clearside will reasonably cooperate in all such efforts. BioCryst will be responsible for all costs of any recall, market suspension or market withdrawal of the Covered Product in the Territory, except in the event and to the extent that such recall, market suspension or market withdrawal resulted from (A) 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, or (B) any event, incident or circumstance relating to a Clearside Device pursuant to Section 3.2(b)(ii), in which case of ((A) and (B)), 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 3.2(b)(i), BioCryst will keep Clearside reasonably informed with respect to such recall, market suspension or market withdrawal.

**(ii)** Clearside will notify BioCryst within [***] ([***]) Business Days 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 a Clearside Device 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 a Clearside Device in the Territory. If a recall, market suspension or market withdrawal of a Clearside Device 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 3.2(b)(ii), as between the Parties, Clearside will be solely responsible for the execution of such recalls, market suspensions or market withdrawals and BioCryst will reasonably cooperate in all such efforts. Clearside will be responsible for all costs of any recall, market suspension or market withdrawal of a Clearside Device, except in the event and to the extent that a recall, market suspension or market withdrawal resulted from BioCryst's or its Affiliate's material breach of its obligations hereunder or from BioCryst's or its Affiliate's fraud, negligence or willful misconduct, in which case, BioCryst 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 3.2(b)(ii), Clearside will keep BioCryst reasonably informed with respect to such recall, market suspension or market withdrawal.

**(c) Global Safety Database**. BioCryst will establish, hold and maintain (at BioCryst's cost and expense) the global safety database for the Covered Product Exploited by BioCryst, its Affiliates, Distributors, 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 BioCryst with all information necessary for BioCryst to comply with its pharmacovigilance responsibilities in the Territory, including, as applicable, any adverse events involving a Clearside Device (including outside the Field), in each case in the form reasonably requested by BioCryst. Within [***] ([***]) days 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 the Covered Product and Clearside Devices.

**(d) Development Services**.

**(i)** During the period commencing on the Effective Date and ending on the date that an IND is filed for the Covered Product, and on a Calendar Quarter-by-Calendar Quarter basis, (A) BioCryst shall pay Clearside Seventy-Five Thousand Dollars ($75,000) (the "**Services Fee**") for Clearside's assistance and support services relating to the Development of the Covered Product, Clearside Devices or the Clearside Technology during such Calendar Quarter, including, without limitation, assistance in the training and use of a Clearside Device or the Clearside Technology, updates to and further development of a Clearside Device (the "**Development Services**"), and (B) BioCryst shall reimburse Clearside for any and all Out-of-Pocket Costs incurred by Clearside during each Calendar Quarter in the course of providing the Development Services, including without limitation, any fees or expenses paid to a Third Party laboratory or vendor engaged by Clearside to perform analytical, contract research or manufacturing services in connection with such Development Services. For clarity, Development Services shall exclude, and no fees shall be owed by BioCryst to Clearside for, any assistance required in Section 2.5 (*Transfer of Know-How*), required elsewhere in this Section 3.2 (*Development*), or otherwise expressly required under this Agreement. Within [***] ([***]) days after the Effective Date, the Parties will agree in writing on the scope of Development Services to be provided and the terms applicable to Clearside's provision of Development Services to

BioCryst, all of which shall be appended hereto as Exhibit 3.2(d) (CLEARSIDE DEVELOPMENT SERVICES).

**(ii)** Clearside shall invoice the Services Fee and the Out-of-Pocket Costs incurred by Clearside during each Calendar Quarter in the course of providing the Development Services within [***] ([***]) days after the end thereof. BioCryst's payment of such invoices shall proceed in accordance with Section 5.6 (*Invoices*).

**3.3 Governance**.

**(a) Alliance Managers**. Each Party will appoint an individual to act as its alliance manager under this Agreement as soon as practicable after the Effective Date (each an "**Alliance Manager**"). The Alliance Managers will: (i) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (ii) be responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties with respect to the status, progress and results of the Development, Commercialization or other Exploitation of the Covered Product under the Agreement; (iii) facilitate the prompt resolution of any disputes; and (iv) perform such other functions as expressly set forth in this Agreement or allocated to the Alliance Managers by the Parties' written agreement. An Alliance Manager may also bring any matter to the attention of the executive officers and other personnel as appropriate if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will use reasonable efforts to keep an appropriate level of continuity but may replace its Alliance Manager at any time upon written notice to the other Party.

**(b) Meetings**. During the Term and until the initiation of a Phase III Clinical Trial for the Covered Product, the Parties shall hold meetings at least [***] per Calendar Year (or such other frequency as mutually agreed by the Parties) for BioCryst to present and share any updates and progress regarding the Exploitation of the Covered Product during such immediately preceding Calendar Year (or such other period as mutually agreed by the Parties). Such meetings may be held in person, by audio or video conference. The Alliance Managers will be responsible for calling meetings and preparing and circulating an agenda to the Parties' respective executive officers in advance of each meeting.

**(c) Decisions**. Notwithstanding any provision to the contrary set forth in this Agreement, without the other Party's prior written consent, no decision of the Alliance Managers may: (i) result in a material increase in the other Party's obligations, costs, or expenses under this Agreement, unless, in each case, such actions are reasonably necessary for each Party to comply with Applicable Law or as the owner and holder of any Regulatory Approval, as applicable, for the Covered Product; (ii) take or decline to take any action that would be reasonably likely to result in a violation of any Applicable Law, the requirements of any Regulatory Authority, or any agreement with any Third Party or would be reasonably likely to result in the infringement or misappropriation of Intellectual Property rights of any Third Party; or (iii) amend, modify, or conflict with this Agreement, any Quality Agreement, the Pharmacovigilance Agreement, the

Commercial Supply Agreement, or any other agreement between the Parties related to the subject matter set forth herein.

**3.4 Commercialization and Manufacture of Covered Product**. As between the Parties, BioCryst (itself or through its Affiliates, Distributors, or its or their Sublicensees) will have the sole right to Commercialize and Manufacture, subject to Section 2.1 (*License Grant*) and Article 4 (*Manufacture and Supply of Clearside Devices*), the Covered Product in the Field and in the Territory at its sole cost and expense. Without limiting the obligations set forth in Section 3.1 (*Diligence*), Clearside further acknowledges that BioCryst is in the business of Exploiting pharmaceutical products and nothing in this Agreement will be construed as restricting such business or imposing on BioCryst the duty to Exploit the Covered Product to the exclusion of, or in preference to, any other product or in any way other than in accordance with its normal commercial practices.

**3.5 Booking of Sales; Distribution**. As between the Parties, BioCryst will have the sole right to invoice and book sales, establish all terms of sale (including pricing and discounts) and warehouse and distribute the Covered Product in the Territory and perform or cause to be performed all related services. Subject to Section 3.2(b) (*Recalls, Suspensions or Withdrawals*), as between the Parties, BioCryst will handle all returns, recalls or withdrawals, order processing, invoicing, collection, distribution and inventory management with respect to Covered Product in the Territory.

**3.6 Progress Reports**. Until the Covered Product receives its first Regulatory Approval anywhere in the Territory, BioCryst shall provide Clearside semi-annual reports summarizing its and its Affiliates' and Sublicensees' significant Development and Commercialization activities with respect to the Covered Product, including a summary of the data, timelines and results of such Development and any planned Commercialization activities, and good faith, non-binding estimates of the timing of completion of the milestone events set forth in Section 5.2 (*Development and Regulatory Milestone Payments*). BioCryst shall provide reports to Clearside at least [***] every [***] ([***]) months, or such other frequency as mutually agreed by the Parties. All reports provided by BioCryst under this Section 3.6 (*Progress Reports*) will be BioCryst's Confidential Information, subject to the terms of Article 7 (*Confidentiality*).

## ARTICLE 4
## MANUFACTURE AND SUPPLY OF CLEARSIDE DEVICES

**4.1 General Obligation; Continuity of Supply**.

**(a) General Obligations**. Clearside will (directly or through a Third Party supplier) Manufacture and supply all of BioCryst's requirements of the Clearside Devices for use with the Covered Product pursuant to this Agreement and the Commercial Supply Agreement.

**(b) Existing Supply**. Clearside currently obtains the Clearside Devices from one or more contract manufacturing organizations (the "**Existing Suppliers**"). Clearside will ensure: (i) material compliance at all times with the terms of its agreements with the Existing Suppliers (the "**Existing Supply Agreements**"); (ii) that any Clearside failure to comply with an

Existing Supply Agreement does not materially adversely impact BioCryst; and (iii) that such Existing Supply Agreements are not terminated unless and until either (A) BioCryst has entered into its own agreement with any Existing Supplier for supply of the Clearside Devices or (B) Clearside has established and qualified another supplier for the Clearside Devices. In the event of a Supply Failure (as defined below), upon BioCryst's reasonable request, Clearside will facilitate negotiations between the Existing Supplier and BioCryst with respect to an agreement for supply of the Clearside Devices.

**4.2 Preclinical and Clinical Manufacture and Supply of Clearside Devices**.

**(a) Development Orders**.

**(i)** Clearside will supply all Clearside Devices reasonably needed by BioCryst for Development of the Covered Product in accordance with the specifications attached hereto as Exhibit 4.2 (CLEARSIDE DEVICE SPECIFICATIONS) ("**Clearside Device Specifications**"), including all Clearside Devices reasonably needed for clinical trials or otherwise as needed to apply for, seek, obtain and maintain any Regulatory Approval for the Covered Product or the use of a Clearside Device in connection with the 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. Clearside represents, warrants and covenants that all Clearside Devices supplied by Clearside shall be Manufactured and supplied in accordance with the Clearside Device Specifications and the applicable Quality Agreement. BioCryst will not, and will not permit its Affiliates, Sublicensees, Distributors and Third-Party Manufacturers to, modify or alter a Clearside Device without Clearside's prior written consent. Any modification or alteration of a Clearside Device by Clearside on behalf of BioCryst will be at BioCryst's sole cost and expense (other than costs and expenses up to [***] Dollars ($[***]) in the aggregate, which shall be borne solely by Clearside) pursuant to a separate services agreement to be agreed by the Parties; *provided*, that Clearside will be under no obligation to modify or alter a Clearside Device unless such modification or alteration is required to comply with (A) Applicable Law, (B) a request from a Regulatory Authority, or (C) the Clearside Device Specifications, Quality Agreement, or Commercial Supply Agreement, as applicable, in accordance with Section 4.2(c) (*Shipment; Risk of Loss*).

