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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

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: 001-34703

Alimera Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-0028718**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
6310 Town Square, Suite 400 Alpharetta, GA	**30005**
(Address of principal executive offices)	**(Zip Code)**

(678) 990-5740

(Registrant's telephone number, including area code)

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, $0.01 par value per share	ALIM	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 Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

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 incen- tive-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 Act). Yes ☐ No ☒

As of June 30, 2022, the last business day of the registrant's last completed second quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $30,711,364 based on the closing price per share of the registrant's Common Stock, on June 30, 2022, as reported by the Nasdaq Global Market. For the purposes of this disclosure, shares of Common Stock held by each executive officer, director and affiliate based on public filings and other information known to the registrant have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 28, 2023, there were 7,227,094 shares of the registrant's Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement with respect to the registrant's 2023 Annual Meeting of Stockholders, which is to be filed pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Alimera Sciences, Inc.

Form 10-K

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND PROJECTIONS

Various statements in this report of Alimera Sciences, Inc. are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this report, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties (some of which are beyond our control) and are based on information currently available to our management. Words such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "contemplates," "predict," "project," "target," "likely," "potential," "continue," "ongoing," "will," "would," "should," "could," or the negative of these terms and similar expressions or words, identify forward-looking statements. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including risks and uncertainties that could delay, divert or change these expectations, and could cause actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under Part I, ITEM 1A: "Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements.

This report contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this report is generally reliable, such information is inherently imprecise and subject to change.

All written and oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely on the forward-looking statements we make or that are made on our behalf as predictions of future events. We undertake no obligation and specifically decline any obligation, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

We encourage you to read the management's discussion and analysis of our financial condition and results of operations and our consolidated financial statements contained in this Annual Report on Form 10-K. There can be no assurance that we will in fact achieve the actual results or developments we anticipate or, even if we do substantially realize them, that they will have the expected consequences to, or effects on, us. Therefore, we can give no assurances that we will achieve the outcomes stated in those forward-looking statements, projections and estimates.

PART I

ITEM 1. *BUSINESS*

Unless the context otherwise requires, throughout this Annual Report on Form 10-K, the words "Alimera" "Alimera Sciences" "we," "us," the "registrant" or the "Company" refer to Alimera Sciences, Inc. and its subsidiaries (as applicable).

The term "ILUVIEN" is our registered trademark. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

Overview

We are a commercial-stage global pharmaceutical company developing and commercializing ILUVIEN for the treatment of diabetic macular edema (DME), a leading cause of blindness, and outside the U.S. for non-infectious uveitis affecting the posterior segment of the eye (NIU-PS). ILUVIEN is a state-of-the-art, sustained release intravitreal implant that enables patients to maintain vision longer, and importantly, with fewer injections. We commercialize ILUVIEN in the U.S., Europe, China and Middle East. We are also studying ILUVIEN in a clinical trial, the NEW DAY Study, where it is being evaluated for efficacy as baseline therapy in patients with early DME by comparing ILUVIEN to the current standard of care, anti-vascular endothelial growth factor (VEGF) therapy. Alimera's mission is to be invaluable to patients, physicians and partners concerned with retinal health and maintaining better vision longer.

Business Strategy

We presently focus on diseases affecting the back of the eye, or retina, because we believe these diseases are not sufficiently treated with current competing therapies and treatment regimens and represent a significant market opportunity. Our strategy is to establish ILUVIEN as a leading therapy for DME and NIU-PS patients for which ILUVIEN is proven safe and effective because of its ability to help patients see better, longer with fewer injections for up to three years. We rely on our management's experience and the breadth of our commercial resources in both the U.S. and Europe to maintain focus on the retinal space to commercialize ILUVIEN. We intend to use those same strengths to acquire, obtain regulatory approval for and commercialize other potential eye care products. To implement our strategy, we intend to:

Maximize the commercial success of ILUVIEN for treatment of DME in the U.S., Europe, and the Middle East where we have obtained regulatory approval. We are seeking to increase our direct sales and sales to distributors in the U.S., Europe and the Middle East where we have obtained regulatory approval and are currently marketing ILUVIEN. We are also pursuing opportunities to sell ILUVIEN in the remaining countries where we have obtained regulatory approval but are not currently marketing ILUVIEN for this indication.

- *Complete our NEW DAY Study.* With the NEW DAY Study, we intend to demonstrate the efficacy of ILUVIEN as a baseline therapy in patients with early DME by comparing ILUVIEN to the current standard of care, anti-VEGF therapy. We believe that ILUVIEN continues to be underutilized in the treatment of DME and should be used much earlier in patients suffering from DME. Our prior clinical data sets demonstrate the ability of ILUVIEN to control the underlying disease process and reduce the recurrence of edema for up to three years, rather than treating recurrent chronic edema with short-term therapies.

Maximize the commercial success of ILUVIEN for the treatment of NIU-PS in Europe where we have obtained regulatory approval. We are seeking to increase our direct sales and sales to distributors in Europe and the Middle East where we have obtained regulatory approval and are currently marketing ILUVIEN. We are also pursuing opportunities to sell ILUVIEN in the remaining countries where we have obtained regulatory approval but are not currently marketing ILUVIEN for this indication.

Continue to pursue approval for ILUVIEN for DME and NIU-PS in additional countries. We will evaluate seeking regulatory approval for the treatment of DME in countries where we do not have approval and of NIU-PS in the remainder of Europe and in the Middle East and Africa where we own the rights to market ILUVIEN. In 2021, we entered into a license agreement with a distributor in China that plans to pursue regulatory approval and commercialization of ILUVIEN for DME in China and the Western Pacific.

Expand our ophthalmic product offerings. We believe there are further unmet medical needs in the treatment of retinal diseases. We intend to continue to evaluate in-licensing and acquisition opportunities for compounds and technologies with potential treatment applications for diseases affecting the eye.

ILUVIEN

Our only commercial product is ILUVIEN®, an intravitreal implant that treats patients by delivering a continuous microdose of the corticosteroid fluocinolone acetonide (FAc) in the eye, for up to 36 months. "Intravitreal" refers to the space inside the eye behind the lens that contains the jelly-like substance called vitreous. ILUVIEN was initially developed to treat DME, a disease of the retina that affects individuals with Type 1 or Type 2 diabetes and can lead to severe vision loss and blindness. ILUVIEN is also used in certain countries in the European Economic Area (EEA) to prevent relapse in recurrent NIU-PS. Uveitis is an inflammatory disease of the uveal tract, which is comprised of the iris, ciliary body and choroid, that can lead to severe vision loss and blindness.

ILUVIEN is inserted into the back of the patient's eye in a non-surgical procedure employing a device with a 25-gauge needle, which allows for a self-sealing wound. We believe that corticosteroids provide the best option in the treatment of DME and NIU-PS because they reduce the inflammatory aspects of the disease. Further, we believe that ILUVIEN's CONTINUOUS MICRODOSING™ delivery makes it the only approved drug therapy for DME that can deliver consistent daily therapeutic levels of corticosteroid and reduce the recurrence of DME and uveitis. The delivery mechanism of ILUVIEN provides lower daily and aggregate exposure to corticosteroids than any other intraocular dosage forms currently available, which we believe mitigates the typical risks associated with corticosteroid therapy. Further, the ILUVIEN implant, which is non-bioerodible, provides consistent delivery as a result of its constant surface area, permitting elution of FAc to the vitreous. This provides a sustained therapeutic effect on DME and NIU-PS. Other therapies that physicians currently use to treat DME, such as anti-VEGF treatments and other corticosteroids, are acute (short-acting) therapies that provide a higher initial daily dose but then rapidly decline, requiring frequent reinjection by the physician to maintain an effective dose or reestablish the therapeutic effect after the disease has recurred.

The active compound in ILUVIEN is FAc, a non-proprietary corticosteroid. ILUVIEN delivers continuous daily sub-microgram levels of FAc in both in vitro and in vivo release kinetic studies for up to 36 months, making it the only single injection therapy available to treat the retina consistently every day for up to three years, allowing patients to see better, longer with fewer injections.

Corticosteroids, including FAc, have demonstrated a range of pharmacological actions, including inhibition of inflammation, inhibition of leukostasis, up regulation of occludin, inhibition of the release of certain inflammatory cytokines and suppression of VEGF secretion. Leukostasis refers to the accumulation of white blood cells at a particular site, which leads to further tissue damage. Occludin is an important protein in maintaining and reinforcing the tight junctions between cells. These pharmacological actions have the potential to treat various ocular conditions, including DME, NIU-PS, Non-Proliferative Diabetic Retinopathy (NPDR), retinal vein occlusion (RVO), dry age-related macular degeneration (AMD) and wet AMD. However, FAc shares many of the same "class effect" side effects seen with other corticosteroids that are currently available for intraocular use. The two main side effects of using corticosteroids to treat ocular conditions are increased intraocular pressure, which may increase the risk of glaucoma, and the acceleration of cataract formation. FAc is uniquely lipophilic, making it very effective at penetrating retina tissue, and allowing it to achieve a therapeutic effect at a very low dose, typically lower than other corticosteroids. In order to mitigate these side effects, ILUVIEN is designed to deliver significantly lower daily exposure than any other available corticosteroid dosage form while maintaining a therapeutic effect. Additionally, as demonstrated with real-world evidence, the side effects of ILUVIEN are consistent with and predictable following the use of shorter duration or acute corticosteroid therapies, increasing the physician's ability to manage those side effects.

March 2023 Financing

In March 2023, we:

- Repurchased and retired all of our outstanding Series A Convertible Preferred Stock for approximately $938,000. The repurchase eliminated the associated $24.0 million liquidation preference. We also repurchased 200,919 shares of common stock held by the holders of Series A Convertible Preferred Stock for approximately $314,000.

- Completed a $12.0 million private placement of Series B Convertible Preferred Stock and warrants to purchase shares of our common stock pursuant to a securities purchase agreement. The securities purchase agreement also provides for the sale of an additional tranche of up to $15.0 million of Series B Convertible Preferred Stock for potential in-licenses or product acquisitions, upon mutual agreement between us and the purchasers.

- Amended our $45.0 million term loan agreement to extend the interest-only period for at least two years and extend the final maturity date to April 30, 2028. The interest-only period may be extended up to three years if certain financial targets are achieved. In connection with the amendment, we borrowed an additional $2.5 million under the loan agreement. The amended loan agreement also provides for an additional tranche of up to $15.0 million, at the discretion of the lenders.

Disease Overview and Market Opportunity

Diabetes and Diabetic Retinopathy

Diabetes mellitus, with its systemic and ophthalmic complications, represents a global public health threat. The International Diabetes Federation (IDF) estimated prevalence of diabetes worldwide in 2021 increased to 537 million people and is expected to increase to 783 million people by 2045.

The 2020 National Diabetes Statistics Reports published by the U.S. Centers for Disease Control and Prevention (CDC) reported that as of 2019, 37.3 million Americans, or 11.3% of the U.S. population, had diabetes and that there were 1.4 million new cases of diabetes diagnosed among people ages 18 and older. Approximately 1 in 4 U.S. adults living with diabetes, 8.5 million Americans, did not know they had the condition and are therefore not being monitored and treated to control their disease and prevent systemic and ophthalmic complications. The report also identified that around 96.0 million people have prediabetes, a condition that if not treated often leads to type 2 diabetes within five years. In this population, only 19.0% of adults know they had prediabetes. In the International Diabetes Federation 10th Edition IDF Diabetes Atlas, it is estimated that there are approximately 61.0 million people in Europe in 2021 with diabetes and that 22.0 million remain undiagnosed. In the Middle East, it is estimated there are approximately 22.4 million people with diabetes and 17.5 million remain undiagnosed.

All patients with diabetes are at risk of developing some form of diabetic retinopathy, an ophthalmic complication of diabetes with symptoms including the swelling and leakage of blood vessels within the retina or the abnormal growth of new blood vessels on the surface of the retina. According to the CDC Vision Health Initiative, diabetic retinopathy causes approximately 12,000 to 24,000 new cases of blindness in the U.S. each year; making diabetes the leading cause of new cases of blindness in adults aged 20 to 70. Diabetic retinopathy can be divided into either non-proliferative or proliferative retinopathy. Non-proliferative retinopathy develops first and causes increased capillary permeability, micro aneurysms, hemorrhages, exudates (when fluid leaks into spaces between vessels), macular ischemia (lack of oxygen) and macular edema (thickening of the retina caused by fluid leakage from capillaries). Proliferative retinopathy is an advanced stage of diabetic retinopathy that, in addition to characteristics of non-proliferative retinopathy, results in the growth of new blood vessels. These new blood vessels are abnormal and fragile, growing along the retina and along the surface of the clear vitreous gel that fills the inside of the eye. By themselves, these blood vessels do not cause symptoms or vision loss. However, these blood vessels have thin, fragile walls that are prone to leakage and hemorrhage.

Diabetic Macular Edema (DME)

When the blood vessel leakage of diabetic retinopathy leads to the build-up of fluid, or edema, in a region of the retina called the macula, the condition is called diabetic macular edema. This area of the eye is important for the sharp, straight-ahead vision that is used for reading, recognizing faces, and driving. There are an estimated 750,000 people with DME in the U.S., according to the National Eye Institute's 2019 update. DME is the most common cause of vision loss among people with diabetic retinopathy and about 30% of people with diabetic retinopathy will develop DME. It is more likely to occur as diabetic retinopathy worsens, although it may occur at any stage of the disease. The onset of DME is painless and may go undetected by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision.

Studies have shown that DME is a multifactorial disease underpinned by inflammatory cytokine activity in the eye. Of the currently approved pharmacotherapies used to treat DME, only corticosteroids, including FAc found in the ILUVIEN implant, affect multiple cytokines.

As the incidence of diabetes continues to increase worldwide, the incidence of DME and other complications is predicted to rise as well. Most patients who suffer from diabetes do not meet glycemic (glucose or blood sugar) targets, resulting in hyperglycemia (elevated levels of glucose in the blood). This, in turn, leads to the development of micro-vascular complications, which manifest in the eye as diabetic retinopathy, as well as elevated cytokines that break down the blood-retina barrier, leading to macular edema in many diabetic retinopathy patients.

Uveitis

Uveitis means inflammation of the uveal tract, which is a layer of tissue located between the outer layer (cornea and sclera) and the inner layer (retina) of the eye. The front portion (anterior) of the uveal tract contains the iris, and the back portion (posterior) of the uveal tract contains the choroid and the stroma of the ciliary body. Inflammation of the uvea encompasses approximately 30 inflammatory disorders characterized by intraocular inflammation, a major cause of visual loss in people of working age in both developed and developing countries. It can affect people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. According to the classification scheme recommended by the International Uveitis Study Group, the disease can be classified on the basis of anatomic locations: anterior, intermediate, posterior or pan uveitis. Uveitis can be caused by a number of factors such as infection (infectious uveitis) or other autoimmune diseases or conditions. Non-infectious uveitis (NIU) is a persistent and recurrent disease that can adversely affect the retina. Additionally, it commonly affects vision, more so than anterior uveitis, and macular edema is the most common mechanism of visual loss, affecting 44% patients with posterior uveitis.

There are two forms of uveitis:

infectious uveitis (bacterial, viral, fungal, or parasitic), which is treated with an appropriate antimicrobial drug as well as corticosteroids and cycloplegics; and

NIU, where corticosteroids are used to reduce inflammation and prevent adhesions in the eye.

Current Treatments for DME

Anti-VEGF therapies are the current standard of care for the treatment of DME. Lucentis® (ranibizumab), Eylea® (aflibercept), Beovu® (brolucizumab-dbll), and Vabysmo® (faricimab) are approved in the U.S. Cimerli is a ranibizumab biosimilar that is approved in the U.S as well. Off-label injections of the anti-VEGF therapy Avastin (bevacizumab) are also used to treat DME. However, anti-VEGF therapies are acute therapies and require multiple and frequent injections to achieve the same therapeutic effect reported in randomized controlled trials. Further, DME is a multi-factorial disease, and anti-VEGF therapy does not address all of these factors. As a result, many patients do not achieve a sufficient response, either because of the limited therapeutic effect or the inability or unwillingness of patients to routinely attend clinic appointments, meaning that anti-VEGF therapy is not optimally administered. When not optimally administered, these acute therapies allow for a recurrence of the edema. In addition, these therapies have safety profiles that include an increased risk of endophthalmitis, a serious eye infection that must be treated with high doses of antibiotics and is associated with any intravitreal injection. There is also evidence that intravitreal anti-VEGF therapy affects systemic VEGF levels, which may have cardiovascular complications and have shown both acute and chronic increases in intraocular pressure (IOP) following injection.