**(ii)** BioCryst may place orders for Clearside Devices needed for Development of the Covered Product (a "**Development Order**") at least [***] ([***]) days 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 [***] ([***]) days after the Effective Date, BioCryst will provide to Clearside an initial non-binding [***] ([***])-month rolling forecast of Development Orders (the "**Forecast**"). Thereafter, BioCryst will provide an updated Forecast for the subsequent [***] ([***])-month period no later than the [***] ([***]) Business Day of each subsequent Calendar Half. Notwithstanding the foregoing, Clearside will use Commercially Reasonable Efforts to ensure that it, the Existing Suppliers, or any other supplier qualified in accordance with this Agreement has at all times sufficient manufacturing capacity to satisfy all Development Orders in the timelines set forth herein.

**(b) Pricing; Payment**. Clearside will invoice BioCryst for the Clearside Devices at the Transfer Price, and BioCryst shall pay such invoice in accordance with Section 5.6 (*Invoices*).

**(c) Shipment; Risk of Loss.** Clearside shall package and ship the Clearside Devices in a manner consistent with BioCryst's reasonable instructions and in compliance with the terms and conditions of this Agreement, any applicable Quality Agreement, and any Development Order, as applicable. Clearside shall deliver all Clearside Devices DDP (Incoterms 2020) to BioCryst's designated location.

**(d) Safety Stock**. Clearside will use Commercially Reasonable Efforts to purchase and store (at BioCryst's expense as set forth below) safety stock of excess Clearside Devices of at least [***] ([***]) months' supply of Clearside Devices pursuant to BioCryst's most recent Forecast (the "**Safety Stock**"). BioCryst's price for the Safety Stock (the "**Safety Stock Price**") will be equal to [***]. Clearside will invoice BioCryst for Safety Stock at the Safety Stock Price, and BioCryst shall pay such invoice in accordance with Section 5.6 (*Invoices*)]. Title to the Safety Stock will pass to BioCryst upon delivery of such Safety Stock to BioCryst or its designee in accordance with Section 4.2(c) (*Shipment; Risk of Loss*). Clearside will maintain a regular rotation of such Safety Stock as necessary to avoid expiration or other spoilage. Clearside shall provide an update regarding its current Safety Stock of Clearside Devices upon BioCryst'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 BioCryst that Clearside is unable to supply despite Commercially Reasonable Efforts after obtaining BioCryst's express written 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. BioCryst 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. From time to time, BioCryst and Clearside may review Safety Stock levels required to be maintained under this Section 4.2(d) (*Safety Stock*) and make mutually agreeable adjustments.

**(e) Supply Failure**.

**(i)** Subject to the provisions of the Commercial Supply Agreement, if, during the term of the Commercial Supply Agreement, Clearside fails to supply BioCryst with Clearside Devices that meet the Clearside Device Specifications and that are not otherwise damaged or defective, in quantities that are at least [***] percent ([***]%) of the quantities of Clearside Devices that Clearside is obligated to supply [***], on at least [***] ([***]) occasions in any consecutive [***] ([***]) month period, for any reason other than due to the material breach by BioCryst of this Agreement (a "**Supply Failure**"), BioCryst may, at its sole discretion, upon not less than [***] ([***]) days written notice to Clearside (a "**Supply Failure Notice**"): (A) require Clearside to supply the undelivered Clearside Devices at a future date to be agreed upon by the Parties; or (B) elect to have one or more Third Parties identified by BioCryst (each, a "**Third Party Manufacturer**") Manufacture Clearside Devices (an "**Alternative Manufacturer Election**"), in which case BioCryst will require its Third Party Manufacturer(s) to only

Manufacture and sell such Clearside Devices for BioCryst's and its Affiliates', Distributors', and Sublicensees' Exploitation in connection with the Covered Product within the scope of the licenses set forth in Section 2.1 (*License Grant*).

**(ii)** Upon the occurrence of a Supply Failure and an Alternative Manufacturer Election and at Clearside's expense: (A) BioCryst (or its designated Third Party Manufacturer(s)) will have the right to Manufacture Clearside Devices within the scope of the license under Section 2.1 (*License Grant*), and (B) Clearside shall transfer the Clearside Manufacturing Know-How to BioCryst and any Third Party Manufacturers identified by BioCryst as specified in the following sentence. Clearside shall promptly (x) disclose to BioCryst and any such Third Party Manufacturer all Clearside Manufacturing Know-How; (y) provide BioCryst 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 BioCryst and such Third Party Manufacturers to Manufacture Clearside Devices; and (z) make appropriately trained personnel available for consultation and advice upon BioCryst's reasonable request to the extent reasonably necessary to provide technical assistance necessary to enable BioCryst or such Third Party Manufacturers to Manufacture Clearside Devices.

**(f) Restricted Use of Clearside Devices**. Any Clearside Devices supplied to BioCryst under a Development Order that are not used for Development of the Covered Product shall, at Clearside's election following BioCryst's written confirmation that it is no longer Developing the Covered Product, be returned to Clearside or destroyed by BioCryst. For clarity, no Clearside Device supplied to BioCryst under a Development Order may be used by BioCryst for any Commercial purposes.

**4.3 Commercial Manufacture and Supply of Clearside Devices**. At an appropriate time during Development of the Covered Product and in any event prior to the initiation of a Phase III Clinical Trial for the Covered Product, the Parties, together with the Existing Suppliers or any other supplier qualified in accordance with this Agreement, will negotiate in good faith and enter into an agreement for commercial supply of the Clearside Devices ("**Commercial Supply Agreement**") and a Quality Agreement. The Commercial Supply Agreement will provide for supply of the Clearside Devices at the Transfer Price, and the Commercial Supply Agreement and Quality Agreement will otherwise contain mutually agreed terms and conditions consistent with this Agreement, including Article 4 (*Manufacture and Supply of Clearside Devices*) and any definitions of terms embodied therein, in addition to other terms that are reasonable and customary, including provisions to ensure quality and audit by or on behalf of BioCryst. For clarity, notwithstanding the negotiation of the Commercial Supply Agreement prior to initiation of the Phase III Clinical Trial for the Covered Product, any Clearside Devices Manufactured and supplied for use in the Phase III Clinical Trial or any Phase IV Clinical Trial will be Manufactured and supplied pursuant to Section 4.2 (*Preclinical and Clinical Manufacture and Supply of Clearside Devices*), not the Commercial Supply Agreement.

**4.4 GMP**. The Parties or their Affiliates will execute, as reasonably requested by BioCryst, 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 BioCryst in writing promptly after receiving knowledge thereof, before any supplier or manufacturer implements any changes in Manufacturing processes for the Clearside Devices that would have regulatory relevance to the Covered Product. Such notice shall be given promptly after Clearside receiving knowledge thereof. Clearside shall use Commercially Reasonable Efforts to secure for BioCryst 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.

## ARTICLE 5
## PAYMENTS TO CLEARSIDE

**5.1 Upfront Fee**. In partial consideration of the rights granted by Clearside to BioCryst hereunder and subject to the terms and conditions of this Agreement, following the execution of this Agreement, BioCryst will pay to Clearside a non-refundable payment of Five Million Dollars ($5,000,000) within [***] ([***]) days following the execution of this Agreement.

**5.2 Development and Regulatory Milestone Payments**.

**(a) Milestone Payments**. In partial consideration of the rights granted by Clearside to BioCryst 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 BioCryst, an Affiliate or a Sublicensee, the corresponding payment will be due:

| Development Milestone | Development Milestone Payment (USD) |
|---|---|
| [***] | $[***] |
| [***] | $[***] |
| [***] | $[***] |
| [***] | $[***] |
| [***] | $[***] |
| **Total** | **$30,000,000** |

The Development Milestone Payments set forth in this Section 5.2(a) (*Development and Regulatory Milestone Payments—Milestone Payments*) shall be payable only once, upon the first achievement of such milestone event by the Covered Product, regardless of the number of times the Covered Product achieves such milestone event.

**(b) Notice; Payments**. Within [***] ([***]) days after the occurrence of a Development Milestone, BioCryst will send Clearside a written notice identifying the Development Milestone and the Development Milestone Payment Amount set forth above with respect to such Development Milestone. Thereafter, Clearside will invoice BioCryst within [***]

([***]) days of Clearside's receipt of such notice for the achievement of the Development Milestone, identifying in its invoice the Development Milestone achieved and the amount of the Development Milestone Payment, and BioCryst shall pay such Development Milestone Payment in accordance with Section 5.6 (*Invoices*).

**5.3 Commercial Milestones**. In partial consideration of the rights granted by Clearside to BioCryst hereunder and subject to the terms and conditions of this Agreement, BioCryst 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**"), whether such milestone is achieved by BioCryst, an Affiliate or a Sublicensee:

| Commercial Milestone | Commercial Milestone Payment (USD) |
|---|---|
| For the first Calendar Year during the Term in which the Net Sales of the Covered Product for such Calendar Year in the Territory exceeds $[***] | $[***] |
| For the first Calendar Year during the Term in which the Net Sales of the Covered Product for such Calendar Year in the Territory exceeds $[***] | $[***] |
| For the first Calendar Year during the Term in which the Net Sales of the Covered Product for such Calendar Year in the Territory exceeds $2,000,000,000 | $[***] |
| **Total** | **$47,500,000** |

Within [***] ([***]) days after the occurrence of a Commercial Milestone, BioCryst 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 invoice BioCryst within [***] ([***]) days of Clearside's receipt of such notice for the achievement of the Commercial Milestone and BioCryst shall pay such Commercial Milestone Payment in accordance with Section 5.6 (*Invoices*).

The Commercial Milestone Payments set forth in this Section 5.3 (*Commercial Milestones*) shall be payable only once, upon the first achievement of such milestone event, regardless of how many times such milestone event is achieved.

**5.4 Royalties**.

**(a) Royalty Rates**. As further consideration for the rights granted to BioCryst hereunder and subject to this Section 5.4 (*Royalties*), with respect to each Calendar Quarter during the Royalty Term applicable to the Covered Product, BioCryst shall pay to Clearside royalties on annual Net Sales of the Covered Product by BioCryst, its Affiliates and Sublicensees in the Territory, as calculated by multiplying the applicable royalty rate by the corresponding amount of incremental Net Sales of the Covered Product in the Territory in such Calendar Quarter, as follows:

| Annual Net Sales of Covered Product | Royalty Rate |
|---|---|
| For that portion of Net Sales of the Covered Product in each Calendar Year less than or equal to $[***] | [***] Percent ([***]%) |
| For that portion of Net Sales of the Covered Product in each Calendar Year greater than $[***] but less than or equal to $[***] | [***] Percent ([***]%) |
| For that portion of Net Sales of the Covered Product in each Calendar Year greater than $1,500,000,000 | [***] Percent ([***]%) |

BioCryst will have no obligation to pay any royalty with respect to Net Sales of the Covered Product in any country after the Royalty Term for the Covered Product in such country has expired. Following the expiration of the Royalty Term for the Covered Product in a country, the license grants in Section 2.1 (*License Grant*) will become fully-paid, royalty-free, perpetual and irrevocable for the Covered Product in such country, and no further royalties will be payable. For clarity, no royalties are due on Net Sales of the Covered Product arising from compassionate use and other programs providing for the delivery of the Covered Product at or below cost.