Intravitreal corticosteroid therapies are also used to treat DME. Acute corticosteroids typically have peak effects within two to three months, and there is a need for repeated injections. Similarly, without optimized treatment frequency, macular edema is allowed to recur when the effect of acute corticosteroids dissipates. Ozurdex (dexamethasone), a short-acting corticosteroid, is marketed for the treatment of vision loss associated with DME in Europe and for the treatment of DME in the U.S. Triamcinolone acetonide, another short-acting steroid, is commonly used off-label to treat DME. In contrast to the dexamethasone implant and triamcinolone acetonide, which are both acute therapies, ILUVIEN is a long-term persistent and continuous steroid delivery therapy. The steroid in the ILUVIEN implant, FAc, is a key lipophilic component that allows a single implant to deliver a sustained daily dose for up to 36 months. Corticosteroids have historically been associated with significant increases in intraocular pressure, which may increase the risk of glaucoma. Additionally, corticosteroids are associated with the acceleration of cataract formation. We believe the low dose of ILUVIEN mitigates these side effects and makes them more manageable. Additionally, the side effects of ILUVIEN are consistent with and predictable following the use of shorter duration or acute corticosteroid therapies, increasing the physician's ability to manage those side effects.

DME is also currently treated by Laser photocoagulation, a retinal procedure in which a laser is used to apply a burn, or a pattern of burns, to cauterize leaky blood vessels to reduce edema. Laser photocoagulation may be used in conjunction with drug therapies as well. Visual acuity gains are less frequently realized with this therapy, as it is used to prevent or slow the loss of vision. Further, this destructive procedure has undesirable side effects including partial loss of peripheral and night vision.

Our NEW DAY Study

We believe that ILUVIEN continues to be underutilized in the treatment of DME and should be used much earlier in patients suffering from DME. Our prior clinical data sets demonstrate the ability of ILUVIEN to control the underlying disease process and reduce the recurrence of edema for up to three years, rather than treating recurrent chronic edema with short-term therapies. With the NEW DAY Study, we intend to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early DME by comparing ILUVIEN to the current standard of care, anti-VEGF therapy.

In July 2020, we announced the initiation of our NEW DAY clinical trial, a multicenter, single masked, randomized and controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its advantages over using the current standard of care of repeat anti-VEGF injections. The NEW DAY Study is planned to enroll approximately 300 treatment-naïve, or almost naïve, DME patients in approximately 40 sites around the U.S. As of February 28, 2023, we have enrolled 261 DME patients. We expect to complete enrollment in the NEW DAY Study in the first half of 2023.

Patients who meet the entry criteria will be randomized to receive either an ILUVIEN intravitreal implant or five injections of intravitreal aflibercept 2 mg at four-week intervals for the first 16 weeks as a loading dose. After the initial 16-week period, both treatment arms will be evaluated every four weeks and receive supplemental intravitreal injections of aflibercept 2 mg only as needed. Criteria for supplemental treatment is set by protocol and will be identical in both treatment arms. The planned treatment period in the study is 18 months. Once the treatment period is concluded, patients will be given the option to participate in an open label extension study for up to 42 months.

The primary outcome measure for the NEW DAY Study is the mean number of supplemental aflibercept injections needed during the trial between treatment groups. Key secondary endpoints include mean best corrected visual acuity (BCVA) score over time up to 18 months, time to first supplemental treatment, retinal thickness amplitude on optical coherence tomography (OCT), and diabetic retinopathy scores. In addition, the trial will collect patient-reported outcome measures to

evaluate the effect on patients' quality of life and level of functioning. Exploratory endpoints will include neuronal functional measures and OCT imaging measures of retinal nerve layer thickness.

Current Treatments for NIU-PS

Historically, the treatment of uveitis varies according to the type and location of uveitis. The inflammation in NIU can be anterior (at the front of the eye) or posterior (at the back of the eye) or in both locations. Importantly though, all forms of NIU can affect the posterior segment of the eye. In anterior forms of NIU, drops are used to address inflammation; however, in patients where the posterior segment is affected, these drops do not penetrate the eye to address the posterior segment. Other agents, both intravitreal and systemic, are specifically licensed for the treatment of active non-infectious posterior uveitis. This means that treatment of NIU-PS focuses on (a) systemic therapy, administered in a tablet form or via injection, which very often leads to side effects that adversely affect the whole body, or (b) the localized delivery of therapies, usually a steroid.

Patients with NIU-PS are initially treated with systemic steroids, which are very effective, but when used at high doses for extended periods can lead to serious side effects. These side effects include acne, weight gain, sleep and mood disorders, hypertension and osteoporosis, which can limit the sustained use of systemic steroids. Patients then often progress to steroid-sparing therapies with systemic immune suppressants or biologics, which themselves can have severe side effects, including an increased risk of cancer and infections. In addition, periocular or intraocular steroids may be used to try to locally control inflammation in NIU-PS. Other therapies that may be used to treat NIU-PS include immunosuppressive drugs and tumor necrosis factor (TNF) antagonists.

A significant problem for patients and clinicians is that recurrence of NIU-PS is very common. In chronic NIU-PS, recurrence often occurs within six months of withholding treatment, and patients and clinicians are forced to go through cycles of treatment initiation and cessation with the accompanying complexity of managing several drug classes, and their side effects, at once. For the patient, this approach to treatment provides temporary relief, but with uncertainty of when the next relapse of their disease will occur. Recurrence is known to put the patient's vision at risk, so there is a need for treatments that can provide longer term control of inflammation in this setting.

For patients with recurrent NIU-PS, locally delivered (intravitreal) steroids present an attractive treatment strategy allowing for effective delivery of steroid therapy at the point of need, while minimizing the risk of systemic side effects. For intravitreal treatment, the short-acting Ozurdex implant is marketed in Europe for the treatment of adult patients with active inflammation of the posterior segment of the eye presenting as NIU and for the treatment of NIU.

In contrast clinical trials have demonstrated that ILUVIEN significantly extends the time to relapse in patients with recurrent NIU-PS, while at the same time reducing the need for adjunctive treatments, including systemic drug treatment.

Where We Market ILUVIEN to Treat Diabetic Macular Edema (DME)

ILUVIEN has received marketing authorization for the use of ILUVIEN to treat DME for the indications and is reimbursed and marketed as shown in the following table:

Indication for the Treatment of DME	Countries Where ILUVIEN Has Received Marketing Authorization to Treat DME	Countries Where ILUVIEN Is Reimbursed to Treat DME	Countries Where ILUVIEN is Currently Marketed to Treat DME
Treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure	U.S., Australia, Canada, Kuwait, Lebanon and the United Arab Emirates	U.S., Kuwait, Lebanon and the United Arab Emirates	U.S., Kuwait, Lebanon and the United Arab Emirates
Treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies	The United Kingdom (U.K.), Germany, France, Italy, Spain, Portugal, Ireland, Austria, Belgium, Denmark, Norway, Finland, Sweden, Poland, the Czech Republic, the Netherlands and Luxembourg	The U.K., Belgium, Germany, France, Italy, Spain, Portugal, Ireland, Luxembourg and the Netherlands	The U.K., Belgium, the Czech Republic, Germany, France, Italy, Spain, Portugal, Ireland, Austria, Luxembourg, Denmark, Norway, Finland, Sweden and the Netherlands

Where We Market ILUVIEN to Treat Recurrent Non-Infectious Uveitis Affecting the Posterior Segment of the Eye (NIU-PS)

ILUVIEN has received marketing authorization for the use of ILUVIEN to treat NIU-PS for the indication and is reimbursed and marketed as shown in the following table:

Indication for the Treatment of NIU-PS	Countries Where ILUVIEN Has Received Marketing Authorization to Treat NIU-PS	Countries Where ILUVIEN Is Reimbursed to Treat NIU-PS	Countries Where ILUVIEN is Currently Marketed to Treat NIU-PS
The prevention of relapse in recurrent NIU-PS	The U.K., Germany, France, Spain, Portugal, Ireland, Austria, Belgium, Denmark, Norway, Finland, Sweden, Poland, the Czech Republic, the Netherlands and Luxembourg	The U.K., Germany, Ireland (private sector), Italy, France, Portugal, Spain, the Czech Republic, Luxembourg and the Netherlands	The U.K. Germany, Ireland, Italy, France, Spain, the Czech Republic, Luxembourg, the Netherlands, Denmark, Norway, Portugal, Sweden, Finland Austria and Belgium

Where We Sell Direct

We commercially market ILUVIEN directly in the U.S., Germany, the U.K., Portugal and Ireland.

Where We Sell Through Distributors

We have entered into various agreements under which distributors are providing or will provide regulatory, reimbursement or sales and marketing support for ILUVIEN in Austria, Belgium, the Czech Republic, Denmark, Finland, France, Italy, Luxembourg, the Netherlands, Norway, Spain, Sweden, Switzerland, Australia, New Zealand, China and several countries in the Western Pacific and several countries in the Middle East. As of December 31, 2022, we have recognized net product revenue from our international distributors in the Middle East, China, Austria, Belgium, the Czech Republic, France, Italy, Luxembourg, Spain and the Netherlands.

ILUVIEN for Other Diseases of the Eye

Although we are not actively conducting clinical trials for a new indication, we believe that ILUVIEN has the potential to address other ophthalmic diseases such as RVO, NPDR, dry AMD and wet AMD.

Sales and Marketing

Our sales personnel focus on physician offices, clinics, pharmacies and hospitals in the U.S. and in European countries where we seek to persuade end users to purchase ILUVIEN. In our promotional efforts, we focus on three main areas to generate demand for ILUVIEN. The first is to gain access for ILUVIEN on formularies, contracts and through national and local health care authorities to achieve a reasonable price in the countries in which we intend to commercialize. Second is to educate physicians on the efficacy and safety of ILUVIEN through direct promotion, advocacy building and indirect marketing activities. Third is to enable patients and caregivers in markets where it is permitted to become more educated on their disease and the possible treatments.

The COVID-19 pandemic negatively affected our sales and marketing efforts in a number of ways, which in turn had an adverse impact on our revenues that has continued to a lesser degree through the date of this report. For example, governments and private parties imposed limitations on in-person access to physicians during certain periods of the pandemic. During the periods in which those limitations were in effect, they made it difficult or impossible for our sales representatives (including those employed by our distributors) to meet with retina specialists and their staff to educate them about the benefits of ILUVIEN and to provide support for insurance pre-certifications. We are continuing to monitor the effects of the pandemic and have increased our engagement with customers to mitigate any loss of revenue in affected markets.

Distributor Agreements

We have various agreements under which distributors are providing or will provide regulatory, reimbursement or sales and marketing support for commercialization of ILUVIEN in Austria, Belgium, Czech Republic, Denmark, Finland, France, Italy, Luxembourg, the Netherlands, Norway, Spain, Sweden, Switzerland, Australia and New Zealand, China and other countries of the Western Pacific and in the Middle East. Pursuant to these agreements, our distributors assisted or will assist us in obtaining and maintaining approval and reimbursement approval, or they will seek approval or reimbursement approval with our oversight in those countries, if such approval or reimbursement approval has not already been obtained. For more information about our April 2021 license agreement with Ocumension Therapeutics (Ocumension) for China and the Western Pacific, see “Licenses and Agreements” below.

Manufacturing

We do not have an in-house manufacturing capability for our products and depend and expect to continue to depend exclusively on third-party contract manufacturers to produce and package ILUVIEN. We manage the quality of our product produced by these manufacturers through quality agreements and our quality system to ensure that they produce active pharmaceutical ingredients (APIs) and finished drug products in accordance with the FDA's current Good Manufacturing Practices (cGMP) and all other applicable laws and regulations. We maintain agreements with potential and existing manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to ILUVIEN.

The manufacturing process for ILUVIEN consists of filling a polyimide tube with a paste consisting of 190 micrograms of FAc in an aqueous slurry of polyvinyl alcohol, cutting the tube into smaller sections in the proper lengths for the ILUVIEN implant, capping each small section with a permeable membrane cap on one end and an impermeable silicone cap on the other end to create the ILUVIEN implant, curing the implant at high temperature, loading the implant inside the ILUVIEN applicator, and packaging and sterilizing the product. This process has been validated at Alliance Medical Products Inc., a Siegfried Company (Alliance).

We have agreements with a single third-party manufacturer for each of the following:

the manufacture of FAc, ILUVIEN's active pharmaceutical ingredient (FARMABIOS SpA/Byron Chemical Company Inc.);
the manufacture of the components of the ILUVIEN applicator (Cadence, Inc. (Cadence));
the manufacture of the ILUVIEN implant, final assembly of the injector with the implant and release testing in the U.S. (Alliance);
the quality release testing of ILUVIEN (Alliance);
final product release to market in the EEA (carried out in Ireland by Packaging Coordinators, Inc.); and
final product release to market in the U.K. (carried out in Ireland by Packaging Coordinators, Inc.).

Although we may seek alternative providers in the future, we do not currently have alternate providers for any of these tasks.

Under our agreement with Alliance, we are responsible for supplying Alliance with the ILUVIEN applicator and the API. We purchased certain equipment at Alliance's facility that Alliance uses solely to manufacture and package ILUVIEN for us. We have agreed to order from Alliance at least 80% of our total requirements for new units of ILUVIEN in the covered territories in a calendar year, provided that Alliance is able to fulfill our supply requirements and is not in breach of its agreements or obligations to us. Although we have approval to sell ILUVIEN in Canada, we do not currently have plans to pursue commercialization there. As of the date of this report, we order 100% of our global requirements for ILUVIEN units from Alliance because we do not have an alternate supplier. The amended and restated agreement had an original term through February 2023 and automatically renews for successive terms of one year unless either party delivers written notice of non-renewal to the other at least 12 months before the end of the then current term. As of the date of this report, we have not received or delivered a notice of non-renewal.

On October 30, 2020, we entered into a Manufacturing Services Agreement with Cadence, to manufacture the components used in the ILUVIEN applicator. Cadence has been manufacturing production components since the second quarter of 2021 following receipt of European and FDA approval of the change.

Business Segments

During the first quarter of 2021, our Chief Executive Officer (CEO), who is the chief operating decision maker (CODM), changed the manner in which the CODM monitors performance, aligns strategies and allocates resources, which resulted in a change in the operating segments. Our operations are now managed as three operating segments: U.S., International and Operating Cost. We determined that each of these operating segments represented a reportable segment. Previously, we were managed as two operating segments: U.S. and International. Financial information about our business segments is included below in Part II, ITEM 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Segment Review" and Note 19 of the accompanying consolidated financial statements.

Customers

Our revenues for the fiscal years ended December 31, 2022 and 2021 were generated from product sales primarily in the U.S., Germany, France and the U.K. and for 2021, the upfront license payment under the Ocumension License Agreement, which resulted in license revenue of approximately $11.0 million. In the U.S., two large pharmaceutical distributors accounted for 63% and 55% of our consolidated product revenues for the years ended December 31, 2022 and 2021, respectively. These distributors maintain inventories of ILUVIEN and sell to physician offices, pharmacies and hospitals. Internationally, in countries where we sell direct, our customers are hospitals, clinics and pharmacies. We sometimes refer to physician offices, pharmacies, hospitals and clinics as end users. In international countries where we sell to distributors, these distributors maintain inventory levels of ILUVIEN and sell to their customers.

Competition

The development and commercialization of new drugs and drug delivery technologies is highly competitive. We face competition with respect to ILUVIEN and any products or product candidates we may develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide, many of whom have substantially greater financial and other resources than we do.

In the countries in which ILUVIEN has received or been recommended for marketing authorization or becomes approved for use in the treatment of DME, it competes or will compete against the use of anti-VEGF therapies, short duration corticosteroids and laser photocoagulation or other therapies that may be approved in the future. Other companies are working to develop other drug therapies and sustained delivery platforms for DME and other indications. These competitive therapies may result in pricing pressure even if ILUVIEN is otherwise viewed as a preferable therapy. We believe that the following drugs and treatments compete with ILUVIEN:

Lucentis© (ranibizumab injection), marketed by Genentech (Roche) in the U.S. and Novartis in the rest of the world, and Avastin (bevacizumab), an oncology product marketed by the Roche group, are both antibodies that inhibit VEGF signaling pathways. Lucentis is currently approved for the treatment of DME, the treatment of diabetic retinopathy in patients with DME, the treatment of neovascular wet AMD and the treatment of macular edema following RVO in the U.S. In the EEA, the indications are similar except for diabetic retinopathy where the indication is for the treatment of proliferative diabetic retinopathy.

Avastin© (bevacizumab), is used by retinal specialists in both the U.S. and in certain countries of the EEA in the treatment of numerous retinal diseases off label but is not formulated or approved for any ophthalmic use.

Eylea© (aflibercept), marketed by Regeneron in the U.S. and by Bayer in the EEA, is a VEGF antagonist that is approved for the treatment of DME, diabetic retinopathy in patients with DME, neovascular wet AMD and RVO in the U.S. In the EEA, the indication does not include diabetic retinopathy.

Beovu® (brolucizumab-dbll), marketed by Novartis, is a VEGF inhibitor indicated for the treatment of neovascular wet AMD. Beovu has been approved for the treatment of wet AMD in the U.S. and in all 27 European Union member states as well as the U.K., Iceland, Norway and Liechtenstein. Novartis has completed trials for the treatment of DME and indicated publicly that they are seeking FDA approval for that indication.

Vabysmo® (faricimab), marketed by Genentech, is a VEGF inhibitor and Ang-2 inhibitor indicated for the treatment of patients with neovascular wet AMD and DME. Vabysmo was approved in January 2022 for the treatment of DME in the U.S. The European Medicines Agency has also validated the faricimab Marketing Authorization Application submission in wet AMD and DME.

Ozurdex© (dexamethasone intravitreal implant), marketed by Allergan (now owned by AbbVie), is a short duration biodegradable implant that delivers the corticosteroid dexamethasone. Ozurdex is approved for the treatment of DME, macular edema following branch or central RVO and NIU in the U.S. In the EEA, the indication for DME is for visual impairment due to DME in persons who are pseudophakic (persons who have had an artificial lens implanted after the natural eye lens has been removed) or who are considered insufficiently responsive to, or unsuitable for, non-corticosteroid therapy. It is also indicated for macular edema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO) and inflammation of the posterior segment of the eye presenting as non-infectious uveitis.

Humira© (adalimumab), marketed by Abbvie, is a TNF-blocker that has an ophthalmic indication. It works by targeting and blocking a specific source of inflammation that plays a role in NIU. In the U.S., Humira is indicated for the treatment of non-infectious intermediate, posterior and pan uveitis. In the EEA, Humira is indicated for the treatment of chronic non-infectious anterior uveitis in children aged two years or older who have had an inadequate response to or are intolerant to conventional therapy.

Intravitreal triamcinolone is used by some physicians for the treatment of DME although it is not approved for DME.

Laser photocoagulation is currently used to treat DME and may be used in conjunction with drug therapies as well. Other laser or surgical treatments for DME may also compete against ILUVIEN.

In addition, a number of other companies are developing drug therapies or delivery platforms for the treatment of retinal diseases.

We believe we will be less likely to face a generic competitor for ILUVIEN for the treatment of DME because of the bioequivalency requirements of a generic form of ILUVIEN. A generic pharmaceutical competitor to ILUVIEN would need to establish bioequivalency through the demonstration of an equivalent pharmacodynamic endpoint in a clinical trial. We believe

conducting such a clinical trial would be cost-prohibitive and time-consuming, although we cannot provide any assurances in that regard.

The licensing and acquisition of pharmaceutical products, which is part of our strategy, is a highly competitive area. A number of more established companies are also pursuing strategies to license or acquire products. These established companies may have a competitive advantage over us due to, among other factors, their size, cash flow and institutional experience.

The active pharmaceutical ingredient in ILUVIEN is FAc, which is not patent protected. As a result, our competitors could develop an alternative formulation or delivery mechanisms to treat diseases of the eye with FAc. For a description of our license of proprietary insert technology for ILUVIEN, see the section immediately below.

The COVID-19 Pandemic and Our Steps to Address its Effects on Our Business

The unprecedented events of the COVID-19 pandemic, and its unpredictable duration, in the regions where we have customers, employees and distributors had an adverse impact on our revenues beginning late in the first quarter of 2020. These adverse effects have continued to the date of this report to a lesser degree in certain of our key markets in Europe that have now begun to recover. These factors may continue to adversely impact our revenue and capital resources, although the extent and duration of that impact is currently uncertain.

In response to these developments, we implemented certain measures to mitigate the impact of the pandemic on our financial position and operations. We are continuing to monitor the effects of the SARS-CoV-2 variants and to increase our engagement with our customers to mitigate any anticipated loss of revenue in those markets that may be affected.

Licenses and Agreements

EyePoint Pharmaceuticals US, Inc.

In 2005, we entered into an agreement with EyePoint Pharmaceuticals US, Inc. (EyePoint), for the use of FAc in EyePoint's proprietary insert technology which was amended and restated in July 2017 (the New Collaboration Agreement). The New Collaboration Agreement provides us with a license to utilize certain underlying technology used in the development and commercialization of ILUVIEN. Pursuant to the New Collaboration Agreement, we hold a worldwide license from EyePoint for the use of steroids, including FAc, in EyePoint's proprietary insert technology for the treatment of all ocular diseases, other than uveitis outside of Europe, the Middle East and Africa.

The New Collaboration Agreement provides us with a license to develop and sell EyePoint's proprietary insert technology to deliver other corticosteroids to the back of the eye for the treatment and prevention of eye diseases in humans or to treat DME by delivering a compound to the back of the eye through a direct delivery method through an incision required for a 25-gauge or larger needle. We do not have the right to develop and sell EyePoint's proprietary insert technology for indications for diseases outside of the eye anywhere in the world, or for the treatment of uveitis outside of Europe, the Middle East and Africa. Further, the New Collaboration Agreement permits EyePoint to grant to any other party the right to use its intellectual property (a) to treat DME through an incision smaller than that required for a 25-gauge needle, unless using a corticosteroid delivered to the back of the eye, (b) to deliver any compound outside the back of the eye unless it is to treat DME through an incision required for a 25-gauge or larger needle, or (c) to deliver non-corticosteroids to the back of the eye, unless it is to treat DME through an incision required for a 25-gauge or larger needle.

In accordance with the New Collaboration Agreement we pay a 6% royalty on net revenues and other related consideration to EyePoint and we will pay an additional 2% royalty on global net revenues and other related consideration in excess of $75.0 million in any year. Following the signing of the New Collaboration Agreement, we retained a right to offset $15.0 million of future royalty payments (the Future Offset). As of December 31, 2022, the balance of the Future Offset was approximately $7.0 million, which is fully reserved on our balance sheet. We will be able to recover the balance of the Future Offset as a reduction of future royalties that would otherwise be owed to EyePoint by reducing the royalty from 6% to 5.2% for net revenues and other related consideration up to $75.0 million annually and from 8% to 6.8% for net revenues and other related consideration in excess of $75.0 million annually. During 2022 and 2021, we recognized approximately $2.8 million and $2.9 million of royalty expense, respectively.

On December 17, 2020, EyePoint entered into a royalty purchase agreement (the SWK Agreement) with SWK Funding, LLC (SWK) pursuant to which EyePoint sold its interest in royalties that we are obligated to pay EyePoint under the New Collaboration Agreement to SWK. We are not a party to the SWK Agreement.

Our license rights to EyePoint's proprietary insert technology could revert to EyePoint in certain instances, including failure to cure contractual breaches and filing for bankruptcy protection. We are not in breach of the New Collaboration Agreement as of the date of this report.

Ocumension License Agreement

On April 14, 2021, we entered into an exclusive license agreement (the License Agreement) with Ocumension (Hong Kong) Limited, a wholly owned subsidiary of Ocumension Therapeutics (Ocumension), for the development and commercialization under Ocumension's own distinct trademark, of our 190 microgram FAc intravitreal implant (the Product, which is currently marketed elsewhere as ILUVIEN®) for the treatment and prevention of eye diseases in humans, other than uveitis, in China and other Western Pacific countries.

We received a nonrefundable upfront payment of $10.0 million from Ocumension and may in the future receive additional sales-based milestone payments totaling up to $89.0 million upon the achievement by Ocumension of certain specified sales milestones during the term of the License Agreement. Our receipt of future milestone payments depends upon whether Ocumension is able to successfully complete product development and commercialization in the covered territory, which requires, among other things, obtaining necessary regulatory approvals and appropriate reimbursement pricing, which may take several years.

The term of the license will continue until the later of (a) the 10th anniversary of the first commercial sale of the Product in Ocumension's licensed territory or (b) as long as Ocumension is commercializing the Product in its licensed territory. The term is subject to our right to partially terminate the License Agreement beginning on the 10th anniversary of the License Agreement with respect to any country or jurisdiction in which Ocumension has not achieved a commercial sale at such time and is not continuing to commercialize the Product. Ocumension will purchase Product from us at a fixed transfer price without royalty obligations on future sale (other than milestone payments as described above). Ocumension is responsible for all costs of development and commercialization in the licensed territory.

When we entered into the License Agreement, we also entered into a share purchase agreement, a voting and investor rights agreement (voting agreement) and a warrant subscription agreement. Under the terms of the voting agreement, Ocumension is required to vote its shares of common stock in favor of any proposals recommended by our Board of Directors at any meeting of the Company's stockholders, subject to certain exceptions. The share purchase agreement and warrant subscription agreement are discussed in Note 11 of the accompanying consolidated financial statements.

Government Regulation

General Overview

Government authorities in the U.S. and other countries extensively regulate, among other things the research, development, testing, quality, efficacy, safety (pre- and post-marketing), manufacturing, labeling, storage, record-keeping, advertising, promotion, export, import, marketing and distribution of pharmaceutical products. In addition, although third parties manufacture ILUVIEN for us, these manufacturing operations and our research and development activities must follow applicable environmental laws and regulations. The cost to comply with these environmental laws and regulations is not currently significant, but in the future complying with these environmental laws and regulations could increase our costs for manufacturing, research and development.

U.S. FDA Approval

In the U.S., the FDA, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other federal and local statutes and regulations, subjects pharmaceutical products to review. If we do not comply with applicable regulations, the government may refuse to approve or place our clinical studies on clinical hold, refuse to approve our marketing applications, refuse to allow us to manufacture or market our products, seize our products, impose injunctions and monetary fines on us, and prosecute us for criminal offenses.

To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting the safety and efficacy as well as detailed information on the manufacture and composition of the product and proposed labeling.

The testing and collection of data and the preparation of the necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approval that could delay or preclude us from marketing additional products. Once approved by the FDA, a drug requires an annual product and establishment fee, which was approximately $394,000 as of our last renewal in October 2022.

Post-Marketing Requirements

We are required to meet post-marketing safety surveillance requirements to continue marketing an approved product. We must report any adverse events with the product to the FDA, and the FDA could impose market restrictions through labeling changes or in product removal. The FDA may withdraw product approvals if we fail to maintain compliance with regulatory requirements or if problems concerning safety and/or efficacy of the product occur following approval. The FDA may, at its discretion, also require post-marketing testing and surveillance to monitor the effects of approved products or place conditions

on any approvals that could restrict the commercial applications of these products. The FDA did not require any post-marketing testing as part of its approval of ILUVIEN.

As part of the approval process in Europe, we completed a five-year, post-authorization, open label registry study in 562 patients treated with ILUVIEN. The results of the study confirmed existing safety information on ILUVIEN, and no new risks were identified.

Also, as part of the approval process in Europe, we are committed to conduct an open label trial in the pediatric population with NIU-PS. We have initiated this trial, and enrollment is expected to start in 2023.

U.S. FDA Regulations

With respect to product advertising and promotion of marketed products, the FDA imposes a number of complex regulations that include standards for direct-to-consumer advertising, off-label promotions, industry-sponsored scientific and educational activities and Internet promotional activities. The FDA has very broad enforcement authority under the FD&C Act, and failure to abide by these regulations can result in (a) penalties, (b) the issuance of warning letters directing the sponsor to correct deviations from FDA standards, (c) a requirement that future advertising and promotional materials must be pre-cleared by the FDA, and (d) federal civil and criminal investigations and prosecutions (as well as state prosecutions).

The manufacturing facility that produces our product, as well as our corporate headquarters facility, must maintain compliance with the FDA's current Good Manufacturing Practices (cGMP) and are subject to periodic inspections by the FDA. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal and regulatory action, including Warning Letters, seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties.

Foreign Regulations

Foreign regulatory systems, although varying from country to country, include risks similar to those associated with FDA regulations in the U.S.

Under the EU regulatory system, applications for drug approval may be submitted either in a centralized or decentralized procedure. Under the centralized procedure, a single application to the European Medicines Evaluation Agency, if approved, would permit marketing of the product throughout the EU (currently 27 member states) and to non-EU countries that are within the EEA. The decentralized procedure provides for applications to be submitted for marketing authorization in a select number of EEA countries. The process is managed by a Reference Member State that coordinates the review process with the other countries in the EEA in which the applicant has applied for marketing authorization.

A mutual recognition procedure of nationally approved decisions is available to pursue marketing authorizations for a product in the remaining EU countries. Under the mutual recognition procedure, the holders of national marketing authorization in one of the countries within the EU may submit further applications to other countries within the EU, who will be requested to recognize the original authorization.

We chose to pursue the decentralized procedure for ILUVIEN for DME and used the mutual recognition procedure due to our limited resources. Through this procedure, we obtained marketing authorizations in the 17 countries in the EEA discussed above. For ILUVIEN for NIU-PS, we filed a type II variation in these 17 countries in the EEA using the same procedure. In each instance, we received the Final Variation Assessment Report for ILUVIEN from the Medicines and Healthcare products Regulatory Agency of the United Kingdom (the MHRA) based on our submission to the MHRA through the mutual recognition procedure. In light of Brexit, we have moved marketing authorizations for certain European approvals from our U.K. subsidiary to our Irish subsidiary. In addition, Ireland is now our Reference Member State, which is the European Union Member State that leads the review of an application in the decentralized process for ILUVIEN. The Irish Health Products Regulatory Authority is our key regulatory body with which to discuss any regulatory submissions pertinent to ILUVIEN in the EEA.

Third-Party Reimbursement and Pricing Controls

In the U.S., the EEA and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (together, the ACA), significantly changed the way healthcare is financed by both governmental and private insurers. The provisions of the ACA became effective beginning in 2010, although some of its key provisions were altered through the Tax Cuts and Jobs Act enacted in December 2017. Through the date of this report, President Biden has enacted certain changes to Medicare reimbursement policies, and we cannot predict further changes that the Biden Administration may make to current federal reimbursement policies and whether those changes will affect us. We expect that additional federal and/or state healthcare reform measures will be adopted in the future, any of which could limit the amounts

that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce our profitability.

In many foreign markets, including the countries in the EEA, pricing of pharmaceutical products is subject to governmental control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of those proposals could have a material adverse effect on our business, financial condition and profitability.

Patents and Proprietary Rights

Our success depends in part on our and our licensor's ability to obtain and maintain proprietary protection for ILUVIEN or any future products or product candidates, technology and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Because we license certain intellectual property relating to ILUVIEN from third parties, we depend on their ability to obtain and maintain such protection. Where we have conducted our own research, our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of December 31, 2022, we owned or licensed two U.S. utility patents and one U.S. design patent as well as numerous foreign counterparts to many of these patents and patent applications relating to ILUVIEN or the ILUVIEN applicator. We licensed our one utility patent right relating to ILUVIEN from EyePoint. Pursuant to the New Collaboration Agreement with EyePoint, our ILUVIEN-related patent rights are only for diseases of the human eye in Europe, the Middle East and Africa, and for diseases of the human eye excluding uveitis in the rest of the world. In addition to the U.S. patents licensed from EyePoint, we also license two European patents from EyePoint. We have a U.S. utility patent directed to our applicator system for ILUVIEN. Our licensed patent portfolio includes U.S. patents (with no currently pending or issued corresponding European applications or patents) with claims directed to methods for administering a corticosteroid with an implantable sustained delivery device to deliver the corticosteroid to the vitreous of the eye wherein aqueous corticosteroid concentration is less than vitreous corticosteroid concentration during release.