**(b) [***] Reductions**.

**(i) Third-Party IP**. If, in connection with the Manufacture, use or Commercialization of the Covered Product, BioCryst is obligated to pay [***] to any Third Parties solely in order to Exploit the Clearside Devices (and not where such [***] would be due in connection with the Exploitation of a BioCryst Compound without a Clearside Device), then on a country-by-country basis, BioCryst shall have the right to deduct from the royalty payment that would otherwise have been due under [***] with respect to Net Sales of the Covered Product in such country an amount equal to [***] percent ([***]%) of any [***] paid by BioCryst to such Third Parties.

**(ii) No Valid Claims**.

**(1) No Valid Claims of Clearside Patent Rights; Valid Claims of Covered Product Patent Rights Remaining**. If, during the Royalty Term for the Covered Product in a country, no Valid Claim of the Clearside Patent Rights exists but one or more Valid Claims of the Covered Product Patent Rights exist that Cover the Covered Product in such country, then [***].

**(2) No Valid Claims of Clearside Patent Rights or Covered Product Patent Rights**. If, during the Royalty Term for the Covered Product in a country, no Valid Claim of the Clearside Patent Rights or Covered Product Patent Rights exists that Covers the Covered Product in such country, then the applicable royalty rates that would otherwise be payable under Section 5.4(a) (*Royalty Rates*) shall be reduced by [***] percent ([***]%) during the period of the Royalty Term in which no such Valid Claim of the Clearside Patent Rights or Covered Product Patent Rights exists.

**(iii) Generic Competition During the Royalty Term**. On a country-by-country basis, if at any time during the Royalty Term a Generic Product is sold in such country and the aggregate Net Sales of the Covered Product in such country in any Calendar Quarter thereafter are at least [***] percent ([***]%) lower as compared to the average quarterly Net Sales of the Covered Product in such country [***] immediately preceding the Calendar Quarter in which the Generic Product was first sold, then, following such reduction in Net Sales, the Net Sales of the Covered Product in such country used for calculation of royalties pursuant to Section 5.4 (*Royalties*) shall be reduced by [***] percent ([***]%).

**(iv) [***] Floor**. In no event shall (A) the application of Section 5.4(b)(i) (*Third-Party IP*), Section 5.4(b)(ii) (*No Valid Claims*) or Section 5.4(b)(iii) (*Generic Competition During the Royalty Term*) reduce the royalty payable on Net Sales of the Covered Product in a country in a Calendar Quarter during the Royalty Term to less than [***] percent ([***]%) of the royalty that would be payable on Net Sales of the Covered Product in such country determined in accordance with Section 5.4(a) (*Royalty Rates*) without application of any such reductions or [***]. [***].

**5.5 Royalty Payments and Reports**. BioCryst will calculate all amounts payable to Clearside pursuant to Section 5.4 (*Royalties*) at the end of each Calendar Quarter, which amounts will be converted to Dollars, in accordance with Section 5.7 (*Currency; Payment Instructions; Late Payments; Offsets*). BioCryst will report to Clearside the royalty amounts due with respect to a given Calendar Quarter within [***] ([***]) days after the end of such Calendar Quarter. Thereafter, Clearside will invoice BioCryst within [***] ([***]) days of Clearside's receipt of such quarterly royalty report for the royalty amounts due for such Calendar Quarter and BioCryst's payment of such royalty amounts due for such Calendar Quarter shall proceed in accordance with Section 5.6 (*Invoices*). Each quarterly royalty report shall include a statement of the amount of Net Sales and number of units of the Covered Product 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 the Covered Product for each country included in the calculation of Net Sales. BioCryst will also include in such reports any additional information reasonably requested by Clearside to calculate Net Sales attributable to its Affiliates and Sublicensees.

**5.6 Invoices**. If either Party (the "**Invoicing Party**") is owed amounts by the other Party (the "**Invoiced Party**") pursuant to this Agreement, the Invoicing Party must invoice the Invoiced Party for such amounts within any applicable time periods set forth in this Agreement. Except as otherwise set forth in Section 5.1 (*Upfront Fee*), the Invoiced Party will pay all undisputed amounts in such invoices within [***] ([***]) days of receipt. In the event the Invoiced Party disputes any portion of an invoice, it shall notify the Invoicing Party in writing within [***] ([***]) days after receipt of invoice. The Parties shall use good faith efforts to resolve such dispute.

**5.7 Currency; Payment Instructions; Late Payments; Offsets**. 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 Accounting Standards. If any payment due to either Party under this 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; *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. Notwithstanding the previous sentence, the total payable interest rate will never be less than [***] ([***]) basis points. BioCryst shall have the right, upon prior written notice to Clearside, to offset any undisputed payment, resolved payment or payment that is the subject of a pending dispute that is owed by Clearside but not timely paid against any payments owed by BioCryst, if any, under this Agreement.

**5.8 Taxes**.

**(a) General**. The milestones, royalties and other amounts payable by BioCryst 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 5.8 (*Taxes*), 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 BioCryst) levied on account of, or measured in whole or in part by reference to, any Payments it receives. BioCryst 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 BioCryst or the appropriate governmental authority (with the assistance of BioCryst 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 BioCryst of its obligation to withhold such tax and BioCryst will apply the reduced rate of withholding or dispense with withholding, as the case may be; *provided* that BioCryst has received evidence, in a form reasonably satisfactory to BioCryst, of Clearside's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [***] ([***]) days prior to the time that the Payments are due. If, in accordance with the foregoing, BioCryst 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 [***] ([***]) days following such payment.

**5.9 Financial Records**.

**(a) BioCryst**. BioCryst 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 the Covered Product hereunder to the extent required to calculate and verify all amounts payable hereunder. BioCryst will, and will cause its Affiliates and its and their Sublicensees to, retain such books and records until [***] ([***]) years after the end of the period to which such books and records pertain.

**(b) Clearside**. Clearside will, and will cause its Affiliates, Existing Suppliers or any other supplier qualified in accordance with this Agreement to, keep complete and accurate financial books and records pertaining to the COGS of the Clearside Devices and the Safety Stock Price hereunder to the extent required to calculate and verify the Transfer Price payable hereunder. Clearside will, and will cause its Affiliates, Existing Suppliers or any other supplier qualified in accordance with this Agreement to, retain such books and records until [***] ([***]) years after the end of the period to which such books and records pertain.

**5.10 Audit**.

**(a) BioCryst**. Upon Clearside's reasonable request, BioCryst will, and will cause its Affiliates and its and their Sublicensees to, permit an independent, nationally recognized accounting firm designated by Clearside and acceptable to BioCryst, at reasonable times and upon at least [***] ([***]) days' notice, to audit the books and records maintained pursuant to Section 5.9(a) (*Financial Records—BioCryst*) to ensure the accuracy of all reports and payments under this Agreement. Such examinations may not be conducted more than [***] in any [***] ([***]) month period and are limited to the preceding [***] ([***]) month period. No record may be audited more than once. The cost of this audit will be borne by Clearside, unless the audit reveals a variance of more than [***] percent ([***]%) from the reported amounts, in which case BioCryst will reimburse Clearside for the accounting firm's fees in performing the audit. If such audit concludes that (a) additional amounts were owed by BioCryst, BioCryst will pay the additional amounts or (b) excess payments were made by BioCryst, Clearside will reimburse or credit such excess payments, in either case ((a) or (b)), within [***] ([***]) days after the date on which such audit is completed.

**(b) Clearside**. Upon BioCryst's reasonable request, Clearside will, and will cause its Affiliates, and will use reasonable efforts to cause its Existing Suppliers or any other supplier qualified in accordance with this Agreement to, permit an independent, nationally recognized accounting firm designated by BioCryst and acceptable to Clearside, at reasonable times and upon at least [***] ([***]) days' notice, to audit the books and records maintained pursuant to Section 5.9(b) (*Financial Records —Clearside*) to ensure the accuracy of all invoices issued pursuant to Section 4.2(b) (*Pricing; Payment*) or Section 4.2(d) (*Safety Stock*). Such examinations may not be conducted more than [***] in any ([***]) ([***]) month period and are limited to the preceding [***] ([***]) month period. No record may be audited more than [***]. The cost of this audit will be borne by BioCryst, unless the audit reveals a variance of more than [***] percent ([***]%) from the invoiced amount, in which case Clearside will reimburse BioCryst

for the accounting firm's fees in performing the audit. If such audit concludes that (a) additional amounts were owed by BioCryst, BioCryst will pay the additional amounts or (b) excess payments were made by BioCryst, Clearside will reimburse or credit such excess payments, in either case ((a) or (b)), within [***] ([***]) days after the date on which such audit is completed.

**5.11 Audit Dispute**. In the event of a dispute with respect to any audit under Section 5.10 (*Audit*), Clearside and BioCryst shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [***] ([***]) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Audit Arbitrator**"). The decision of the Audit Arbitrator shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Audit Arbitrator shall determine. Not later than [***] ([***]) days after such decision and in accordance with such decision, BioCryst or Clearside shall pay the additional amounts, as applicable, or BioCryst or Clearside shall reimburse the excess payments, as applicable.

**5.12 Confidentiality**. The Receiving Party will treat all information subject to review under this Article 5 (*Payments to Clearside*) in accordance with the confidentiality provisions of Article 7 (*Confidentiality*) 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.

## ARTICLE 6
## PATENT MATTERS; OWNERSHIP OF INTELLECTUAL PROPERTY

**6.1 Filing, Prosecution and Maintenance of Patent Rights**. [***.]

**(a) Clearside Patent Rights and [***]**. Clearside has the first right, at its discretion and using counsel it selects, to Prosecute and Maintain all Clearside Patent Rights and [***] in Clearside's name in the Territory and Clearside will be solely responsible for all costs and expenses incurred in connection with such Prosecution and Maintenance. Clearside shall: (i) provide BioCryst with copies of all filings and formal correspondences relating to [***] 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); (ii) keep BioCryst advised of the status of actual and prospective patent filings; (iii) give BioCryst the opportunity to provide and will reasonably consider in good faith comments on the Prosecution and Maintenance of the [***]; (iv) reasonably consult with BioCryst prior to electing not to continue to Prosecute and Maintain any [***]; (v) not make any decision regarding the Prosecution and Maintenance of such [***] that materially disadvantages BioCryst as compared to any other licensee of such Patent Rights; and (vi) upon BioCryst's reasonable request, seek claims related to the combined use of a Clearside Device for delivery of the BioCryst Compound in the Field. Each Party will treat any consultation regarding the Prosecution and Maintenance of the [***], along with any information disclosed by each Party in connection therewith (including any information concerning patent

expenses), as both Parties' Confidential Information. If Clearside elects not to continue to Prosecute and Maintain any Clearside Patent Rights, then: [***].

**(b) BioCryst Patent Rights**.

**(i) Compound Patent Rights**. As between the Parties, BioCryst shall have the sole right (but not the obligation), using counsel it selects, to Prosecute and Maintain the Patent Rights Covering the Compound IP ("**Compound Patent Rights**"). BioCryst will be solely responsible for all costs and expenses incurred in connection with such Prosecution and Maintenance.

**(ii) [***]**.

**(c) Joint Patent Rights**. With respect to any Patent Rights Covering the Joint Inventions (the "**Joint Patent Rights**"), the Parties shall meet to determine in what countries, if any, Joint Patent Rights should be filed and the appropriate filing Party for such Joint Patent Rights. The Parties shall equally share costs incurred by the Party filing such Joint Patent Rights. If a Party elects not to equally share costs related to any Joint Patent Right, the other Party shall provide written notice upon the decision to not share any Joint Patent Right costs and the Party not giving such notice shall have the right to assume responsibility for such Prosecution and Maintenance, at its own sole expense.

**(d) Claim Separation**. The Parties shall use commercially reasonable efforts (including, as appropriate, by Prosecuting and Maintaining separate continuation applications, continuation-in-part applications, or divisional applications), in each case, as reasonably determined based on then-available scientific or other evidence, to segregate into separate Patents claims that would cause a Patent to constitute: (a) a Compound Patent; (b) a Covered Product Patent Right; (c) a Clearside Patent Right; (d) [***]; and (e) a Joint Patent Right.

**6.2 Enforcement and Defense of Patent Rights**. [***]

**(a) Notification**. In the event that either Party becomes aware of any (i) actual or threatened infringement or (ii) alleged or threatened assertion of invalidity or unenforceability, in each case ((i) and (ii)), of any Compound Patent Right, Covered Product Patent Right, Joint Patent Right, Clearside Patent Right or [***] in the Territory by a Third Party, such Party will promptly notify the other Party in writing and will provide any information available to such Party relating to such infringement or assertion of invalidity or unenforceability.

**(b) Compound Patent Rights**. As between the Parties, BioCryst shall have the sole right (but not the obligation), using counsel it selects, to enforce or defend the Compound Patent Rights. BioCryst will be solely responsible for all costs and expenses incurred in connection with such enforcement.

**(c) Covered Product Patent Rights**. BioCryst shall have the first right but not the obligation, at its own expense, to enforce or defend the Covered Product Patent Rights in the Territory. BioCryst will notify Clearside of its election within [***] ([***]) days after notification

of such Covered Product Patent Right infringement or assertion of invalidity or unenforceability pursuant to Section 6.2(a) (*Notification*). If BioCryst elects not to pursue or defend against such action, Clearside will have the right, but not the obligation, at its own expense, to commence a suit or take action relating to such infringement or defend the validity or enforceability of the Covered Product Patent Rights in any claim, suit, or proceeding in the Territory. The Party not bringing or defending against an action with respect to the Covered Product 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 or defending Party. Additionally, the Party not bringing or defending against an action under the Covered Product Patent Right 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 or defending Party elects to bring or defend against such action hereunder and, whether or not the Party not bringing or defending against the action elects to participate, the Party bringing or defending against the action will provide regular updates on the status of the action to the Party not bringing or defending against the action.

**(d) Joint Patent Rights** . The Parties shall mutually determine whether (i) to take action to obtain a discontinuance of infringement or bring suit against a Third Party infringer or (ii) defend the validity or enforceability in any claim, suit, or proceeding, in each case ((i) and (ii)), of any Joint Patent Rights within [***] ([***]) days (or earlier as required by Applicable Law) from the date of notice, *provided* that neither Party shall be obligated to join any such action. In the event that either Party does not want to join an action as a party to such action, then the Party not seeking to enforce or defend against such claims shall have the right to assign the relevant Joint Patent Rights to the other Party, *provided* that such assignment is solely and sufficient for purposes of commencing or maintaining the action or defense. The Party seeking to enforce or defend against such claims shall solely bear all of its expenses. The Parties will reasonably cooperate, at the expense of the Party seeking to enforce or defend against such claim, in any such suit and shall have the right to consult with the other Party and to participate in and be represented by independent counsel in such litigation at its own expense.

**(e) Clearside Patents Rights and [***]**. Clearside shall have the first right but not the obligation, at its own expense, to enforce or defend (as applicable) the Clearside Patent Rights and [***], including in the Field, in the Territory. Clearside will notify BioCryst of its election within [***] ([***]) days after notification of such Clearside Patent Right or [***] infringement or assertion of invalidity or unenforceability pursuant to Section 6.2(a) (*Notification*). In the case where Clearside elects not to pursue or defend against such action: (i) if BioCryst is the sole exclusive licensee with respect to such Clearside Patent Rights or [***], BioCryst will have the right, but not the obligation, at its own expense, to commence a suit or take action relating to such infringement or defend the validity or enforceability of such Covered Product Patent Rights in any claim, suit, or proceeding in the Territory; or (ii) if BioCryst is not the sole exclusive licensee with respect to such Clearside Patent Rights or [***], BioCryst and the other exclusive licensees may negotiate in good faith regarding the commencement of any suit or the taking of any action relating to such infringement or the defense of the validity or enforceability of such Covered Product Patent Rights in any claim, suit, or proceeding in the Territory. The Party not bringing or defending against an action with respect to the Clearside Patent Right or [***] 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 or defending Party. Additionally, the Party not bringing or defending against an action under the Clearside Patent Rights or [***] 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 or defending Party elects to bring or defend against such action hereunder and, whether or not the Party not bringing or defending against the action elects to participate, the Party bringing or defending against the action will provide regular updates on the status of the action to the Party not bringing or defending against the action. Notwithstanding the foregoing, BioCryst shall have the first right (but not the obligation), at its own expense, to enforce or defend the Clearside Patent Rights [***] to the extent the alleged Clearside Patent Right [***] infringement concerns any kallikrein inhibitor administered or delivered through the use of a device for delivery of therapeutic agents to the eye other than a Clearside Device.

**(f) Recovery**. If the enforcing Party recovers monetary damages (whether by way of settlement or otherwise) from any Third Party in a suit or action for infringement of Covered Product Patent Rights pursuant to Section 6.2(c) (*Covered Product Patent Rights*), Joint Patent Rights pursuant to Section 6.2(d) (*Joint Patent Rights*), or Clearside Patent Rights or [***] pursuant to Section 6.2(e) (*Clearside Patents and [***]*), such recovery will be allocated 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). Any remaining damages after such reimbursement is made shall (i) in the case of the Covered Product Patent Rights pursuant to Section 6.2(c) (*Covered Product Patent Rights*), [***]; (ii) in the case of Joint Patent Rights pursuant to Section 6.2(d) (*Joint Patent Rights*), [***]; and (iii) in the case of the Clearside Patent Rights or [***] pursuant to Section 6.2(e)(*Clearside Patents and [***]*), [***].

**(g) In General; Settlement**. In any action, suit or proceeding instituted under this Section 6.2 (*Enforcement and Defense of Patent Rights*), the Parties will cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party initiating or defending against 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 or defending Party's expense, or assign the right to enforce or defend the patents to the Party initiating or defending against such action. Neither Party will have the right to settle any action, suit or proceeding under this Section 6.2 (*Enforcement and Defense of Rights*) 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, conditioned, or delayed).

**6.3 Defense of Third Party Claims**.

**(a) Notice**. If a Party becomes aware of any actual or potential claim that the Exploitation of the Covered Product in the Territory infringes or misappropriates the Intellectual Property of any Third Party (a "**Third Party Infringement Claim**"), such Party shall promptly notify the other Party.

**(b) Control of Defense** . Subject to Article 10 (*Limitation on Liability, Indemnification and Insurance*), BioCryst shall have the first right, but not the obligation, to defend and control the defense of any Third-Party Infringement Claim at its own expense using counsel of its own choice. Clearside may participate in any such Third-Party Infringement Claim with counsel of its choice at its own expense; *provided* that BioCryst shall retain control of the defense of such claim, suit, or proceeding. Without limiting the foregoing, if BioCryst finds it necessary or desirable for Clearside to join as a party to any such action, Clearside shall execute all papers and perform such acts as shall be reasonably required. If BioCryst fails to assume such defense within [***] ([***]) months of the first notice under Section 6.3(a) (*Notice*) with respect thereto (or such shorter period as may be required to comply with applicable legal or regulatory deadlines which relate to such claim), Clearside shall thereafter have the right (but not the obligation), upon written notice to BioCryst, to defend and dispose of (including through settlement or license) such Third Party Infringement Claim; *provided*, that Clearside may not dispose of such Third Party Infringement Claim without BioCryst's prior written consent (not to be unreasonably withheld, conditioned, or delayed). In any event, the Parties will reasonably assist each other and cooperate in any such Third Party Infringement Claim at the other Party's request and expense. Each Party may at its own expense and with its own counsel join any defense initiated or directed by the other Party under this Section 6.3(b) (*Control of Defense*). Each Party will provide the other Party with prompt written notice of the commencement of any such Proceeding under this Section 6.3(b) (*Control of Defense*), and such Party will promptly furnish the other Party with a copy of each communication relating to the alleged infringement that is received by such Party.

**6.4 Patent Term Extension and Supplementary Protection Certificate**. (a) BioCryst shall be responsible for making decisions regarding patent term extensions for any Compound Patent Rights and Covered Product Patent Rights, and (b) the Parties will cooperate regarding patent term extensions for any Joint Patent Rights, ["***"] or Clearside Patent Rights, in each case, Covering the Covered Product, in each case of (a) and (b), 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 BioCryst or the Parties, as applicable, determine to apply for any patent term extension or supplementary protection certificate for any Compound Patent Right, Covered Product Patent Right, Joint Patent Right, [***] or Clearside Patent Right, in each case Covering the Covered Product in the Field in the Territory, each Party shall provide the other Party with prompt and reasonable assistance, as applicable, as is required under any Applicable Law to obtain such extension or supplementary protection certificate.