U.S. utility patents generally have a term of 20 years from the date of filing. The utility patent rights relating to ILUVIEN that EyePoint licensed to us include one U.S. patent that will expire August 2027, two European patents that are directed to our low-dose device that expired in April 2021 and will expire in October 2024, respectively, and counterpart filings to these patents in a number of other jurisdictions. No patent term extension or supplementary protection certificate will be available for any of these U.S. or European patents or applications.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our and our licensor's success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology we develop. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before such product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Research and Development

We invested $5.4 million and $4.6 million in research and development during 2022 and 2021, respectively.

Employees

As of February 27, 2023, we had 158 employees, 150 of whom were full-time employees.

Corporate Information

We are a Delaware corporation incorporated on June 4, 2003. Our principal executive office is located at 6310 Town Square, Suite 400, Alpharetta, Georgia 30005 and our telephone number is (678) 990-5740. Our website address is www.alimerasciences.com. The information contained in our website, or that can be accessed through our website, is not part of this report and should not be considered part of this report or incorporated into any of our other filings with the Securities and Exchange Commission (SEC), except where we expressly incorporated such information.

Available Information

We file annual, quarterly and current reports, proxy statements, and other documents with the SEC under the Securities Exchange Act of 1934, as amended (the Exchange Act). Also, the SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at www.sec.gov. Copies of each of our filings with the SEC on Form 10-K, Form 10-Q and Form 8-K, and all amendments to those reports, can be viewed and downloaded free of charge at our website, www.alimerasciences.com, as soon as reasonably practicable after the reports and amendments are electronically filed with or furnished to the SEC. Our code of ethics, other corporate policies and procedures, and the charters of our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee, are also available through our website.

ITEM 1A. *RISK FACTORS*

Investing in our common stock involves risk. You should carefully consider the risks described below as well as all the other information in this Annual Report on Form 10-K, including the consolidated financial statements and the related notes included in this report. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. In that event, the trading price of our common stock could decline, and you may lose all or part of your investment. The risks discussed below also include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements.

SUMMARY OF PRINCIPAL RISK FACTORS

We face risks from:

- our dependence on the commercial success of our only product, ILUVIEN;
- the competition we face, given that the number of competitive products is growing and our competitors include larger, more established, fully integrated pharmaceutical companies and biotechnology companies that have substantially greater capital resources, existing competitive products, larger research and development staffs and facilities, greater marketing capabilities, and greater experience in drug development and in obtaining regulatory approvals than we do;
- uncertainty associated with our ability to retain our current employees and to recruit and retain the new employees we need in the future, in particular a productive sales force;
- the possibility that the NEW DAY Study may (a) fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early diabetic macular edema (DME) or to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, and (b) take longer or be more costly to complete than we currently anticipate;
- our inability to expand our portfolio of ophthalmic products;
- the negative effects of inflation, which may increase the compensation we must pay to retain and attract a high-quality workforce and is likely to increase our operational costs;
- our dependence on third-party manufacturers to manufacture ILUVIEN or any future products or product candidates in sufficient quantities and quality, in a timely manner (particularly during the COVID-19 pandemic), and at an acceptable price;
- the possibility that we may fail to plan appropriately to meet the demand of our customers for ILUVIEN, which could lead either to (a) ILUVIEN being out of stock or (b) our investment of a greater amount of cash in inventory than we need;
- the possibility that the issues affecting global supply chains may negatively impact our ability to source materials and components to make ILUVIEN or to deliver ILUVIEN into our current markets;
- uncertainty associated with manufacturing components and materials being superseded or becoming obsolete;
- the possibility that we may again fail to comply with the financial covenants in our credit facility, and in that event be unable to obtain a waiver for any resulting default;
- our need to raise additional financing, the terms of which may restrict our operations and, if the capital we raise is equity or a debt security that is convertible into equity, could dilute our stockholders' investment;
- uncertainty regarding our ability to achieve profitability and positive cash flow through the commercialization of ILUVIEN in the U.S., the European Economic Area (EEA) and other regions of the world where we sell ILUVIEN;
- a slowdown or reduction in our sales due to, among other things, a reduction in end user demand, unexpected competition, regulatory issues or other unexpected circumstances, including COVID-19;
- the effects of inflation on the SOFR-based interest rate we pay under our credit facility, which could cause our financing costs to increase materially and thus adversely affect our financial results;
- the possible continued delays in enrollment of patients in our NEW DAY Study;
- the possible delay in enrollment of patients in our pediatric study for non-infectious uveitis affecting the posterior segment of the eye (NIU-PS);
- uncertainty associated with our pursuit of reimbursement from local health authorities in certain countries for the recently obtained additional indication for ILUVIEN for NIU-PS;
- delay in or failure to obtain regulatory and reimbursement of ILUVIEN or any future products or product candidates in additional markets where we do not currently sell ILUVIEN;
- uncertainty associated with our ability to meet any post market requirements for NIU-PS in the EEA;
- the possibility that we may fail to secure regulatory approval in the greater China market, which would have an adverse effect on our ability to receive milestone payments under the Ocumension license agreement;
- uncertainty associated with our ability to successfully commercialize ILUVIEN following regulatory approval in additional markets;
- political, economic, legal and social risks, including those related to the COVID-19 pandemic; and
- the possibility that we may be adversely affected by the expiration of patents that protect key aspects of ILUVIEN in the near- to medium-term.

Risks Related to Our Business, Including Our Dependence on ILUVIEN

Our business depends on our only product, ILUVIEN.

We are a pharmaceutical company with only one product available for commercial sale in the U.S., the U.K., most of the countries in the EEA and a limited number of other markets. Because we do not currently have any other products or product candidates available for sale or in clinical development, our future success depends on our and our distributors' successful commercialization of ILUVIEN.

We have incurred and expect to continue to incur significant expenses:

- to continue to support our sales efforts in the U.S., Germany, Portugal, the U.K. and Ireland;
- to pursue the regulatory and reimbursement approval for ILUVIEN in other countries for both DME and NIU-PS;
- to grow our operational capabilities;
- to support our NEW DAY Study; and
- to support our NIU-PS study in pediatric patients.

These represent a significant investment in the commercial and regulatory success of ILUVIEN, which is uncertain.

If we or our distributors do not successfully maintain our sales in countries where we are approved to sell ILUVIEN or our distributors do not successfully commence and grow our sales of ILUVIEN in other countries where we are seeking to begin selling ILUVIEN or have recently done so, our business may be seriously harmed. In addition, we may experience delays and unforeseen difficulties in the commercialization of ILUVIEN, including unfavorable pricing or reimbursement levels in certain countries that could negatively affect our ability to increase revenues.

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

The development and commercialization of new drugs is highly competitive, and the commercial success of ILUVIEN or any of our future products or product candidates will depend on several factors, including our ability to differentiate any such products or product candidates from our competitors' current or future products. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to ILUVIEN and to any future products or product candidates that we may develop or commercialize in the future.

Our commercial opportunities for ILUVIEN will be reduced or eliminated if our competitors develop or market products that:

- are more effective;
- receive better reimbursement terms;
- have higher rates of acceptance by physicians;
- have fewer or less severe adverse side effects;
- are better tolerated;
- are more adaptable to various modes of dosing;
- have better distribution channels;
- are easier to administer; or
- are less expensive, including a generic version of ILUVIEN.

Many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engage in research and development of products, some of which may target the same indications as ILUVIEN or any future products or product candidates. Our competitors include larger, more established, fully integrated pharmaceutical companies and biotechnology companies that have substantially greater capital resources, existing competitive products, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater marketing capabilities than we do. Genentech, Novartis, Regeneron and AbbVie (Allergan) provide a short-term therapy that competes with ILUVIEN.

Our business is subject to political, economic, legal, and social risks, which could adversely affect our operations and financial position.

There are significant regulatory, economic and legal barriers in markets in the United States and outside the United States that we must overcome. Changes in United States social, political, regulatory, and economic conditions or in laws and policies governing foreign trade, manufacturing, development, and investment, and any negative sentiments towards the United States as a result of such changes, could adversely affect our business. Concerns over economic weakness, including trade wars, unemployment, and continuing inflation and interest rate increases; natural disasters, public health epidemics or pandemics, such as the COVID-19 pandemic, and actions taken in response to such events; supply chain delays and disruptions; and policy priorities of the U.S. presidential administration, to continued volatility and diminished expectations for the economy and markets. Additionally, concern over geopolitical issues may also contribute to prolonged market volatility and instability. For example, the conflict between Russia and Ukraine could lead to disruption, instability, and volatility in global markets and industries. The U.S. government and other governments in jurisdictions have imposed severe economic sanctions and export controls against Russia and Russian interests, have removed Russia from the Society for Worldwide Interbank Financial Telecommunication payment (SWIFT) system, and have threatened additional sanctions and controls. The ultimate impact of these measures, as well as potential responses to them by Russia, is unknown. Any changes related to these and other factors could adversely affect our business, both in the United States and internationally.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, it will impair our ability to commercialize ILUVIEN and identify develop and commercialize any future products or product candidates.

We depend on the principal members of our management team, including Richard S. Eiswirth, Jr., our President and Chief Executive Officer, Philip Ashman, Ph.D., our Chief Operating Officer and Senior Vice President Commercial Operations Europe, Russell Skibsted, our Chief Financial Officer, and David Holland, our Chief Marketing Officer and Senior Vice President Corporate Communications and Managed Markets. These executives have significant ophthalmic, regulatory industry, sales and marketing, operational and/or corporate finance experience. From time to time, there have been and may in the future be changes in our executive management team resulting from the hiring or departure of executives, which could disrupt our business. The loss of any such executives or any other principal member of our management team may impair our ability to market ILUVIEN and identify, develop and commercialize any future ophthalmic products or product candidates.

In addition, future growth may require us to hire a significant number of qualified technical, commercial and administrative personnel. We face intense competition from other companies and research and academic institutions for the qualified personnel we need in our business. For example, in 2019 our revenues in the U.S. market were negatively affected by a competitor's hiring some of our key sales personnel. We may need to invest significant amounts of cash and equity to attract and retain new and existing employees and we may never realize returns on these investments. If we are not able to effectively increase and retain our talent, our ability to achieve our strategic objectives will be adversely impacted, and our business will be harmed. Employees may be more likely to leave us if the shares of our capital stock they own or the shares of our capital stock underlying their equity incentive awards have significantly reduced in value. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain or grow our operations.

We may not be successful in our efforts to expand the number of ophthalmic products we sell.

In the future, we may choose to commercialize one or more new ophthalmic products in addition to ILUVIEN. We may seek to do so by establishing an internal research program or through licensing or otherwise acquiring the rights to potential new products and future product candidates for the treatment of ophthalmic disease.

A significant portion of the research that we may choose to conduct may involve new and unproven technologies. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources, whether or not we ultimately identify any candidates. Any future research programs may initially show promise in identifying potential products or product candidates, yet fail to yield products or product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential products or product candidates; or
- we may learn after further study that potential products or product candidates have harmful side effects or other characteristics that indicate they are unlikely to be effective.

We may be unable to license or acquire suitable products or product candidates or products from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is highly competitive. Several more established companies are also pursuing strategies to license or acquire products in the ophthalmic field. These established companies may have a competitive advantage over us due to their greater size, resources and development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable products or product candidates include the following:

- we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return from the product;
- we may need to obtain our lender's consent to any significant payment or potential payment in conjunction with a license of acquisition of technology;
- companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or
- we may be unable to identify suitable products or product candidates within our areas of expertise.

Additionally, it may take greater human and financial resources to develop suitable potential products or product candidates through internal research programs or by obtaining rights than we will possess, thereby limiting our ability to develop a diverse product portfolio.

If we are unable to develop suitable potential product candidates through internal research programs or by obtaining rights to novel therapeutics from third parties, opportunity for future growth could be limited.

Our internal information technology systems, or those of our third-party contract research organizations (CROs) or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data and other disruptions, which could result in a material disruption of certain parts of our business, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We depend on information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. Maintaining the confidentiality and integrity of that confidential information is essential to our business. We also have outsourced elements of our operations to third parties, and as a result we work with a number of third-party contractors that have access to some of our confidential information.

Although we have implemented security, backup and recovery measures, our internal information technology systems and those of our third-party manufacturers, CROs and other contractors or consultants are potentially vulnerable to breakdown or other damage or interruption from:

- service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners or other third parties, and
- cyber-attacks by malicious third parties, including cyber-related threats of spoofed or manipulated electronic communications that lead to misdirected or fraudulent payments, the deployment of harmful malware or ransomware, malicious websites, denial-of-service attacks, and social engineering and other means to adversely affect service reliability and threaten the confidentiality, integrity and availability of information.

Any of the foregoing may compromise our system infrastructure or lead to data leakage.

While we have not experienced any such cyber-related fraud, system failure, accident or security breach through the date of this report that has materially affected our business, we cannot assure that our and our vendors' data protection efforts and our and our vendors' investment in information technology will prevent cyber-attacks by malicious third parties, significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations or a direct financial loss due to misdirected or fraudulent payments, it could result in a material disruption of our business operations, including, distribution and manufacturing, or to a direct financial loss.

We sell ILUVIEN in the U.S. primarily to two distributors and in Europe we use two logistics providers, and a security breach that impairs these distribution or logistics operations could significantly impair our ability to deliver our products to healthcare providers. In addition, ILUVIEN is manufactured and tested by third parties, and a security breach that impairs these third parties could significantly impair our ability to procure ILUVIEN and deliver it to our distributors in a timely manner. There can be no assurance that our or their efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks or breaches of systems, any of which could adversely affect our business and operations and/or result in the loss of critical or sensitive data, which could result in financial, legal, business or reputational harm to us or impact our stock price.

In addition, the loss of clinical trial data for our product candidates or our post-market studies could result in delays in our regulatory approval efforts or marketing efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions or security breaches of our internal information technology systems or our vendors' technology systems could adversely affect or result in the loss of, misappropriation of, unauthorized access to, use of, disclosure of or the prevention of access to our confidential information, including trade secrets or other intellectual property, proprietary business information and personal information of our employees and patients in studies conducted on our behalf, which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access to, use of or disclosure of

personal information, including personal information regarding our employees or information we may have regarding patients, could harm our reputation directly, compel us to comply with federal and state breach notification laws and foreign law equivalents, subject us to mandatory corrective action and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Maintaining and growing our commercial infrastructure is a significant undertaking that requires productive, well-trained sales and marketing personnel, effective managers and substantial financial resources, and we may not be successful in our efforts to meet these needs.

We anticipate that in the near term our ability to generate revenues will depend almost entirely on our ability to continue the successful commercialization of ILUVIEN, both in the U.S. and abroad. A commercial launch of ILUVIEN is a significant undertaking that requires substantial financial and managerial resources. As our commercialization plans and strategies evolve, we will need to further expand the size of our organization by recruiting additional managerial, operational, sales, marketing, financial and other personnel.

We may not be able to maintain and expand our commercial operation in a cost-effective manner or realize a positive return on this investment. In addition, we have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize ILUVIEN or any future products include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel or maintain our sales and marketing infrastructure;
- our inability to successfully enter into additional collaboration arrangements with third parties;
- the inability of sales personnel to obtain access to or persuade adequate numbers of ophthalmologists to prescribe our products;
- the lack of complementary products or additional labeled indications for ILUVIEN to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with maintaining and growing a commercial organization.

Additionally, we may encounter unexpected or unforeseen delays in expanding our commercial operations that delay the commercial launch in one or more countries in which ILUVIEN has received marketing authorization. These delays may increase the cost of, and the resources required for successful commercialization of, ILUVIEN. Further, a delay in the commercial launch of ILUVIEN in certain jurisdictions could result in the withdrawal of our marketing or regulatory authorization for ILUVIEN in those jurisdictions, including certain EEA member states where ILUVIEN has already received marketing authorization.