**6.5 Ownership of Intellectual Property**.

**(a) Background IP**. Subject to the licenses granted by Clearside pursuant to this Agreement, each Party owns and will continue to own all Intellectual Property: (i) owned or Controlled by such Party as of the Effective Date, or (ii) that are Invented solely by or on behalf of Representatives of such Party or its Affiliates outside the performance of activities under this Agreement. Without limiting the foregoing, BioCryst owns and will continue to own all Intellectual Property that Covers the BioCryst Compound as of the Effective Date.

**(b) Foreground IP**.

**(i) BioCryst Solely-Owned IP**. BioCryst shall solely own all Intellectual Property Invented by or on behalf of Representatives of a Party or its Affiliates after the Effective Date in the performance of activities under this Agreement ("**Foreground IP**") that relates solely to [***].

**(ii) Clearside Solely-Owned IP**. Clearside shall solely own all Foreground IP that (A) is not Covered Product IP or Compound IP, and (B) is related to the use of a Clearside Device alone or in combination with any substance other than the BioCryst Compound for use in the Field ("**Clearside Inventions**").

**(iii) Jointly-Owned IP**. The Parties shall jointly own all Foreground IP that is not Covered Product IP, Compound IP or Clearside IP ("**Joint Inventions**"). With respect to Exploitation of Joint Inventions outside the scope of the license granted hereunder, the Parties shall (A) 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 (B) subject to any transaction contemplated by the foregoing clause (A), neither Party shall be permitted to sublicense such Joint Invention without the other Party's prior written consent, not to be unreasonably withheld. For the avoidance of doubt, the BioCryst Patent Application shall be deemed a Covered Product Patent Right hereunder and owned solely by BioCryst.

**(iv) Further Assurances**. 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 Covered Product IP, Compound IP, Clearside IP, [***] and Joint IP. If a Clearside Patent Right [***] issues that would otherwise constitute a Covered Product Patent Right, Clearside shall assign its right, title and interest in and to (or, if unable to do so, shall exclusively license (or sublicense, as applicable)) such Clearside Patent Right or [***] to BioCryst and, for purposes of this Agreement thereafter, such assigned Clearside Patent Right or [***] shall be deemed a Covered Product Patent Right.

**6.6 Patent Listings**. BioCryst shall have the sole right to make all filings with Regulatory Authorities in the Territory with respect to Compound IP, Covered Product IP, Clearside Patent Rights (solely to the extent such Clearside Patent Rights contain one or more Valid Claims Covering the Covered Product), [***] and Joint Patent Rights (solely to the extent such Joint Patent Rights contain one or more Valid Claims Covering the Covered Product), as required or allowed (a) in the United States, in the FDA's Orange Book (titled "Approved Drug Products With Therapeutic Equivalence Evaluations"), and (b) outside the United States, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents. Clearside shall (i) provide to BioCryst all information, including a correct and complete list of Clearside Patent Rights, [***] or Joint Patent Rights containing one or more Valid Claims Covering the Covered Product or otherwise necessary or reasonably useful to enable BioCryst to make such filings with Regulatory Authorities in the Territory with respect to such Patent Rights, and (ii) cooperate with BioCryst's reasonable requests in connection therewith,

including meeting any submission deadlines, in each case ((i) and (ii)), to the extent required or permitted by Applicable Law.

## ARTICLE 7
## CONFIDENTIALITY

**7.1 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 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 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 7.1 (*Protection of Confidential Information*) shall be in full force during the Term and for a period of [***] ([***]) years thereafter.

**7.2 Certain Permitted Disclosures**.

**(a) Disclosure of Confidential Information**.

**(i) Disclosure to Representatives**. Notwithstanding the foregoing and subject to Section 7.2(a)(ii) (*Disclosures under Applicable Law*), the Receiving Party may disclose Confidential Information of the Disclosing Party to officers, directors, employees, consultants, subcontractors, contractors, or agents of the Receiving Party or its Affiliates or, in the case of BioCryst, its Sublicensees and Distributors, advisory board members and collaboration and financial partners (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 7 (*Confidentiality*).

**(ii) 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 Prosecute and Maintain 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 7 (*Confidentiality*)), or to the extent necessary to pursue a legal proceeding pursuant to Section 5.11 (Audit Dispute), Section 9.2(e) (Alternative Remedy) or Section 11.11 (*Dispute Resolution*) (including a proceeding to enforce or challenge an arbitration award);

*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).

**(b) 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: (i) 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 (ii) to a Third Party in connection with (A) an actual or potential equity investment in or by, or underwriting by, such Third Party, (B) an actual or potential merger, consolidation or similar transaction involving such Third Party, (C) 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 (D) a potential or actual sublicensee hereunder; provided that such Party will make 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 7 (*Confidentiality*).

**7.3 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 Authority 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 7.3 (*Securities Law Filings and Other Disclosures*), 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 7.3 (*Securities Law Filings and Other Disclosures*), 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.

**7.4 Publications**. During the Term, BioCryst will have the sole right to publish and make scientific presentations with respect to the Covered Product. BioCryst shall submit all such intended publications or presentations to Clearside at least [***] ([***]) days prior to any submission or other public disclosure. Clearside shall have [***] ([***]) days in which to review such proposed publication or presentation, and BioCryst shall consider Clearside's comments in good faith with respect to such publication or presentation. Clearside shall have the right to remove any of its Confidential Information prior to submission for publication or presentation. If Clearside fails to notify BioCryst during the [***] ([***]) day period set forth above, BioCryst may proceed with the proposed publication or presentation. Each Party agrees to acknowledge the contributions of the other Party and its employees in all publications as scientifically appropriate.

**7.5 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 7.3 (*Securities Law Filings and Other Disclosures*), neither Party will make any other public announcement regarding this Agreement without the prior written approval of the other Party. Notwithstanding the foregoing, BioCryst and its Affiliates and its and their Distributors and Sublicensees will have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding the Covered Product; *provided*, that 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 any Clearside Device in a manner that is contrary to, or would not reasonably be expected have an adverse effect on, any Regulatory Approval held by Clearside related to any 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 any 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.

**7.6 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. The Receiving Party will also be permitted to retain such additional copies of or any computer records or files containing the Disclosing Party's Confidential Information that have been created solely by automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with the Receiving Party's standard archiving and back-up procedures, but not for any other use or purpose.

## ARTICLE 8
## REPRESENTATIONS AND WARRANTIES

**8.1 Mutual Representations and Warranties**. Each of Clearside and BioCryst hereby represents and warrants to the other Party that as of the Effective Date:

**(a)** it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;

**(b)** 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;

**(c)** it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

**(d)** 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; and

**(e)** 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.

**8.2 Representations and Warranties of Clearside**. Clearside hereby represents and warrants to BioCryst that (i) as of the Effective Date, [***] except as otherwise disclosed to BioCryst in a written disclosure letter:

**(a)** [***];

**(b)** [***];

**(c)** [***];

**(d)** [***];

**(e)** [***];

**(f)** except as expressly set forth [***], the Clearside Technology was not and will not be funded by the U.S. federal government or otherwise subject to any rights of the U.S. federal government under the Bayh-Dole Act;

**(g)** other than [***], there are no agreements pursuant to which Clearside has been granted any rights in, to or under the Clearside Technology;

**(h)** [***];

**(i)** to Clearside's Knowledge, after consultation with employees of Clearside having responsibility for or involvement in patent matters: (i) Clearside and its Affiliates [***], as applicable, has 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; (ii) the pending applications included in Clearside Patents Rights are being diligently Prosecuted and Maintained in the respective patent offices in the Territory in accordance with Applicable Law, and Clearside and its Affiliates [***], as applicable, 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 (iii) Clearside and its Affiliates [***], as applicable, has timely paid all filing and renewal fees payable with respect to any such Clearside Patent Rights;

**(j)** [***];

**(k)** [***];

**(l)** to Clearside's Knowledge, there is no (i) 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 BioCryst's rights or Clearside's obligations hereunder, or (ii) 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;

**(m)** [***];

**(n)** 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;

**(o)** the rights granted to BioCryst by Clearside pursuant to Section 6.6 (*Patent Listings*) with respect to the Clearside Patent Rights and [***] do not conflict with any rights Clearside has granted any Affiliate or Third Party;

**(p)** neither Clearside nor any of its Affiliates, nor any of its or their respective officers, employees, or agents, has made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Clearside Devices, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the Clearside Devices, or committed an act, made a statement, or failed to make a statement with respect to the Clearside Devices that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory;

**(q)** (i) the development of Clearside Technology (other than [***]) has been conducted in compliance in all material respects with all Applicable Law; and (ii) to Clearside's Knowledge, the development of [***] has been conducted in compliance in all material respects with all Applicable Law; and

**(r)** neither Clearside nor any of its Affiliates has 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.

**8.3 Additional Covenants**.

**(a)** Clearside and its Affiliates shall not: (i) 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 BioCryst hereunder; (ii) 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 BioCryst hereunder; or (iii) during the Term, enter into any material agreements or contracts that would be inconsistent with its obligations under this Agreement;

**(b)** [***];

**(c)** Each Party and its Affiliates (and with respect to BioCryst, its Sublicensees and Distributors, and with respect to Clearside, its Existing Suppliers and any other supplier qualified in accordance with this Agreement) 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; and

**(d)** Each Party will maintain as and when necessary the financial and other capabilities reasonably necessary to discharge its obligations under this Agreement.

**8.4 Debarment**. Each Party represents, warrants, and covenants to the other Party that: (a) it is not debarred, excluded, disqualified, or the subject of disbarment, exclusion or disqualification proceedings under the United States Food, Drug, and Cosmetic Act or comparable laws in any country or jurisdiction other than the United States; and (b) to its knowledge, does not, and will not during the Term knowingly, employ or use, directly or indirectly, including through Affiliates, Sublicensees, Distributors, Existing Suppliers, or any other supplier qualified in accordance with this Agreement, or the services of any person who is debarred, excluded, disqualified, or the subject of disbarment, exclusion, or disqualification proceedings in connection with activities relating to this Agreement. In the event that either Party becomes aware of the debarment, exclusion, or disqualification or threatened debarment, exclusion, or disqualification of any person providing such services, such Party shall promptly notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

**8.5** [***].

**8.6 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.

## ARTICLE 9
## TERM AND TERMINATION

**9.1 Term** . The term of this Agreement will commence upon the Effective Date and, unless sooner terminated as provided in this Article 9 (*Term and Termination*), will expire: (a) on a country-by-country basis, upon the expiration of the Royalty Term in such country for the Covered Product; or (b) in its entirety upon the expiration of all payment obligations by BioCryst under this Agreement in all countries pursuant to the foregoing sentence. The period from the Effective Date until the date of expiration of this Agreement pursuant to this Section 9.1 (*Term*) or earlier termination of this Agreement pursuant to Section 9.2 (*Termination*), is the "**Term**." For

clarity, the term of any Commercial Supply Agreement, Pharmacovigilance Agreement, or Quality Agreement will be governed by the terms of such agreement and will not be affected by expiration or termination of this Agreement unless otherwise set forth in such Commercial Supply Agreement, Pharmacovigilance Agreement, or Quality Agreement.