Clinical trials for our products may not generate the outcomes we expect, may take longer or be more costly to complete than we anticipate.

From time to time, we initiate or participate in clinical trials for ILUVIEN and may in the future participate in clinical trials or studies for other products. The timing of patient enrollment in these trials, and related costs, can be unpredictable, and any such trials or studies may be more expensive or take longer than we expect. Data from clinical trials are not always conclusive. Even if successful, these studies and trials may fail to change physician prescribing practices.

In addition, the ongoing COVID-19 pandemic can make the conduct of clinical trials more challenging given the paramount importance of adequate safety monitoring, collection of data and distribution of study drug, all of which are traditionally achieved by in-person visits. Challenges may continue to arise from site closures, site staffing shortages, potential interruptions to the supply chain for investigational products, or other considerations if site personnel or trial participants become infected with COVID-19. We may also experience a shortage of supplies and materials or a suspension of services from third parties.

The NEW DAY Study may fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early DME, fail to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, take longer or be more costly to complete than we currently anticipate or fail to change physician prescribing practices.

We are conducting our NEW DAY Study, which is a multicenter, single-masked, randomized, controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its potential advantages over the current standard of care of repeat anti-VEGF (aflibercept) injections. The NEW DAY Study is planned to enroll approximately 300 treatment-naïve, or almost naïve, DME patients in approximately 40 sites around the U.S. As of February 28, 2023, we have enrolled 261 DME patients in this study. The NEW DAY Study may fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early DME, fail to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, take longer or be more costly to complete than we currently anticipate, including due to complications from the ongoing COVID-19 pandemic, and/or fail to change physician prescribing practices despite a successful result. The occurrence of any of these events could materially and adversely affect our business, financial condition and cash flows, and results of operations.

We may acquire additional businesses or form strategic alliances in the future, and we may not realize the benefits of those acquisitions or alliances.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing ILUVIEN-based business, including adding new products in the ophthalmic field. The identification of suitable acquisition or alliance candidates can be difficult, time-consuming, and costly, and we may not be able to complete these transactions on favorable terms, if at all. If we acquire businesses with promising markets or ophthalmic products, we may be unable to realize the benefit of acquiring those businesses if we are unable to successfully integrate them with our existing operations and company culture. We may have difficulty in developing, manufacturing and marketing the ophthalmic products of a newly acquired company that enhances the performance of our combined businesses or product lines to realize value from expected synergies, and the process of integrating acquired businesses or products may create unforeseen operating difficulties and expenditures. We cannot assure that, following an acquisition or strategic alliance, we will achieve the revenues or other results that justify the transaction.

If we fail to successfully manage our international operations, our business, operating results and financial condition could suffer.

Our international operations require significant management attention and financial resources. Our international operations today cover the U.K. and much of Europe and the Middle East. There is a high level of regulation in all markets where ILUVIEN is sold and great diversity in how those markets operate. Consequently, experience and expertise is vital in understanding the market dynamics of each country, the rules and regulations in place governing the sale of medicines, the codes of practice governing promotion of medicines, different currencies, the financial frameworks applying to taxation (both corporate and VAT) and the need to communicate in different languages. There is always a risk of loss of expertise through attrition of key roles within these international areas.

Moreover, we rely on distributors in many countries to provide adequate levels of experience and expertise on our behalf. We seek to monitor and manage these relationships appropriately, including through a quarterly “Joint Steering Committee” process to address business issues and assess risks in each of these markets.

We believe that China and the Western Pacific may become substantial markets for us under our license agreement with Ocumension Therapeutics, which is currently working through regulatory filings and plans to commence a real-world study estimated to start later in 2023. Additionally, they plan to begin a phase III study for the Chinese market in the second half of 2023. We cannot assure that these efforts will ultimately prove to be successful, however, particularly in light of the currently strained trade and other relationships between the U.S. and China.

In addition, there are many risks inherent in international business activities, including:

- extended collection timelines for accounts receivable and greater working capital requirements;
- multiple, conflicting legal systems and unexpected changes in legal requirements such as privacy and data protection laws and regulations, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- tariffs, export restrictions, trade barriers and other regulatory or contractual limitations on our ability to sell or develop our product in certain foreign markets;
- changes in currency exchange rates;
- currency transfer and other restrictions and regulations that may limit our ability to sell ILUVIEN or repatriate profits to the United States
- difficulties adapting to new cultures, business customs, and legal systems;
- trade laws and business practices favoring local competition;
- potential tax issues, including restrictions on repatriating earnings, resulting from multiple, conflicting and complex tax laws and regulations;
- weaker intellectual property protection in some countries;
- natural disasters, political, economic, and social instability, including the effects of ongoing United States-China diplomatic and trade friction and social unrest in China and the recent conflict between Russia and Ukraine, and global sanctions imposed in response thereto, the possibility of a wider European or global conflict, or other war or terrorist activities or the threat of war and terrorism; and
- adverse economic conditions, including increasing inflation and the stability and solvency of business financial markets, financial institutions and sovereign nations.

In addition, compliance with foreign and U.S. laws and regulations that are applicable to our international operations is complex and may increase our cost of doing business in international jurisdictions, and our international operations could expose us to fines and penalties if we fail to comply with these regulations. These laws and regulations include import and export requirements, U.S. laws such as the Foreign Corrupt Practices Act, and local laws prohibiting corrupt payments to governmental officials. Although we have implemented policies and procedures designed to help ensure compliance with these laws, there can be no assurance that our employees, partners and other persons with whom we do business will not take actions in violation of our policies or these laws. Any violations of these laws could subject us to civil or criminal penalties, including substantial fines or

prohibitions on our ability to offer our products in one or more countries, and could also materially and adversely harm our business and financial condition.

The COVID-19 pandemic has had, and may continue to have, certain negative impacts on our business, and those impacts may have an adverse effect on our results of operations, financial condition and cash flows.

The public health crisis caused by the COVID-19 pandemic and the measures taken by governments, health authorities, businesses, and the public at large to limit the COVID-19 pandemic's spread have had, and may continue to have, certain negative effects on, and present certain risks to, our business. In 2020 and 2021, we experienced decreases in sales of ILUVIEN in the U.S. and in our international markets that have been affected by the COVID-19 pandemic, though sales recovered in 2022. The sales decreases resulted from, among other things, limitations on in-person access to physicians and patient behavior, particularly in light of governmental authorities citing diabetes as a factor that places a person at higher risk for severe illness from COVID-19. If the COVID-19 pandemic intensifies again, its negative effect on our sales and thus our liquidity and financial condition could be more prolonged and may be severe. Financial uncertainty associated with the adverse effects of the ongoing COVID-19 pandemic, and the duration of those effects, could have an impact in future periods on certain estimates used in the preparation of our quarterly financial results, including impairment of intangible assets, the income tax provision and realizability of certain receivables. Other effects or possible effects of the ongoing COVID-19 pandemic on us include:

- Limitations on travel have curtailed our in-person marketing activities in the past and may again do so if reimposed.
- Restrictions placed on regulatory and pricing bodies may delay or defer market access for ILUVIEN as we seek to secure reimbursement.
- While most of our personnel have returned to work in the office, we may in the future experience reductions in productivity and disruptions to our business routines if a large percentage of our employees again works remotely, whether in the U.S. or in Europe.
- The manufacturing or distribution of the ILUVIEN insert or applicator may be disrupted by government action related to COVID-19 or by the effect of the COVID-19 pandemic on our manufacturers' or distributors' workforces or supply chains, which may lead to product shortages.
- We may fail to plan appropriately to meet the demand of our customers for ILUVIEN, which could lead either to ILUVIEN being out of stock or excessive inventory.

Any of the above events could have an adverse effect on our results of operations, financial condition and cash flows.

Manufacturing Risks and Dependence on Third Parties

We rely on third parties to manufacture and test ILUVIEN, and our business would be seriously harmed if any of these third parties is unable to satisfy our demand, given that obtaining these products or services from alternative sources can require a long transition period.

We do not have, nor do we currently intend to establish, in-house manufacturing capability. We depend entirely on, and have agreements with, a single third-party manufacturer for each of:

- the manufacture of ILUVIEN's active pharmaceutical ingredient,
- the manufacture of the ILUVIEN applicator,
- the manufacture of the ILUVIEN implant, final assembly of the injector with the implant and release testing in the U.S., and
- the quality release testing of ILUVIEN in the EEA.

If any of these third-party manufacturers breaches its agreement, is unable to meet its contractual or quality requirements or becomes unwilling to perform for any reason, we may be unable, in a timely manner or at all, to locate alternative acceptable manufacturers or testing facilities, as applicable, enter into favorable agreements with them and ensure that they are approved by the applicable regulatory authorities, such as the U.S. Food and Drug Administration (FDA). For example, in the first quarter of 2020, we suffered from a supply shortage of ILUVIEN due in part to an equipment issue at our third party manufacturer. Further, all of our manufacturers rely on additional third parties for the manufacture of component parts. Any inability to acquire sufficient quantities of the active pharmaceutical ingredient, the ILUVIEN implants or the ILUVIEN applicator in a timely manner from these third parties could delay commercial production of ILUVIEN. Moreover, staffing and supply chain difficulties, which may be intensified by resurgences of the ongoing COVID-19 pandemic, may make it more difficult for our third-party manufacturers to provide sufficient quantities of their respective materials in a timely manner. Any such difficulties or delays could adversely affect our ability to fulfill demand for ILUVIEN, which could in turn adversely affect our revenue, operations and cash flow.

We rely on third parties for several important aspects of our business and have significant customer concentration.

We rely heavily upon our third-party contractors, suppliers and distributors. Especially during challenging and uncertain times like the present, there may be disruptions or delays in the performance of these third parties. We rely entirely on third

parties to manufacture, assemble and test our ILUVIEN applicators, as described in "Business—Manufacturing". We also rely on distributors for a majority of our sales of ILUVIEN. We sell to two large pharmaceutical distributors in the U.S., which accounted for 63% of our consolidated product revenues in 2022. These same two customers accounted for approximately 71% and 68% of our consolidated accounts receivable at December 31, 2022 and 2021, respectively. Internationally, our distributors produced approximately 39% of our international product revenues in 2022. If the business relationship with any such distributor is terminated, whether through industry consolidation or otherwise, and we are unable to find a suitable replacement, or if any large customer defaults in their obligation to pay, our operations and operating results could be materially adversely affected. These distributors also are not subject to any minimum sales requirements or obligations to market ILUVIEN to their customers. In turn, distributors could reduce their sales efforts for ILUVIEN or choose to terminate their representation of us. They may also fail to perform their obligations under the agreements with us. Additionally, in the Nordic Region we operate with the support of an exclusive wholesaler to support tendering processes in hospitals. The replacement or poor performance of this wholesaler, or our inability to collect accounts receivable from this wholesaler, could also materially and adversely affect our results of operations and financial condition. If one or more of our key third-party contractors, suppliers, manufacturers and/or distributors fail or are unable to satisfy their commitments to us, or if any of these key third-party relationships are terminated, our business and results of operations could be adversely affected.

Materials necessary to manufacture ILUVIEN may not be available on commercially reasonable terms, or at all.

We rely on our manufacturers to purchase materials from third-party suppliers necessary to produce ILUVIEN. Suppliers may not sell these materials to our manufacturers when needed or on commercially reasonable terms. We do not have any control over the process or timing of our manufacturers' acquisition of these materials. If our manufacturers are unable to obtain these materials in sufficient amounts, our sales of ILUVIEN would be hampered or there would be a shortage in supply, which would materially affect our ability to generate the revenues from the sale of ILUVIEN that we expect. Moreover, although we have agreements with our suppliers for the supply of the active pharmaceutical ingredient in ILUVIEN, the commercial production of the ILUVIEN implant and the commercial production of the ILUVIEN applicator, the suppliers may be unable to meet their contractual or quality requirements or choose not to supply us in a timely manner or in the minimum guaranteed quantities. If our manufacturers are unable to obtain these essential supplies, their ability to manufacture ILUVIEN and thus our supply of ILUVIEN for sale would be delayed, which could significantly reduce our sales of ILUVIEN and have an adverse impact on our business. We may incur higher costs in acquiring component parts for the ILUVIEN inserter and insert as a result of increases in applicable inflationary indexes specified in our contracts with manufacturers. Moreover, economic or political instability or disruptions, such as the conflict in Ukraine, could negatively affect our manufacturers' supply chains or further increase our costs.

Financial Risks

Our existing cash may be inadequate to fund our operations and support our growth.

As of December 31, 2022, we had approximately $5.3 million in cash and cash equivalents. We raised gross proceeds of $12.0 million in March 2023 through the sale of shares of our Series B Convertible Preferred Stock and warrants to purchase common stock to certain institutional investors. Whether this amount will be sufficient to fund our operations and support our growth will be determined by many factors, some of which are beyond our control, and we may need additional capital to fund our operations and support our growth sooner than we might anticipate. These factors include:

- the level of continued success of the commercialization of ILUVIEN in the U.S., and in our international markets,
- expenses relating to the commercialization of ILUVIEN;
- our research, development and general and administrative expenses;
- the timing of approvals, if any, of ILUVIEN for additional indications or in additional jurisdictions;
- the timing of and extent to which we enter into, maintain and derive revenues from licensing agreements, including agreements to license ILUVIEN in additional countries or regions; research and other collaborations; joint ventures; and other business arrangements;
- the timing of and extent to which we acquire, and our success in integrating, products or companies;
- regulatory changes and technological developments in our markets;
- increasing inflation; and
- the extent to which we can manage the use of cash in our business operations.

If we need additional capital to fund our operations and support our growth and we are unable to obtain that capital as noted below, our business may suffer.

We may need to raise additional capital to fund and grow our business, and in that event we may be unable to do so on commercially reasonable terms, the terms on which we obtain the capital may restrict our operations and if the capital we raise is equity or a debt security that is convertible into equity, our stockholders' investment could be diluted.

For the reasons described above, we may need to raise alternative or additional financing to fund our operations and support growth. General market conditions or the market price of our common stock may not support capital-raising transactions such as an additional public or private offering of our common stock or other securities. If we need additional financing, we may seek to

fund our operations through the sale of equity securities, additional debt financing and strategic collaboration agreements. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders. In addition, our ability to raise additional capital may depend upon obtaining stockholder approval. There can be no assurance that we will be able to obtain stockholder approval for a capital raise if it is necessary under applicable Nasdaq rules. If we are unable to obtain adequate financing or financing on terms satisfactory to us, when we require it, our ability to continue to fund and grow our business would be significantly limited.

If we raise additional funds by selling shares of our capital stock or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. If we attempt to raise additional funds through strategic collaboration agreements, we may not be successful in obtaining those agreements, or in receiving milestone or royalty payments under those agreements. If we raise additional funds by incurring additional debt (assuming our lenders would permit such debt, which would be subordinated to the debt outstanding under our credit facility), the terms of the debt may include significant installment payments as well as covenants and specific financial ratios that may restrict our ability to continue to commercialize ILUVIEN or commercialize any future products or product candidates or otherwise successfully operate our business.

Our ability to access any existing or future capital is also dependent on the condition of the banking system and financial markets. For example, in March 2023, the Federal Deposit Insurance Corporation (FDIC) took control and was appointed receiver of Silicon Valley Bank (SVB) and Signature Bank (Signature). As of the date of this report, we do not have direct exposure to SVB or Signature, but we cannot predict the broader impact or follow-on effects of these insolvencies. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition.

The terms of our credit facility require us to meet certain operating covenants and restrict our operating and financial flexibility, and any breach of the covenants in that agreement, if the lenders elected to accelerate the due date of the loan, could significantly harm our business and prospects and lead to the liquidation of our business.