**9.2 Termination**.

**(a) 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 [***] ([***]) days (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: (i) 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 and, *provided*, *further*, that, to the extent such breach is curable, the Breaching Party's cure right will be extended for up to an additional [***] ([***]) days if the Breaching Party commences actions to cure such breach within the Notice Period and thereafter diligently continues such actions; and (ii) if either Party initiates a dispute resolution procedure under Section 11.11 (*Dispute Resolution*) 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 [***] ([***]) days after the resolution of the dispute through such dispute resolution procedure.

**(b) Patent Challenge**. Unless unenforceable under Applicable Law, Clearside may terminate this Agreement upon written notice to BioCryst if BioCryst, 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 Clearside Patent Rights 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, (i) such proceeding is not terminated within [***] ([***]) days after BioCryst's receipt of written notice from Clearside or (ii) BioCryst does not terminate the applicable sublicense within such [***] ([***]) day period.

**(c) Termination by BioCryst**. BioCryst may terminate this Agreement:

**(i)** immediately upon written notice to Clearside where, after exercising Commercially Reasonable Efforts, BioCryst in good faith determines that it is not advisable for BioCryst to continue to Develop or Commercialize the Covered Product due to a Material Safety Issue; or

**(ii)** in its entirety or in part [***], for any or no reason, upon [***] ([***]) days' prior written notice to Clearside, *provided*, that, in such event, beginning on the effective date of termination and for a period of two (2) years thereafter, BioCryst shall not initiate any Phase III Clinical Trial in which a BioCryst Compound is administered to the suprachoroidal

space of the eye through the use of a device other than a Clearside Device in the applicable Terminated Territory.

**(d) Termination for Insolvency**. In the event that either Party: (i) files for protection under bankruptcy or insolvency laws; (ii) makes an assignment for the benefit of creditors; (iii) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [***] ([***]) days after such filing; (iv) proposes a written agreement of composition or extension of its debts; (v) proposes or is a party to any dissolution or liquidation; (vi) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [***] ([***]) days of the filing thereof; or (vii) admits in writing its inability generally to meet its obligations as they fall due in the general course (the events described in subsections (i) though (vii), collectively, "**Insolvency Proceedings**"), then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

**(e) [***]**.

**9.3 Consequences of Termination**.

**(a) Termination in the Entire Territory**. In the event of a termination of this Agreement for the entire Territory for any reason, all rights and licenses granted by either Party hereunder will immediately terminate.

**(b) Termination in a Terminated Territory**. In the event of a termination of this Agreement in a Terminated Territory (but not in the case of any termination of this Agreement in its entirety), BioCryst will not, and will not permit any of its Affiliates or any of its and their Sublicensees or Distributors to, (A) Exploit the Clearside Devices for use with the Covered Product directly or indirectly or (B) assist another Person to Exploit the Clearside Devices for use with the BioCryst Compound directly or indirectly; in each case ((A) and (B)), to (x) any Person for commercial use in the Terminated Territory or (y) any Person in the Territory that BioCryst knows, or any of its Affiliates or any of its or their Sublicensees or Distributors knows, is likely to Exploit a Clearside Device for use with the Covered Product for commercial use in the Terminated Territory.

**(c) Sell-Off; Clinical Studies**. Notwithstanding the termination of BioCryst's licenses and other rights under this Agreement, (A) BioCryst will have the right for [***] ([***]) months after the effective date of such termination to sell or otherwise dispose of all Clearside Devices for use with the 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; *provided*, that BioCryst will continue to make payments thereon as provided in Section 5.3 (*Commercial Milestones*) and Section 5.4 (*Royalties*) (as if this Agreement had not terminated); and (B) solely upon termination of this Agreement by BioCryst because of an uncured Clearside material breach or Clearside Insolvency Proceeding, if there are any clinical studies relating to the Covered Product being conducted at the date of termination, BioCryst shall be

entitled to continue Developing and, as applicable pursuant to Section 4.2(e) (*Supply Failure*) or the Commercial Supply Agreement, Manufacturing the Covered Product to the extent and for the period necessary to effect an orderly transfer or wind down of such clinical studies in a timely manner and in accordance with all Applicable Law.

**9.4 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.

**9.5 Survival of Certain Obligations**.

**(a)** Expiration or termination of this Agreement in whole or in part will not relieve the Parties of any rights, obligations, or remedies that accrued before such expiration or termination.

**(b)** The following provisions will survive expiration or termination of this Agreement: Article 1 (*Definitions*) (to the extent necessary for interpretation of any surviving provisions), Section 3.2(b) (*Recalls, Suspensions or Withdrawals*), Section 5.2 (*Development and Regulatory Milestone Payments*) (solely to the extent of payment obligations that accrued prior to the effective date of termination), Section 5.3 (*Commercial Milestones*) (solely to the extent of payment obligations that accrued prior to the effective date of termination), Section 5.4 (*Royalties*), Section 5.5 (*Royalty Payments and Reports*) through Section 5.9 (*Financial Records*) (in each case solely to the extent of payment obligations that accrued prior to the effective date of termination), Section 5.10 (*Audit*), Section 5.11 (*Audit Dispute*), Section 5.12 (*Confidentiality*), Section 6.2 (*Enforcement and Defense of Patent Rights*) (with respect to any action initiated prior to the effective date of expiration or termination), Section 6.3 (*Defense of Third Party Claims*), Section 6.5 (*Ownership of Intellectual Property*), Article 7 (*Confidentiality*), Section 8.6 (*Disclaimer*), Section 9.2(c)(ii), Section 9.3 (*Consequences of Termination*) through Section 9.5 (*Survival of Certain Obligations*), Article 10 (*Limitation of Liability, Indemnification and Insurance*), and Article 11 (*Miscellaneous*). For clarity, any other Section that explicitly states it survives expiration or termination of this Agreement will so survive.

**(c)** If this Agreement is terminated with respect to 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 BioCryst and its Affiliates and its and their Sublicensees and Distributors to exercise their rights in the Territory) and all provisions not surviving in accordance with the foregoing will terminate upon termination of this Agreement for such Terminated Territory and be of no further force and effect (and for clarity all provisions of this Agreement will remain in effect with respect to all countries in the Territory other than the Terminated Territory).

## ARTICLE 10
## LIMITATION ON LIABILITY, INDEMNIFICATION AND INSURANCE

**10.1 No Consequential Damages**. EXCEPT WITH RESPECT TO LIABILITY ARISING FROM OR RELATED TO A PARTY'S (A) BREACH OF ARTICLE 6 (*PATENT MATTERS; OWNERSHIP OF INTELLECTUAL PROPERTY*) ARTICLE 7 (*CONFIDENTIALITY*) OR SECTION 2.6 (*EXCLUSIVITY COVENANTS*), (B) GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR INTENTIONALLY WRONGFUL ACT (INCLUDING FRAUD AND FRAUDULENT MISREPRESENTATION), OR (C) INDEMNIFICATION OBLIGATIONS UNDER SECTION 10.2 (*INDEMNIFICATION BY BIOCRYST*) OR SECTION 10.3 (*INDEMNIFICATION BY CLEARSIDE*), 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, 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.

**10.2 Indemnification by BioCryst**. BioCryst will indemnify, defend and hold harmless Clearside, its Affiliates, 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:

**(a)** the material breach by BioCryst or its Affiliates or Sublicensees of any of its representations, warranties or covenants set forth in this Agreement;

**(b)** the gross negligence, recklessness or willful misconduct of any BioCryst Indemnified Party in the conduct of this Agreement; or

**(c)** the Exploitation by BioCryst or any of its Affiliates or Sublicensees of the Covered Product in the Territory to the extent caused by the BioCryst Compound, including Liability caused by the Exploitation of the Covered Product infringing upon the Intellectual Property rights of a Third Party (to the extent such infringement is caused by the BioCryst Compound);

*provided*, that such indemnity will not apply to the extent Clearside has an indemnification obligation pursuant to Section 10.3 (*Indemnification by Clearside*) for such Liability, as to which Liability each Party will indemnify the other to the extent of their respective liability for such Liability.

**10.3 Indemnification by Clearside**. Clearside will indemnify, defend and hold harmless BioCryst, its Affiliates, Sublicensees, subcontractors, contractors, Distributors and each of its and their respective employees, officers, directors and agents (each, a "**BioCryst Indemnified Party**") from and against any and all Liabilities that the BioCryst Indemnified Party

may incur or be required to pay to one or more Third Parties to the extent resulting from or arising out of:

**(a)** the material breach by Clearside or its Affiliates or Existing Suppliers or any other supplier qualified in accordance with this Agreement of any of its representations, warranties or covenants set forth in this Agreement;

**(b)** the gross negligence, recklessness or willful misconduct of any Clearside Indemnified Party in the conduct of this Agreement; or

**(c)** the Exploitation by BioCryst or any of its Affiliates, Sublicensees or Distributors of the Covered Product in the Territory to the extent caused by the Clearside Devices Manufactured by or on behalf of Clearside, including Liability caused by injury to persons or death caused by the Clearside Devices Manufactured by or on behalf of Clearside;

*provided*, that such indemnity will not apply to the extent BioCryst has an indemnification obligation pursuant to Section 10.2 (*Indemnification by BioCryst*) for such Liability, as to which Liability each Party will indemnify the other to the extent of their respective liability for such Liability.

**10.4 Procedure**.

**(a) 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 any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

**(b) Control**. The Indemnifying Party will have the right, exercisable by notice to the Indemnified Party within [***] ([***]) Business Days 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.

**(c) 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.

**10.5 Insurance.** 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 [***] Dollars ($[***]) per occurrence for personal injury and [***] Dollars ($[***]) 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 [***] ([***]) days' 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 [***] years after termination of this Agreement. This Section 10.5 (*Insurance*) 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.

## ARTICLE 11
## MISCELLANEOUS

**11.1 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 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 11.1 (*Assignment*) will be null and void.