Our Loan and Security Agreement dated December 31, 2019 with SLR Investment Corp. (SLR) as collateral agent, and the lenders party thereto, including SLR as a lender (as amended from time to time, the 2019 Loan Agreement) contains certain operating covenants and restricts our operating and financial flexibility. The 2019 Loan Agreement is secured by a lien covering all of our U.S. assets (and certain ownership interests in one of our foreign subsidiaries), including our intellectual property. The 2019 Loan Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include covenants requiring us to comply with applicable laws, maintain our legal existence, deliver certain financial reports and maintain insurance coverage. Negative covenants restrict our ability to transfer any part of our business or property, to change our business or key management, to incur additional indebtedness, to engage in mergers or acquisitions, to pay dividends or make other distributions, to make investments, to create other liens on our assets and to allow revenues from the sale of ILUVIEN to fall below certain minimums, in each case subject to customary exceptions.

If an event of default under the 2019 Loan Agreement occurs, SLR may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to raise additional financing, renegotiate the 2019 Loan Agreement on terms less favorable to us or immediately cease operations. Any declaration by SLR of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline significantly. Any declaration by SLR of an unwaived event of default could significantly harm our business and prospects and could cause the price of our common stock to decline significantly. Further, if we were liquidated, the lenders' right to repayment would be senior to the rights of our stockholders.

During each of the six-month periods ended September 30, 2021 and December 31, 2021, we did not generate sufficient revenue to meet the trailing six-month revenue covenant included in the 2019 Loan Agreement (the Revenue Covenant). For each such six-month period, the lenders provided a consent that permitted us not to maintain the Revenue Covenant as of September 30, 2021 and December 31, 2021, respectively, and waived any event of default that may have occurred or may be deemed to have occurred. We can offer no assurances, however, that the lenders will accommodate such a request for a consent and waiver if in the future we fail to meet the Revenue Covenant or any other covenant that would result in an event of default under the 2019 Loan Agreement. We expect to comply with the Revenue Covenant at the next reportable date, and throughout 2023. However, if we fail to comply with the Revenue Covenant and the lenders do not provide a consent and waiver, acceleration of the maturity of the loan is one of the remedies available to the lenders. If the lenders accelerate the maturity of the loan, we would be forced to find alternative financing or enter into an alternative agreement with the lenders. We cannot be sure that alternative financing will be available when needed or that, if available, the alternative financing could be obtained on terms that are not significantly detrimental to us or our stockholders.

We have incurred operating losses in each year since our inception and expect to continue to incur losses in 2023.

We have incurred recurring losses and negative cash flow from operations, and we have accumulated a deficit of $415.4 million from our inception through December 31, 2022. Our ability to achieve profitability and positive cash flow depends on our ability to maintain revenue and contain our expenses. We are uncertain if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to maintain and increase revenue and achieve profitability depends on our ability to continue to successfully market and sell ILUVIEN in the geographic areas where we or our distributors offer ILUVIEN. We cannot assure that we will be profitable even if we successfully commercialize ILUVIEN or future products or product candidates. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. In that regard, the audit report issued by our independent registered public accounting firm for the audit of our 2022 financial statements, included elsewhere in this report, includes an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern.

There is no assurance that sufficient financing will be available to us when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

Our quarterly operating results and cash flows are expected to fluctuate significantly.

We expect our operating results and cash flows to be subject to quarterly fluctuations. Our revenues and operating results will be affected by numerous factors, including:

- the ongoing commercial success of ILUVIEN (or lack thereof);
- inconsistent timing and ordering patterns from our U.S. distributors;
- seasonality caused by insurance renewals for patients in the U.S. and by doctor and or patient absences due to holidays and vacations;
- sales, marketing and medical affairs expenses;
- the timing and amount of royalties, milestone payments or product purchases by our distributors;
- our ability to obtain regulatory approval of ILUVIEN in additional jurisdictions or for additional indications;
- regulatory developments affecting ILUVIEN, our future product candidates or our competitors' products;
- the emergence of products or treatments that compete with ILUVIEN;
- variations in the level of expenses related to our products or future development programs;
- the status of our clinical development programs;
- our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- any lawsuit or intellectual property infringement in which we are or may become involved;
- general economic and political conditions in our domestic and international markets, including inflation and fluctuations in supply chains;
- global pandemics, such as COVID-19, or other public health emergencies and the responses thereto;
- unexpected events, including those resulting from climate change or geopolitical events;
- the timing and recognition of stock-based compensation expense; and
- the timing and amount of patient enrollments in our clinical studies, including the NEW DAY Study and related expenses.

If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results or cash flows may, in turn, cause significant volatility in the price of our stock. We believe that comparisons of our quarterly financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Prolonged economic uncertainties or downturns, as well as unstable market, credit and financial conditions, may exacerbate certain risks affecting our business and have serious adverse consequences on our business.

Economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control. In recent years, the United States and other significant markets have experienced cyclical downturns and worldwide economic conditions remain uncertain, particularly as a result of increasing inflation and related market and macroeconomic responses including interest rate increases, the ongoing COVID-19 pandemic and its related resurgences and variants, and the ongoing conflict arising out of the Russian invasion of Ukraine. Economic uncertainty and associated macroeconomic conditions, including geopolitical tensions, escalating inflation, supply chain issues and the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased market volatility or market declines,

make it extremely difficult for our partners, suppliers, and us to accurately forecast and plan future business activities. Sales of our products will depend, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations in the U.S., Germany, Portugal, Ireland, the U.K. and other countries. Negative trends in the general economy in any of the jurisdictions in which we may do business may cause these organizations to be unable to satisfy their reimbursement obligations or to delay payment. In addition, health authorities in some jurisdictions may reduce reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenue.

Exchange rate fluctuations of foreign currencies relative to the U.S. Dollar could materially and adversely affect our business.

Approximately 37% of our product revenues in 2022 were international. A substantial majority of our international revenues and expenses are denominated in British Pounds and Euros, and as such are sensitive to changes in exchange rates. We also have balances, such as cash, accounts receivable, accounts payable and accruals, that are denominated in foreign currencies. These foreign currency transactions and balances are sensitive to changes in exchange rates. Fluctuations in exchange rates of the British Pound and Euro in relation to the U.S. Dollar could materially reduce our future revenues as compared to prior periods. We do not seek to mitigate this exchange rate effect by using derivative financial instruments. To the extent we are unable to match revenues received in foreign currencies with costs paid in the same currency, exchange rate fluctuations in that currency could have a material adverse effect on our business and results of operations. As our international operations continue to grow, our risks associated with fluctuations in currency rates will become greater.

New or revised tax regulations, unfavorable resolution of tax contingencies or changes to enacted tax rates could adversely affect our tax expense.

As a multinational organization, we may be subject to taxation in several jurisdictions around the world with increasingly complex tax laws, the application, interpretation and enforcement of which can be uncertain. Changes in tax laws or their interpretations could result in changes to enacted tax rates and may require complex computations to be performed that were not previously required, significant judgments to be made in interpretation of the new or revised tax regulations and significant estimates in calculations, as well as the preparation and analysis of information not previously relevant or regularly produced. Future changes in enacted tax rates could negatively affect our results of operations.

For example, the recently enacted Inflation Reduction Act of 2022 includes a minimum tax equal to fifteen percent of the adjusted financial statement income of certain corporations as well as a one percent excise tax on share buybacks, effective for tax years beginning in 2023. When effective, it is possible that the minimum tax could result in an additional tax liability over the regular federal corporate tax liability in a given year based on differences between book and taxable income (including as a result of temporary differences).

Relevant foreign taxing authorities may disagree with our determinations as to whether we have established a taxable nexus, often referred to as a "permanent establishment", or the income and expenses attributable to specific jurisdictions. In addition, these authorities may take aggressive tax recovery positions that the funds flows we process are subject to value added tax or goods and services tax. If disagreements with relevant taxing authorities on other unknown matters were to occur, and our position was not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows and lower overall profitability of our operations.

Our tax returns and positions are subject to review and audit by federal, state, local and international taxing authorities. An unfavorable outcome to a tax audit could result in higher tax expense, thereby negatively affecting our results of operations and cash flows. We have recognized estimated liabilities on the balance sheet for material known tax exposures relating to deductions, transactions and other matters involving some uncertainty as to the proper tax treatment of the item. These liabilities reflect what we believe to be reasonable assumptions as to the likely final resolution of each issue if raised by a taxing authority. While we believe that the liabilities are adequate to cover reasonably expected tax risks, there can be no assurance that, in all instances, an issue raised by a tax authority will be finally resolved at a financial amount no more than any related liability. An unfavorable resolution, therefore, could negatively affect our financial position, results of operations and cash flows in the current and/or future periods.

Our ability to use our net operating loss carry-forwards may be limited.

As of December 31, 2022, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately $147.2 million and $107.7 million, respectively. Except for the NOLs generated after 2017, the U.S. federal NOLs not fully utilized will expire at various dates between 2029 and 2037; most state NOL carry-forwards will expire at various dates between 2022 and 2042. Under the Tax Cuts and Jobs Act of 2017, U.S. federal NOLs and some state NOLs generated after 2017 will carry forward indefinitely. These NOLs may be subject to further limitation based upon the final results of our Internal Revenue Code sections 382 and 383 analyses. Sections 382 and 383 of the Internal Revenue Code limit the annual use of NOL carry-forwards and tax credit carry-forwards, respectively, following an ownership change. NOL carry-forwards may be subject to annual limitations under Section 382 (or comparable provisions of state law) if certain changes in ownership of our company were to occur. In

general, an ownership change occurs for purposes of Section 382 if there is a more than 50% change in ownership of a company over a 3-year testing period. We have determined that a Section 382 change in ownership occurred in December of 2015. As a result of this change in ownership, we estimated that approximately $18.6 million of our federal NOLs and approximately $382,000 of federal tax credits generated prior to the change in ownership will not be utilized in the future. We are currently in the process of refining and finalizing these calculations, and upon finalization, will determine if a write-off is necessary. The reduction to our NOL deferred tax asset due to the annual Section 382 limitation and the NOL carryforward period would result in an offsetting reduction in valuation allowance recorded against the NOL deferred tax asset. Therefore, the limitation does not affect the statements of operations for the periods presented. Any future changes in our ownership or sale of our stock, including our March 2023 financing, could further limit the use of our NOLs in the future. If we need to obtain alternative or additional financing to meet our liquidity requirements under the 2019 Loan Agreement and we raise those funds by selling additional equity, this could further limit the use of our NOLs in the future.

Because our interest rate under the 2019 Loan Agreement is based on SOFR, a floating rate, we are exposed to the risks of higher interest rates, which could decrease our liquidity and capital resources and adversely affect our financial performance.

Our interest rate under the 2019 Loan Agreement is based on SOFR, a floating rate. The Federal Reserve raised interest rates seven times in 2022 and has indicated it may continue to do so to combat the effects of inflation, which is currently higher than it has been since the early 1980s. An increase in SOFR would increase our interest costs. Significant increases in our interest costs could materially and adversely affect our results of operations and our ability to pay amounts due under the 2019 Loan Agreement, and any increase in the interest we pay would reduce our cash available for working capital, acquisitions, and other uses.

Regulatory Risks

The manufacture and packaging of pharmaceutical products such as ILUVIEN are subject to the requirements of the FDA and similar foreign regulatory entities. If we or our third-party manufacturers fail to satisfy these requirements, our commercialization and regulatory approval efforts may be materially harmed.

The FDA and similar foreign regulatory agencies regulate the manufacture and packaging of pharmaceutical products such as ILUVIEN, which must be conducted in accordance with the FDA's current Good Manufacturing Practices (cGMP) and comparable requirements of foreign regulatory agencies. Only a limited number of manufacturers that operate under these cGMP regulations are both capable of manufacturing ILUVIEN and willing to do so. If we or our third-party manufacturers fail to comply with applicable regulations, requirements or guidelines, the regulatory agencies could refuse to grant marketing approval of ILUVIEN or any future products or product candidates and could impose sanctions on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. Failure of our manufacturers to maintain compliance could interrupt the production of ILUVIEN, resulting in delays and additional costs that could significantly and adversely affect our business. Any significant delays in the manufacture of ILUVIEN or issues with the quality of the product could materially harm our business and prospects.

Changes in certain aspects of the manufacturing process or procedures require prior FDA review or approval of the manufacturing process and procedures in accordance with the FDA's cGMP regulations. There are comparable foreign requirements as well. This review may be costly and time-consuming and could delay or prevent the launch of a product. If we elect or are required to manufacture products at another facility, we will transfer the manufacturing to a registered medical device manufacturing company to seek to ensure that the new facility and the manufacturing process comply with cGMP and comparable foreign regulations. Any such new facility would also be subject to inspection. In addition, we would be required to demonstrate by physical and chemical methods, which are costly and time consuming, that the product made at any new facility is equivalent to the product made at the former facility. The FDA or a foreign regulatory agency may require clinical testing to prove equivalency of the product manufactured at any new facility compared to the old facility, which would result in additional costs and delay.

Further, we are required to complete testing on both the active pharmaceutical ingredient and on the finished product in the packaging that we propose for commercial sales. This includes testing of stability, identification of impurities and testing of other product specifications by validated test methods. In addition, our manufacturers are required to consistently produce our product in commercial quantities and of specified quality in a reproducible manner and document their ability to do so. This requirement is referred to as process validation. The FDA and similar foreign regulatory agencies may also implement new standards, or change their interpretation and enforcement of existing standards and requirements, for the manufacture, packaging or testing of products at any time.

Regulatory agencies may impose limitations on the indicated uses for which ILUVIEN may be marketed, or on our promotional activities, which would be adverse to our business.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the applicable regulatory authorities, including the FDA in the U.S. and various regulatory authorities in Europe. If a regulatory agency approves ILUVIEN for only a limited indication, the size of our potential market for ILUVIEN will be reduced. ILUVIEN has received marketing authorization in numerous countries in the EEA and elsewhere in the world for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. In the U.S., Australia, Canada, Kuwait, Lebanon and the United Arab Emirates, the indication for ILUVIEN is different, as ILUVIEN is indicated for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. Either of these indications or future indications may limit the use of ILUVIEN to a narrower segment of the DME population than we believe is warranted. As a result, our potential revenues are now and may be in the future less that they would be with broader indications for ILUVIEN.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by regulatory authority. These "off-label" uses by physicians are common across medical specialties and may constitute an appropriate treatment for some patients in some circumstances. Regulatory authorities generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do restrict, however, communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow regulatory authority rules and guidelines relating to promotion and advertising may cause the regulatory authority to suspend or withdraw an approved product from the market in the applicable country, require a recall or payment of fines, or impose sanctions that could include disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

In the U.S., ILUVIEN and any future products or product candidates may not remain commercially viable if we fail to obtain or maintain an adequate level of reimbursement for these products from: private insurers, the Medicare and Medicaid programs or other third-party payers.

Our revenue from sales of ILUVIEN in the U.S. depends on our ability to maintain pricing and reimbursement guidelines at our desired levels. Those guidelines, however, may fall well below our current expectations. The same could also occur for any future products or product candidates we may develop that receive approval, if any. Sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (together, the ACA), significantly changed the way healthcare is financed by both governmental and private insurers. The provisions of the ACA became effective beginning in 2010, although some of its key provisions were altered through the Tax Cuts and Jobs Act enacted in December 2017. Through the date of this report, President Biden has enacted certain changes to Medicare reimbursement policies, and we cannot predict further changes that the Biden Administration may make to current federal reimbursement policies under this law and whether those changes will affect us. Changes to the ACA or any replacement law may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of ILUVIEN or new products. Any rebates, discounts, taxes, costs or regulatory or systematic changes on healthcare resulting from changes to the ACA may have a significant effect on our profitability in the future. We cannot predict whether the ACA will continue in its present form or what other laws or proposals will be made or adopted, or what impact these efforts may have on us. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce our profitability.

Our list pricing in the U.S. for ILUVIEN is based upon the burden of DME, the current pricing of approved therapies for DME, our perception of the overall cost-to-benefit ratio of ILUVIEN and the pricing of other therapies. Due to numerous factors beyond our control, including efforts to provide for containment of health care costs, the U.S. may not support our current level of governmental pricing and reimbursement for ILUVIEN, which would reduce our anticipated revenue from ILUVIEN.

In the U.S., the Medicare and Medicaid programs currently provide reimbursement for ILUVIEN, but the reimbursement amount for ILUVIEN could be modified in the future, and the types of patients for whom ILUVIEN is reimbursed could be reduced to a smaller subset of patients. In addition, in some states, Medicare reimburses physicians for less than the cost of ILUVIEN. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the U.S. healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. The Biden administration may seek further reform of the Medicare program and the U.S. healthcare system. Some of these changes and reforms could result in reduced reimbursement rates for ILUVIEN and our future product candidates, which would adversely affect our business strategy, operations and financial results. Our business could also be adversely affected if retinal specialists are not reimbursed for the cost

of the procedure in which they administer ILUVIEN at a level that is satisfactory to them. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Our business could be materially adversely affected if the Federal Medicare program, or local Medicare carriers (MACS) or fiscal intermediaries were to make such a determination and deny or limit the reimbursement of ILUVIEN. If the local contractors that administer the Medicare program are slow to reimburse retinal specialists for ILUVIEN, that delay could ultimately affect the timing of payments to us, which would in turn adversely affect our working capital.

In the U.S., almost all private insurers, including managed care organizations, have agreed to reimburse for ILUVIEN, but the reimbursement amount could be modified in the future, and the types of patients for whom ILUVIEN is reimbursed could be reduced to a smaller subset of patients. We expect that private insurers will consider the efficacy, cost effectiveness and safety of ILUVIEN in determining whether to maintain approval for reimbursement for ILUVIEN in the U.S. and at what level. Maintaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not maintain approval for reimbursement of ILUVIEN from private insurers on a timely or satisfactory basis or such approvals are changed to reduce the level of reimbursements.

We may experience pricing pressures in connection with the sale of ILUVIEN due to the potential healthcare reforms discussed above, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations, additional legislative proposals and the economic health of the U.S. economy. If reimbursement for our products is unavailable, limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

In the European Economic Area and the U.K., ILUVIEN and any future products or product candidates may not be commercially viable if we fail to obtain or maintain an adequate level of reimbursement for these products from any of the following: governments, private insurers or other third-party payers.

In the EEA and the U.K., each country has a different reviewing body that evaluates reimbursement dossiers submitted by marketing authorization holders of new drugs and then makes recommendations as to whether or not the drug should be reimbursed. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval. In some countries, to obtain reimbursement approval or pricing approval at a level that we believe is appropriate, we may be required to conduct a clinical trial that compares the cost-effectiveness of ILUVIEN to other available therapies. Limitations on reimbursement could be imposed at the national, regional or local level or by fiscal intermediaries in each country, either through the initial authorization process or at some point in the future.

In addition, due to price referencing within the EEA, the U.K. and certain other countries, existing pricing in our current markets could be negatively affected by a change in pricing in a country where we currently have reimbursement or by a new price in a country where we obtain reimbursement approval in the future. We have been affected by such changes in the past, and any future cross-border price referencing could have a material adverse effect on our business.

Our business could also be adversely affected if governments, private insurers or other reimbursing bodies or payers limit the indications for reimbursement approval to a smaller subset than we believe ILUVIEN is effective in treating or establish a limit on the frequency with which ILUVIEN may be administered that is less often than we believe would be effective. Those actions could limit our revenues and harm our business.

Failure to comply with government regulations regarding the sale and marketing of our products could harm our business.

Our and our distribution partners' activities, including the sale and marketing of our products, are subject to extensive government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act and other federal and state statutes, along with requirements in Europe, such as the Medicines Act of 1968 in the U.K. In the U.S., we are also subject to the provisions of the Federal Anti-Kickback Statute, the Federal False Claims Act and several similar state laws, which prohibit payments intended to induce physicians or others either to purchase or arrange for or recommend the purchase of healthcare products or services. While the federal law applies only to products or services for which payment may be made by a federal healthcare program, state laws may apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of drugs by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians and other potential purchasers of drugs. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial, including the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid).

Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting antitrust violations, violations of the Federal False Claim Act, the Anti-Kickback Statute, the Prescription Drug Marketing Act and other violations in connection with off-label promotion of products and Medicare and/or Medicaid reimbursement and claims under state laws, including state anti-kickback and fraud laws. In

Europe, each country has different regulations that govern the promotional claims and activities of pharmaceutical and biotechnology companies. The violation and enforcement of these regulations by each country may result in heavy fines, further legal action, public reprimand, injunction and may include the loss of market authorization.

While we have implemented a compliance program to assist with monitoring and complying with these activities and we strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing practices are ever evolving. If any such actions are instituted against us or our partners and we or they are not successful in defending those actions or asserting our rights, those actions could have a significant and material adverse effect on our business, including the imposition of significant fines or other sanctions. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition.

The regulatory approval of ILUVIEN in any additional countries is uncertain, and our regulatory approval in certain countries is contingent on our ability to sell ILUVIEN in an appropriate time frame. Failure to obtain regulatory approval in additional foreign jurisdictions or maintain regulatory approval in jurisdictions where we have received regulatory approval but have not yet sold ILUVIEN would prevent us from marketing and commercializing ILUVIEN in those additional markets.

ILUVIEN has received marketing authorization in the U.S., in numerous countries in Europe and in other places in the world as described above in "Business – Overview." We sell ILUVIEN directly in the U.S., Germany, the U.K., Portugal, Ireland, Denmark, Finland, Norway and Sweden. Our distributors will continue to sell ILUVIEN in the Middle East, Austria, Czech Republic, France, the Netherlands, Belgium, Luxembourg, Italy and Spain in 2023. In addition, beginning in April 2023, ILUVIEN will be sold by Horus Pharma in the Nordic countries (Sweden, Norway, Finland and Denmark). When we received marketing authorization in the remaining countries in the EEA, those marketing authorizations required that we sell at least one ILUVIEN in those countries within three years or our license in those countries could be revoked unless we negotiate to extend the deadline. We intend to either sell one ILUVIEN in each of those countries or negotiate to extend the deadline, but we may not be able to make such a sale or extend the deadline, in which case our license in that country could be revoked. If our license in any of these countries is revoked, we will need to pursue marketing authorization again for that country, and we may be unsuccessful in that effort.

We intend to continue to pursue market authorizations for ILUVIEN internationally in additional jurisdictions. To market our products in foreign jurisdictions, we will be required to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We may not receive necessary approvals to commercialize ILUVIEN in any additional market.

The process of obtaining regulatory approvals and clearances in jurisdictions where ILUVIEN is not approved will require us to expend substantial time and capital. Despite the time and expense incurred, regulatory approval is never guaranteed. The number of preclinical and clinical tests that will be required for regulatory approval varies depending on the drug candidate, the disease or condition for which the drug candidate is in development, the jurisdiction in which we are seeking approval and the regulations applicable to that particular drug candidate. Regulatory agencies can delay, limit or deny approval of a drug candidate for many reasons, including that:

- regulatory agencies may interpret data from preclinical and clinical testing in different ways than we do;
- regulatory agencies may not approve of our manufacturing processes;
- a drug candidate may not be safe or effective;
- regulatory agencies may conclude that the drug candidate does not meet quality standards for stability, quality, purity and potency; and
- regulatory agencies may change their approval policies or adopt new regulations.

The applicable regulatory authorities may make requests or suggestions regarding our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval. For example, the regulatory authorities may not approve of certain of our methods for analyzing our trial data, including how we evaluate the relationship between risk and benefit. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain additional foreign regulatory approvals 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 foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to data protection laws and regulations. In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health related and other personal information. In California, the California Consumer Privacy Act (CCPA) establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The California Privacy Rights Act (CPRA) currently in effect, significantly amends the CCPA. Virginia, Colorado, Utah, and Connecticut have

enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. The obligations to comply with the CCPA and evolving legislation may involve, among other things, updates to our notices and the development of new processes. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws.

In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our product) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, (collectively, HIPAA). HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their "business associates"—certain persons or entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly receive individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.

Further at the federal level, the Federal Trade Commission (FTC) also sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act (FTC Act). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

EU Member States and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the General Data Protection Regulation (GDPR) imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Switzerland has adopted laws that impose restrictions and obligations similar to the GDPR. The obligations and restrictions under the GDPR and Switzerland's laws concern, in particular, in some instances the consent of the individuals to whom the personal data relate, the processing details disclosed to the individuals, the sharing of personal data with third parties, the transfer of personal data out of the European Economic Area (EEA) or Switzerland, contracting requirements (such as with clinical trial sites and vendors), and security breach notifications, as well as substantial potential fines, in some cases up to 4% of annual global turnover, for breaches of the data protection obligations. Data protection authorities from the different EU Member States and the EEA may interpret the GDPR and applicable related national laws differently which could effectively result in requirements additional to those currently understood to apply under the GDPR. In addition, guidance on implementation and compliance practices may be updated or otherwise revised, which adds to the complexity of processing personal data in the EU. When processing personal data of subjects in the EU, we have to comply with applicable data protection and electronic communications laws. In particular, as we rely on service providers processing personal data of subjects in the EU, we have to enter into suitable contract terms with such providers and receive sufficient guarantees that such providers meet the requirements of the applicable data protection laws, particularly the GDPR which imposes specific and relevant obligations. Enforcement by EU and UK regulators is active, and failure to comply with the GDPR or applicable Member State law may result in substantial fines.

Legal mechanisms to allow for the transfer of personal data from the EEA or UK to the US may impact our ability to transfer personal data or otherwise may cause us to incur significant costs to do so legally. On July 16, 2020, the European Court of Justice ruled that the Privacy Shield is an invalid data transfer mechanism and confirmed that the Standard Contractual Clauses (SCCs) remain valid. If companies are relying on the SCCs as their transfer mechanism to transfer personal information from the EEA to the US (or to other jurisdictions not recognized as adequate by the EU), they must be incorporated into new and existing agreements within prescribed timeframes. The UK adopted versions of their own SCCs. Updating agreements to incorporate these new SCCs for the EEA and UK may require significant time and resources to implement, including through adjusting our operations, conducting requisite data transfer assessments, and revising our contracts. Companies that have not taken steps to demonstrate that their SCCs and personal data recipients in the US or other non-adequate jurisdictions are suitable to receive the personal data may be subject to enforcement actions by competent authorities in the EU for failure to comply with related data privacy rules.

Additionally, the European Commission adopted a draft adequacy decision for the EU-US Data Privacy Framework, which reflects the assessment by the European Commission of the US legal framework. The draft decision concludes that the United States ensures an adequate level of protection for personal data transferred from the EU to US companies. After an approval

process, the European Commission is expected to adopt the final adequacy decision, which will allow data to flow freely from the EU to the U.S.

If we or our distributors fail to comply with applicable data privacy laws concerning, or if the legal mechanisms we or our distributors rely upon to allow, the transfer of personal data from the EEA or Switzerland to the US (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions, including an order to stop transferring the personal data outside of the EEA and significant penalties against us. Moreover, our business could be adversely impacted if our ability to transfer personal data out of the EEA or Switzerland to the US is restricted, which could adversely impact our operating results.

Failure to comply with data protection laws and regulations could result in unfavorable outcomes, including increased compliance costs, delays or impediments in the development of new products, increased operating costs, diversion of management time and attention, government enforcement actions and create liability for us (which could include civil, administrative, and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business.

Risks Related to Intellectual Property and Other Legal Matters

We may be adversely affected by the expiration of patents that protect key aspects of ILUVIEN in the near- to medium-term.

The patent rights relating to ILUVIEN licensed to us from EyePoint include one U.S. patent that will expire in August 2027, two European patents that expired in April 2021 and will expire in October 2024, respectively, and counterpart filings to these patents in a number of other jurisdictions. No patent term extension will be available for any of these U.S. patents, European patents or any of our licensed U.S. or European pending patent applications. After these patents expire in August 2027 in the U.S. and October 2024 in Europe, we will not be able to block others from marketing FAc in an implant similar to ILUVIEN.

We rely on patent, trademark and other intellectual property protection in the discovery, development, manufacturing and sale of our products. In particular, patent protection is, in the aggregate, important in our marketing of pharmaceutical products in the United States and most major markets outside of the United States. Patents covering our products normally provide market exclusivity, which is important for the profitability of many of our products.

As patents for certain of our products expire, we will or could face competition from lower priced generic or biosimilar products. In general, the expiration or loss of patent protection for a product may allow market entry by substitute products that could significantly reduce sales for the original product in a short amount of time. If our competitive position is compromised because of generics, biosimilars or otherwise, it could have a material adverse effect on our business and results of operations. In addition, proposals emerge from time to time for legislation to further encourage the early and rapid approval of generic drugs or biosimilars. Any such proposals that are enacted into law could increase the negative effect of generic competition.

If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are material to our business.

Our licenses are material to our business, and we may enter into additional licenses in the future. We hold a license from EyePoint to intellectual property relating to ILUVIEN pursuant to the New Collaboration Agreement. Our ability to pursue the development and commercialization of ILUVIEN depends upon the continuation of our license from EyePoint. The New Collaboration Agreement imposes various commercialization, milestone payment, royalty payments, insurance and other obligations on us, including the right by EyePoint to audit. If we fail to comply with these obligations, EyePoint may have the right to terminate the license. Our license rights to EyePoint's proprietary insert technology utilized in ILUVIEN could revert to EyePoint in certain circumstances, including failure to cure contractual breaches and filing for bankruptcy protection. We have from time to time amended the New Collaboration Agreement, and we may again seek to do so in the future if the need arises. We believe that given the terms of the SWK Agreement, however, it could be more difficult for us to do so, because SWK must consent to any amendment that could reasonably be expected to adversely affect the amount of the royalty payments that EyePoint has sold to SWK. Similarly, if we were to be engaged in a dispute with EyePoint regarding its enforcement or termination by either party, SWK's rights could complicate the resolution of any such dispute.

If our license with EyePoint, or any other current or future material license agreement, were terminated, or if we were unable to amend the New Collaboration Agreement or resolve any dispute related to such agreement, we may be unable to market the applicable products, such as ILUVIEN, that may be covered by such license, which would materially and adversely affect our business, results of operations and future prospects.

We do not control the commercialization of ILUVIEN in China, East Asia and the Western Pacific, and receipt of the value we currently anticipate will depend on, among other factors, Ocumension's ability to further commercialize ILUVIEN in that region.

We have granted an exclusive license to Ocumension Therapeutics (Ocumension) for the development and commercialization of our 0.19mg FAc intravitreal injection in China, East Asia and the Western Pacific. Our ability to receive aggregated potential sales milestone payments of up to $89.0 million depend upon achievement by Ocumension of specified amounts of net sales of ILUVIEN in that region in the future. However, we cannot assure you as to the amount, if any, we might receive. If there are any adverse developments or perceived adverse developments with respect to Ocumension's ability to commercialize ILUVIEN in China, East Asia and the Western Pacific, we may not realize the value we currently anticipate from this license, which would harm our business and may cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- regulatory hurdles in China, including related to the ongoing COVID-19 pandemic or the geopolitical tensions between the U.S. and China;
- competition, whether from current competitors or new products developed by others in the future;
- claims relating to intellectual property;
- global economic conditions;
- disruptions in Ocumension's business;
- disappointing or lower than expected sales of ILUVIEN;
- disputes between Ocumension and us; or
- Ocumension deciding to modify, delay or halt its development and commercialization of ILUVIEN.

If our license with Ocumension were terminated, or if Ocumension is unable to sell our licensed product, we will not receive any milestone payments under our license agreement, and our future revenues may be materially lower than expected.

If we or our licensors are unable to obtain and maintain protection for the intellectual property incorporated into our products, the value of our technology and products will be adversely affected.

Our success depends largely on our ability or the ability of our licensors to obtain and maintain protection in the U.S. and other countries for the intellectual property incorporated into our products. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. We or our licensors may be unable to obtain additional issued patents relating to our technology. Our success will depend in part on the ability of our licensors to obtain, maintain (including making periodic filings and payments) and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights.

Under our license with EyePoint, EyePoint controls the filing, prosecution and maintenance of all patents. Our licensors may not successfully prosecute or continue to prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such litigation less aggressively than we ordinarily would. Without protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Moreover, FAc is an off-patent active ingredient that is commercially available in several forms, including the extended release ocular implant Retisert.

Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection that we may have for our products. In addition, our patents and our licensors' patents may not afford us protection against competitors with similar technology.

Litigation or third-party claims of intellectual property infringement would require us to divert resources and may prevent or delay our commercialization of ILUVIEN or the development or regulatory approval of other product candidates.