**11.2 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 BioCryst, 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, BioCryst 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 BioCryst's possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon BioCryst'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 BioCryst.

**11.3 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.

**11.4 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.

**11.5 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 BioCryst will be addressed as follows:

BioCryst Pharmaceuticals, Inc.
4505 Emperor Blvd.
Suite 200
Durham, NC 27703
Attention: Chief Legal Officer

with copies to:

BioCryst Pharmaceuticals, Inc.
4505 Emperor Blvd.
Suite 200
Durham, NC 27703
Attention: Chief Business Development Officer

Freshfields Bruckhaus Deringer
700 13th St. NW
Washington, DC 20005
Attention: [***]
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:

Cooley LLP
11951 Freedom Drive, Suite 1400
Reston, VA 20194
Email: [***]

**11.6 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.

**11.7 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.

**11.8 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 most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law.

**11.9 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.

**11.10 Governing Law**. This Agreement will be governed by the laws of the State of New York, U.S.A., 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.

**11.11 Dispute Resolution**. Except as provided in Section 5.11 (*Audit Dispute*) and Section 9.2(e) (*Alternative Remedy in Lieu of Termination*), any dispute, controversy or claim arising out of, relating to or in connection with this Agreement, including with respect to its formation, interpretation, applicability, breach, termination, validity or enforceability thereof will be referred to the CEO of Clearside and the CEO of BioCryst (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. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party. If any dispute is not resolved by these individuals (or their designees) within [***] ([***]) days after written notice of the dispute, or such longer period as they may mutually agree, either Party may refer the dispute to arbitration in accordance with this Section 11.11 (*Dispute Resolution*).

Any arbitration under this Agreement shall be conducted by three arbitrators and administered by the American Arbitration Associations (the "**AAA**") in accordance with its Commercial Arbitration Rules ("**Rules**") in effect at the time, except as they may be modified herein or by agreement of the Parties. The claimant shall nominate an arbitrator in its demand for arbitration. The respondent shall nominate an arbitrator within [***] days of the receipt of the demand for arbitration. The two arbitrators nominated by the parties shall nominate a third arbitrator within [***] days after the nomination of the later-nominated arbitrator. The third arbitrator shall act as chair of the tribunal. If any of the three arbitrators are not nominated within the time prescribed above, then the AAA shall appoint the arbitrator(s) in accordance with its Rules. The seat of arbitration shall be New York, New York. The award rendered by the arbitral tribunal shall be final and binding upon the Parties, and may be enforced as an arbitral award and entered as a judgment in any court of competent jurisdiction.

The Parties agree that any dispute under the Agreement shall be kept confidential. The existence of the dispute and any arbitration, any non-public information provided in an arbitration, and any submissions, orders or awards made in an arbitration (together, the "**Confidential Dispute Information**") shall not be disclosed to any non-party except the tribunal, the AAA, their counsel, experts, witnesses, accountants and auditors, insurers and reinsurers, and any other person necessary to the conduct of the dispute. Notwithstanding the foregoing, a party may disclose Confidential Dispute Information to the extent that disclosure may be required to fulfill a legal duty, protect or pursue a legal right, or enforce or challenge an award in bona fide legal proceedings. The provisions of this Section 11.11 (*Dispute Resolution*) will survive the termination or expiration of this Agreement.

**11.12 Compliance with Laws**. Each Party will, and will ensure that its Affiliates will, comply with all Applicable Law in exercising its rights and fulfilling its obligations under this Agreement. No Party will, or will be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Law.

**11.13 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, the Material Transfer Agreement, and the Technology Access Agreement, which are hereby terminated effective as of the Effective Date.

**11.14 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.

**11.15 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.

**11.16 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. Electronically scanned signatures shall have the same effect as their originals.

**11.17 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," (g) the word "or" is used in the inclusive sense (and/or); and (h) references to any specific law, rule, or regulation, or article, section, or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule, or regulation thereof.

**11.18 Expenses**. Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incurred in connection with the negotiation, preparation, execution, delivery, and performance of this Agreement.

**11.19 No Third Party Rights or Obligations**. Notwithstanding a Clearside Indemnified Party or a BioCryst Indemnified Party's right to indemnification under Section 10.2 (*Indemnification by BioCryst*) and Section 10.3 (*Indemnification by Clearside*) (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. 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 CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

| | |
|---|---|
| **BIOCRYST PHARMACEUTICALS, INC.** | **CLEARSIDE BIOMEDICAL, INC.** |
| By: /s/ Alane Barnes | By: /s/ George Lasezkay |
| Name: Alane Barnes | Name: George Lasezkay |
| Title: CLO | Title: President and CEO |

[*Signature Page to License Agreement*]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

# Exhibit 1.27

## CLEARSIDE PATENT RIGHTS

**[***]**

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

# Exhibit 1.58

**[***]**

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

**Exhibit 4.2**

# CLEARSIDE DEVICE SPECIFICATIONS

[***]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

**Exhibit 10.33**

# FOURTH AMENDMENT TO THE LICENSE AGREEMENT

**This Fourth Amendment to the License Agreement** (the "**Fourth Amendment**") is entered into as of January 31, 2024 (the "**Fourth Amendment Execution Date**") but effective as of the original Effective Date by and among **Emory University** ("**EMORY**"), the **Georgia Tech Research Corporation** ("**GTRC**") and **Clearside Biomedical, Inc.** ("**COMPANY**"), each hereinafter referred to as a Party and both hereinafter referred to as "Parties".

## Recitals

**Whereas**, the Parties previously entered into that certain License Agreement effective July 4, 2012 (the "**Agreement**");

**Whereas**, the Parties have made prior amendments to the Agreement on or around April 2, 2014 (the "**First Amendment**"); on or around December 12, 2016 (the "**Second Amendment**"); and on or around April 1, 2018 (the "**Third Amendment**"); and

**Whereas**, the Parties desire to enter into this Fourth Amendment, to clarify and amend certain financial terms in the Agreement and set forth their mutual understandings with respect thereto.

**Now, Therefore**, in consideration of the foregoing and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree that the Agreement shall be amended, effective as of the Effective Date, as set forth below.

**1.** **Amendment of Section 3.4**. The Parties agree that Section 3.4 of the Agreement is hereby amended to read in its entirety as follows:

> "3.4 Sublicensee Payments. Within thirty (30) days of receipt by COMPANY, or no later than March 31, 2025 with respect to amounts received by Company on or after July 1, 2023 but prior to January 1, 2025, COMPANY shall pay LICENSOR [***] percent ([***]%) of any fees or payments paid to COMPANY by a Sublicensee ("**Sublicensee Percentage**") as consideration for a sublicense grant under this Agreement. Such Sublicense Percentage shall be applied to any payments made to COMPANY by a Sublicensee on or after July 1, 2023 pursuant to an agreement between COMPANY and such Sublicensee that includes a sublicense grant of the Licensed Patents and/or Licensed Technology, such payments including but not limited to any initial licensing fees, milestone fees, maintenance fees and minimum royalty payments, but excluding (i) amounts paid to COMPANY by a Sublicensee on or after July 1, 2023 to reimburse COMPANY for actual costs (including overhead but excluding profit) incurred in connection with research and development of Licensed Products and the prosecution,

maintenance and enforcement of intellectual property rights covering Licensed Products (collectively, "Reimbursed Costs"), provided that such Reimbursed Costs are paid to COMPANY pursuant to a written agreement between COMPANY and such Sublicensee that expressly provides for reimbursement to COMPANY by such Sublicensee of such Reimbursed Costs, (ii) the value of any intellectual property rights transferred or granted to COMPANY if such rights are necessary or helpful to the development or commercialization of Licensed Products and (iii) amounts paid for shares of Company stock. If COMPANY in-licenses third party technology and/or intellectual property rights and incorporates it into Licensed Product, and receives sublicense revenue with respect to such Licensed Product, then the [***] percent ([***]%) sublicense revenue sharing provided for above shall apply to that portion of the value of the Licensed Product that is attributable to the intellectual property licensed from LICENSOR. For example, the sublicense revenue that is subject to sharing with LICENSOR shall be that fraction A/(A+B) of non-royalty revenue received where A is the amount attributable to the LICENSOR intellectual property, and B is the aggregate amount attributable to the remainder of the technology so licensed. If it is not feasible to accurately determine such amounts, then the allocation shall be commercially reasonable and determined by good faith negotiation between COMPANY and LICENSOR. COMPANY shall not structure any sublicense of the Licensed Patents and/or Licensed Technology, alone or in connection with other assets (e.g., technology, know-how, and/or intellectual property rights) owned or controlled by COMPANY, in a single transaction or series of related transactions, in order to minimize or avoid payments to LICENSOR under this Section 3.4."

**2.** **Amendment of Section 3.6**. The Parties agree that Section 3.6 of the Agreement is hereby amended to read in its entirety as follows:

"3.6 License Maintenance Fees.

(a) From and after the Effective Date through December 31, 2022, in the event no Milestone Payment bas been paid to LICENSOR prior to an anniversary of the Effective Date as set forth on **APPENDIX G,** COMPANY shall pay to LICENSOR the corresponding Maintenance Fee. No Maintenance Fee pursuant to this Section 3.6(a) shall be payable by COMPANY during any year in which (i) it has achieved at least one Milestone Event, (ii) it has spent at least $100,000 on research and development of the Licensed Products or (iii) it has sold a Licensed Product.

(b) From and after January 1, 2023, COMPANY shall pay to LICENSOR the Maintenance Fees set forth on APPENDIX G for the applicable calendar years no later than October 1st of the applicable calendar year (except with respect to the 2023 payment, which shall be made within five days subsequent to the Fourth Amendment Execution Date)."

**3.** **Amendment of Appendix G**. The Parties agree that Appendix G of the Agreement is hereby amended to read in its entirety as set forth on Appendix G attached hereto.

**4.** **Miscellaneous**.

(a) Defined Terms. Capitalized terms undefined herein shall have the meaning ascribed to them in the Agreement.

(b) No Other Amendment; Effectiveness. Except as expressly amended herein, the Agreement, as amended by the First Amendment, the Second Amendment and the Third Amendment, shall remain in full force and effect according to their original terms.

(c) Governing Law. This Fourth Amendment shall be construed under and governed by the laws of the State of Georgia and the United States of America.

(d) Severability. All rights and restrictions contained herein may be exercised and shall be applicable and binding only to the extent that they do not violate any applicable laws and are intended to be limited to the extent necessary so that they will not render this Agreement illegal, invalid or unenforceable. If any provision or portion of any provision of this Agreement, not essential to the commercial purpose of this Agreement, shall be held to be illegal, invalid or unenforceable by a court of competent jurisdiction, it is the intention of the parties that the remaining provisions or portions thereof shall constitute their agreement with respect to the subject matter hereof, and all such remaining provisions, or portions thereof, shall remain in full force and effect. To the extent legally permissible, any illegal, invalid or unenforceable provision of this Agreement shall be replaced by a valid provision which shall implement the commercial purpose of the illegal, invalid, or unenforceable provision.

(e) Counterparts. This Fourth Amendment may be executed electronically and in counterparts, each of which is deemed an original, but all of which together shall constitute one and the same instrument.

*[Signature Page Follows]*

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

**In Witness Whereof,** the Parties have caused this Fourth Amendment to be executed by their respective duly authorized representatives as of the Fourth Amendment Execution Date.

| **Emory University** | **Georgia Tech Research Corporation** |
|---|---|
| By: /s/Todd Sherer | By: /s/Raghupathy Sivakumar |
| Name: Todd Sherer | Name: Raghupathy Sivakumar |
| Title: Executive Director | Title: Assistant Secretary, GTRC |

**Clearside Biomedical, Inc.**

By: /s/ George Lasezkay

Name: George Lasezkay

Title: CEO

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

## APPENDIX G

## LICENSE MAINTENANCE FEES

| Effective Date Anniversary | License Maintenance Fee |
|---|---|
| First and Second Anniversary | None |
| Third and Each Subsequent Anniversary until 12/31/22 | $25,000 |
| Within five days subsequent to the Fourth Amendment Execution Date (2024): | $250,000 |
| October 1, 2024 | $250,000 |
| October 1, 2025 | $250,000 |
| October 1, 2026 | $350,000 |
| October 1, 2027 | $400,000 |
| October 1, 2028 | $500,000 |

No further payments after October 1, 2028

Exhibit 10.35

# FIRST AMENDMENT TO CONSULTING AGREEMENT

This First Amendment to Consulting Agreement (the "***Amendment***"), effective as of February 17, 2024 (the "***Amendment Effective Date***") by and among Dr. Thomas Ciulla ("***Consultant***"), and Clearside Biomedical, Inc ("***Client***"), amends the Consulting Agreement dated February 17, 2023 (the "***Agreement***"). Each of Consultant and Client shall be referred to herein individually as a "***Party***" and collectively as the "***Parties***."

**NOW, THEREFORE**, in consideration of the mutual promises set forth herein, the Parties hereby agree as follows:

## ARTICLE I. AGREEMENT AMENDMENT

**Section 1. Engagement of Services. Exhibit A** ("Services") shall be deleted and replaced in its entirety with **Exhibit A** attached hereto.

**Section 10.1**. **Term.** The Agreement is hereby renewed for a period of one (1) year beginning on the Amendment Effective Date ("Renewal Term").

## ARTICLE II. MISCELLANEOUS

Capitalized terms not defined herein shall have the same meanings as set forth in the Agreement.

Except as set forth herein, all other terms and conditions of the Agreement shall remain in full force and effect.

This Amendment may be signed in counterparts, each of which shall be an original, with the same effect as if the signatures were upon the same instrument. This Amendment shall become binding when each Party shall have received a counterpart of such agreement signed by the other Parties.

[*Signature Page Follows*]

**THIS FIRST AMENDMENT TO CONSULTING AGREEMENT IS EXECUTED** by the authorized representatives of the Parties as of the Amendment Effective Date.

**CLEARSIDE BIOMEDICAL, INC.**

Signature: /s/George Lasezkay
Title: President and CEO
Date: February 21, 2024

**CONSULTANT:**
**Dr. Thomas Ciulla**

Signature: /s/Thomas Ciulla
Title: Chief Medical Advisor
Date: February 21, 2024

**EXHIBIT A – First Amendment to Consulting Agreement**
**Dated: February 17, 2024**

**Services:**
Consultant will render the following services to Client:
• Consultant shall serve as Chairman of the Clearside Biomedical, Inc. Scientific Advisory Board.
• Consultant shall serve as Client's Chief Medical Advisor – Retina.
• Consultant shall assist as needed, if reasonably requested by Client, in the recruitment and evaluation of successor candidates for the following positions: Chief Medical/Development Officer
• Consultant shall organize, attend and participate in two Scientific Advisory Board meetings in each of the Initial Term and the first Renewal Term, as requested by and in cooperation with Client.
• Consultant shall perform such other advisory or consulting services as may reasonably requested by Client, including but not limited to cooperating with Client in presentation of Client's scientific and clinical information and participating in Client's due diligence activities.

**Schedule Of Services:**
During the Term of this Agreement, Consultant agrees to make himself available to perform the Services for up to ten (10) hours per month, and such additional hours as may be mutually agreed upon by Consultant and Client.

**Fees And Reimbursement:**
**Monthly Consulting Fee**. As consideration for the Services rendered pursuant to this Agreement and for the assignment of certain of Consultant's right, title and interest pursuant hereto during the Term of the Agreement, Consultant will be paid a monthly consulting fee of $8,000 for each calendar month during the Term of this Agreement beginning on March 1, 2023 (the "***Monthly Consulting Fee***"). Any undisputed Monthly Consulting Fee will be paid on a monthly basis within thirty (30) days following Client's receipt of Consultant's invoice (as described below). If the Agreement is terminated prior to the conclusion of any calendar month, the Monthly Consulting Fee shall be prorated based on the number of days this Agreement was in effect for such partial calendar month. For Services rendered in February 2023, Consultant will be paid a pro-rated portion of the Monthly Consulting Fee based on the number of days this Agreement was in effect for such month.

**Equity Vesting.** Consultant has been granted equity compensation in the form of stock options and Restricted Stock Unit awards, in connection with Consultant's prior employment relationship with the Client (the "***Equity Grants***"). Notwithstanding anything to the contrary in Consultant's Stock Option Grant Notices and Agreements and Consultant's Restricted Stock Unit Grant Notices and Agreements to the contrary, then effective as of the Effective Date of this Agreement, Consultant acknowledges and agrees that:

• All vesting with respect to any restricted stock units (each, an "***RSU***") held by Consultant as of the Termination Date ceased as of the Termination Date, with the remaining unvested RSUs being cancelled and of no further force or effect;

• Except as provided in the immediately following paragraphs, any options to purchase shares of the Client's Common Stock (each, an "***Option***") held by Consultant as of the Termination Date will continue to vest in accordance with their terms through August 31, 2023, provided that

Consultant remains in continuous service with the Client through such date, with any then-remaining unvested Option shares being cancelled and of no further force or effect;

• With respect to that certain Option granted to Consultant on January 4, 2023 (the "***January 2023 Option***"), the January 2023 Option will continue to vest in accordance with its terms through January 4, 2024, provided that Consultant remains in continuous service with the Client through January 4, 2024, at which time 25% of the January 2023 Option shares (46,875 shares) will immediately vest and become exercisable with any then remaining unvested January 2023 Option shares being cancelled and of no further force or effect;

• With respect to that certain Option granted to Consultant on January 18, 2024 (the "***January 2024 Option***"), the January 2024 Option will continue to vest in accordance with its terms in twelve equal monthly installments provided that Consultant remains in continuous service with the Client on each such vesting date;

Any then-outstanding and vested Options shall remain exercisable until the date that is three months following the termination date of this Agreement (subject in any event to earlier expiration in accordance with the agreements evidencing such Options and the terms of the plan pursuant to which such Option was granted); and

Any Options originally intended to qualify as incentive stock options under Section 422 of the U.S. Internal Revenue Code of 1986, as amended, shall no long so qualify if exercised more than 3 months after the Termination Date.

Consultant acknowledges and agrees that the extension of his exercise period, as described above, is a substantial benefit to him and constitutes additional consideration for the Services hereunder and for Consultant's entering into this Agreement.

Consultant will be reimbursed for third party expenses (at cost) if approved in writing in advance by Client.

Consultant will invoice Client monthly (on the first day of each month, beginning on April 1, 2023) for services rendered and expenses incurred during the previous month and will provide such reasonable receipts or other documentation of expenses as Client might request, including copies of time records. The parties have executed this Exhibit A as of the date first written above.

**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. 333-235880) of Clearside Biomedical, Inc.,

4. Registration Statement (Form S-3 No. 333-271902) of Clearside Biomedical, Inc.,

5. 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.,

6. Registration Statement (Form S-8 No. 333-231383) pertaining to the 2016 Equity Incentive Plan of Clearside Biomedical, Inc.,

7. Registration Statement (Form S-8 No. 333-238133) pertaining to the 2016 Equity Incentive Plan of Clearside Biomedical, Inc., and

8. Registration Statement (Form S-8 No. 333-256212) pertaining to the 2016 Equity Incentive Plan of Clearside Biomedical, Inc.

9. Registration Statement (Form S-8 No. 333-264885) pertaining to the 2016 Equity Incentive Plan of Clearside Biomedical, Inc.

10. Registration Statement (Form S-8 No. 333-271877) pertaining to the 2016 Equity Incentive Plan of Clearside Biomedical, Inc.

of our report dated March 12, 2024, with respect to the consolidated financial statements of Clearside Biomedical, Inc. included in this Annual Report (Form 10-K) of Clearside Biomedical, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Atlanta, Georgia

March 12, 2024

**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, 2023 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 12, 2024

/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 FINANCIAL 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, 2023 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 12, 2024

/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, 2023, 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 12th day of March, 2024.

/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.

**Exhibit 97**

**CLEARSIDE BIOMEDICAL, INC.**

**INCENTIVE COMPENSATION RECOUPMENT POLICY**

## 1. INTRODUCTION

The Board of Directors (the "***Board***") of Clearside Biomedical, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

## 2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

## 3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

**4. RECOUPMENT**

**(a) Applicability of Policy.** This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

**(b) Recoupment Generally.** Pursuant to the provisions of this Policy, if there is an

Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

**(c) Impracticability of Recovery.** Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

**(d) Sources of Recoupment.** To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

**(e) No Indemnification of Covered Officers.** Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

**(f) Indemnification of Administrator.** Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any

action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

**(g) No "Good Reason" for Covered Officers.** Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

## 5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

## 6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

## 7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("**SOX 304**") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

**8. Amendment; Termination**

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

**9. Successors**

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

**10. Required Filings**

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

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**Clearside Biomedical, Inc.**

**Incentive Compensation Recoupment Policy**

**Form of Executive Acknowledgment**

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Clearside Biomedical, Inc. Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Clearside Biomedical, Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

**Agreed and Acknowledged:**

____

Name: __

Title: ____

Date: ____