ILUVIEN or any future products or product candidates may infringe upon other parties' intellectual property rights that are protected by patents or patent applications. Third parties may now or in the future own or control these patents and patent applications in the U.S. and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses or divert substantial employee resources from our business. If those claims are successful, we could be required to pay substantial damages or could be prevented from developing any future product candidates. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay manufacturing, sales, research or development of the product or product candidate that is the subject of the suit.

Several issued and pending U.S. patents claiming methods and devices for the treatment of eye diseases, including through the use of steroids, implants and injections into the eye, purport to cover aspects of ILUVIEN. For example, one of our potential competitors holds issued and pending U.S. patents and a pending European patent application with claims covering injecting an

ocular implant into a patient's eye similar to the ILUVIEN applicator. There is also an issued U.S. patent with claims covering implanting a steroidal anti-inflammatory agent to treat an inflammation-mediated condition of the eye. If these or any other patents were held by a court of competent jurisdiction to be valid and to cover aspects of ILUVIEN, then the owners of such patents would be able to block our ability to commercialize ILUVIEN unless and until we obtain a license under such patents (which license might require us to pay royalties or grant a cross-license to one or more patents that we own), until those patents expire or unless we are able to redesign our product to avoid any such valid patents.

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be forced to cease some aspect of our business operations, or be prevented from commercializing a product if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U.S. Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings better than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

If our efforts to protect the proprietary nature of the intellectual property related to our products are inadequate, we may not be able to compete effectively in our markets.

The strength of our patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. In addition to the rights we have licensed from EyePoint relating to ILUVIEN, we rely upon intellectual property we own, including patents, patent applications and trade secrets. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. Moreover, it is possible that a third party could successfully challenge the scope (i.e., whether a patent is infringed), validity and enforceability of our licensed patents before patent expiration and obtain approval to market a competitive product.

Further, the patent applications that we license or have filed may fail to result in issued patents. Patent examiners have rejected some claims in pending patent applications that we have filed or licensed. We may need to amend these claims. Even after amendment, a patent may not be permitted to issue. Further, the existing or future patents to which we have rights based on our New Collaboration Agreement with EyePoint may be too narrow to prevent third parties from developing or designing around these patents. Additionally, we may lose our rights to the patents and patent applications we license in the event of a breach or termination of our license agreement with EyePoint. Manufacturers may also seek to obtain approval to sell a generic version of ILUVIEN before the expiration of the relevant licensed patents. If the sufficiency of the breadth or strength of protection provided by the patents we license with respect to ILUVIEN or the patents we pursue related to ILUVIEN or any future product candidate is threatened, it could dissuade companies from collaborating with us to commercialize ILUVIEN and develop any future product candidates. Further, if we encounter delays in our clinical trials for any future product candidate, the period during which we could market those product candidates under patent protection would be reduced.

Third-party claims of intellectual property infringement may prevent or delay our commercialization efforts with respect to ILUVIEN and our discovery, development or commercialization efforts with respect to any future product candidates.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. In addition, at least several issued and pending U.S. patents claiming methods and devices for the treatment of eye diseases, including through the use of steroids, implants and injections into the eye, purport to cover aspects of ILUVIEN.

Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to ILUVIEN, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may in the future allege that our activities infringe their patents or that we are employing their proprietary technology without authorization. We may not have identified all the patents, patent applications or published literature that could potentially affect our business either by blocking our ability to commercialize our products or product candidates, by preventing the patentability of one or more aspects of our products or those of our licensors or by covering the same or similar technologies that may affect our ability to market our product. We cannot predict whether we would be able to obtain a license on commercially reasonable terms, if at all. Any inability to obtain such a license under the applicable patents on

commercially reasonable terms, or at all, may have a material adverse effect on our ability to commercialize ILUVIEN or any future products or product candidates until such patents expire.

In addition, third parties may obtain patents in the future and claim that use of ILUVIEN, our technologies or future products or product candidates infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further commercialize ILUVIEN or develop and commercialize any future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties, or we may be enjoined from further commercializing ILUVIEN or developing and commercializing any future product candidates or technologies. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of ILUVIEN or any future product candidate, and we have done so from time to time. We may fail to obtain future licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be unable to further commercialize ILUVIEN or develop and commercialize any future product candidates, which could harm our business significantly.

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings brought by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. 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 have a substantial adverse effect on the price of our common stock.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our development processes with respect to ILUVIEN that involve proprietary know-how, information and technology that is not covered by patent applications. Any involuntary disclosure or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

Our products may become subject to unauthorized sales through parallel import or diversion into unintended markets, resulting in lower sales in those markets.

As interest in and demand for ILUVIEN grows, and we expand distribution into new markets, ILUVIEN may become subject to parallel importing or diversion into unintended markets. Under EU law, parallel imports of approved products from one

member country into another are expressly permitted and cannot be prohibited. Furthermore, as our distribution expands, the possibility may increase for diversion of ILUVIEN into unanticipated markets. Sales of product by other companies through parallel import or diversion may adversely affect our product revenue, business and results of operations.

Product liability lawsuits could divert our resources, reduce the commercial potential of our products and result in substantial liabilities, which insurance may not cover.

Our business exposes us to the risk of product liability claims, which is inherent in the manufacturing, testing and marketing of drugs and related products. We face an increased risk of product liability as we further commercialize ILUVIEN, especially in the U.S. If the use of ILUVIEN or one or more of our future products causes physical harm, we may be subject to costly and damaging product liability claims. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because ILUVIEN is inserted into the eye, and it is possible that we may be held liable for eye injuries of patients who receive ILUVIEN. Any product liability lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of ILUVIEN or one or more of our future products. Even if we are not held liable, product liability lawsuits could cause adverse publicity and decrease the demand for ILUVIEN, which could have a material adverse effect on our business, results or operations and financial condition. Through the date of this report we have not had any material claims against us.

Although we maintain product liability insurance covering our clinical trial activities and our product sales, our aggregate coverage limit under these insurance policies is limited to $10 million in most jurisdictions, and while we believe this amount of insurance is sufficient to cover our product liability exposure, these limits may not be high enough to fully cover potential liabilities. The insurance provides worldwide coverage where allowed by law. As we generate product revenue in new countries, we intend to obtain compulsory coverage in those countries that require it. However, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our product development and commercialization efforts.

Certain Risks of Owning Our Common Stock

Conversion of all of our Series B Convertible Preferred Stock is contingent upon stockholder approval.

Pursuant to the listing rules of The Nasdaq Global Market (Nasdaq), until our stockholders approve the issuance of the common stock underlying our Series B Convertible Preferred Stock (the Series B Preferred Stock), the Series B Preferred Stock may not be converted if such conversion would cause (i) the aggregate number of shares of common stock that would be issued pursuant to the related securities purchase agreement and the transactions contemplated thereby to exceed 1,401,901 (19.99% of the voting power or number of shares of common stock, issued and outstanding immediately prior to the execution of the purchase agreement), which number will be reduced, on a share-for-share basis, by the number of shares of common stock issued or issuable pursuant to any transactions that may be aggregated with the transactions contemplated by the related securities purchase agreement under applicable Nasdaq rules; or (ii) the aggregate number of shares of common stock that would be issued pursuant to such conversion, when aggregated with any shares of common stock then beneficially owned by the holder (or group of holders required to be aggregated) of such shares, would result in a "change of control" under applicable Nasdaq listing rules. We have agreed to file a proxy statement with the SEC for the purpose of having our stockholders vote on a proposal to approve such issuances. Our stockholders may reject such a proposal, which would result in the Series B Preferred Stock to continue to accrue dividends at a rate of 6% per annum, accrued daily. For more information about the Series B Preferred Stock, see Part II, ITEM 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview—Recent Developments".

The Series B Preferred Stock ranks senior to our common stock with respect to payments upon liquidation, dividends, and distributions.

The rights of the holders of the Series B Preferred Stock rank senior to the obligations to our common stockholders. Upon our liquidation, the holders of Series B Preferred Stock are entitled to receive $1,000.00 per share plus all accumulated and unpaid dividends (the Liquidation Preference). Until the holders of Series B Preferred Stock receive their Liquidation Preference in full, no payment will be made on any junior shares, including shares of our common stock. Further, the holders of Series B Preferred Stock have the right to participate in any payment of dividends or other distributions made to the holders of common stock to the same extent as if they had converted such preferred shares. The existence of senior securities such as the Series B Preferred Stock could have an adverse effect on the value of our common stock.

Holders of Series B Preferred Stock have rights that may restrict our ability to operate our business.

Under the Certificate of Designation of the Series B Preferred Stock, we are subject to certain covenants that limit our ability to create new series of preferred stock, other than series junior to the S Series B Preferred Stock, and our ability to incur

certain indebtedness. Such restrictions may have an adverse effect on our ability to operate our business while the Series B Preferred Stock is outstanding.

Our common stockholders may experience significant dilution upon the issuance of common stock upon conversion of the Series B Preferred Stock or exercise of outstanding warrants to purchase common stock.

The issuance of common stock upon conversion of some or all of the Series B Preferred Stock will dilute the ownership interests of existing holders of shares of our common stock. As of March 24, 2023, if all of the Series B Preferred Stock were converted and all of our outstanding warrants to purchase common stock were exercised in full, we would have issued 11,428,572 shares of common stock (without giving effect to any limitation on conversions or exercise). The number of shares of common stock issuable upon conversion of the Series B Preferred Stock will increase as dividends continue to accrue on such shares at a rate of 6% per annum, accrued daily. The conversion price of the Series B Preferred Stock and the exercise price of the warrants to purchase common stock are subject to certain customary adjustments, including a weighted average anti-dilution adjustment (which will remain in effect until the Series B Preferred Stock converts). If stockholder approval is obtained, the Series B Preferred Stock will automatically be converted into shares of common stock and the exercise price of the warrants will no longer be subject to a weighted average anti-dilution adjustment.

The Series B Preferred Stock contains covenants and other terms that may limit our business flexibility and affect the market price of our common stock.

For so long as at least 20% of the shares of Series B Preferred Stock are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least a majority of the then outstanding shares of Series B Preferred Stock:

- amend the Certificate of Designation of the Series B Preferred Stock;
- amend our certificate of incorporation (including by filing any new certificate of designation or elimination) or our bylaws, in a manner that adversely affects the rights, preference or privileges of the Series B Preferred Stock;
- increase or decrease the authorized number of shares of Series B Preferred Stock or issue additional shares of Series B Preferred Stock, other than to the investors;
- authorize, create, issue or obligate us to issue (by reclassification, merger or otherwise) any security (or any class or series thereof) or any indebtedness, in each case that has any rights, preferences or privileges senior to, or on a parity with, the Series B Preferred Stock, or any security convertible into or exercisable for any such security or indebtedness, subject to certain exceptions;
- redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any shares of capital stock, subject to certain exceptions;
- declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series B Preferred Stock is made pursuant to the Certificate of Designation of the Series B Preferred Stock; or
- incur any indebtedness in excess of $5,000,000 or any secured indebtedness other than as permitted by the Certificate of Designation of the Series B Preferred Stock.

There is no guarantee that the holders of the Series B Preferred Stock would approve any such restricted action, even where such an action would be in the best interests of our stockholders. Any failure to obtain such approval could harm our business and result in a decrease in the value of our common stock.

Our failure to meet the continued listing requirements of The Nasdaq Global Market could result in a delisting of our common stock and make harder for shareholders to trade in our common stock.

Our common stock is listed on Nasdaq, which imposes, among other requirements, a minimum bid price requirement and a minimum market value requirement. In 2019 we failed on three occasions to meet the standards for continued listing on Nasdaq. If the closing bid price for our common stock is less than $1.00 per share for 30 consecutive business days or the total market value of our publicly held shares closes at less than $15 million for 30 consecutive business days, Nasdaq may send us a notice stating we will be provided a period of 180 days to regain compliance with these requirements or else Nasdaq may make a determination to delist our common stock.

On March 23, 2023, we received a notice (the MVPHS Notice) from Nasdaq, stating that our listed securities failed to comply with the $15 million market value of publicly held shares (Market Value of Publicly Held Shares) requirement for continued listing on The Nasdaq Global Market in accordance with Nasdaq Listing Rule 5450(b)(2)(C) based on our Market Value of Publicly Held Shares for the 30 consecutive business days prior to the date of the MVPHS Notice.

In accordance with Nasdaq Listing Rule 5810(c)(3)(D), we have been provided a period of 180 calendar days from the date of the MVPHS Notice, or until September 19, 2023, in which to regain compliance (the Compliance Period). In order to regain compliance, our Market Value of Publicly Held Shares must close at $15.0 million or more for a minimum of ten consecutive trading days during the Compliance Period. We intend to consider our available options to resolve this noncompliance, but there can be no assurance that we will be able to regain compliance with the Market Value of Publicly Held Shares requirement or maintain compliance with other Nasdaq listing requirements.

In the event that we do not regain compliance within the Compliance Period, we may be eligible to transfer to The Nasdaq Capital Market before the expiry of the Compliance Period. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are not otherwise eligible, Nasdaq will provide notice to us that our common stock will be subject to delisting. In the event of such notification, we may appeal Nasdaq's determination to delist its securities, but there can be no assurance Nasdaq would grant our request for continued listing.

The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future. Such a delisting would likely have a negative effect on the price of our common stock and would impair our stockholders' ability to sell or purchase our common stock when they wish to do so. Further, if we were to be delisted from Nasdaq, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities. Even if we regain compliance, there is no assurance that any actions that we take to restore our compliance with Nasdaq's listing requirements would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from remaining below the Market Value of Publicly Held Shares required for continued listing or prevent future non-compliance with Nasdaq's listing requirements. Delisting may also result in our common stock trading on the over-the-counter market, which may be a less liquid market. In such case, our stockholders' ability to trade, or obtain quotations of the market value of, shares of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities.

In addition to the foregoing, if our common stock is delisted from Nasdaq and it trades on the over-the-counter market, the application of the "penny stock" rules could adversely affect the market price of our common stock and increase the transaction costs to sell those shares. The SEC has adopted regulations which generally define a "penny stock" as an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The last reported trade of our common stock on The Nasdaq Global Market was at a price below $5.00 per share. If our common stock is delisted from Nasdaq and it trades on the over-the-counter market at a price of less than $5.00 per share, our common stock would be considered a penny stock. The SEC's penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's agreement to the transaction. If applicable in the future, these rules may restrict the ability of brokers-dealers to sell our common stock and may affect the ability of investors to sell their shares, until our common stock no longer is considered a penny stock.

As long as we remain subject to the rules of Nasdaq, we will be unable to access equity capital without stockholder approval if such equity capital sales would result in an equity issuance above regulatory thresholds and consequently, we may be unable to obtain financing sufficient to sustain our business if we are unsuccessful in soliciting requisite stockholder approvals.

Our ability to access equity capital is subject to Nasdaq Listing Rule 5653(d), commonly referred to as the Nasdaq 20% Rule, which requires stockholder approval of a transaction other than a public offering involving the sale, issuance, or potential issuance by a company of common stock (or securities convertible into or exercisable for common stock) equal to 20% or more of the common stock, or 20% or more of the voting power outstanding before the issuance for less than the greater of book or market value of the shares. The operation of the Nasdaq 20% Rule could limit our ability to raise capital through issuance of common stock or convertible securities without jeopardizing our listing status. If we were to violate the Nasdaq 20% Rule, our common stock would be subject to delisting from Nasdaq and share prices and trading volumes would likely suffer.

Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.

The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. The trading price of our common stock has from time to time been and may in the future be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including those discussed in this "Risk Factors" section.

From time to time, we estimate the timing of the accomplishment of various regulatory, scientific, clinical and other product development goals or milestones. These milestones may include:

- the submission of regulatory filings,
- the notification of the results of regulatory filings,
- the anticipated commercial launch of ILUVIEN in various new jurisdictions or for new or expanded indications,
- any future products or product candidates and
- the commencement or completion of scientific studies and clinical trials.

Also, from time to time, we publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the further commercialization of ILUVIEN or any future products or product candidates may be delayed.

In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies, including us. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been initiated against these companies. This litigation, if brought against us, could result in substantial costs and a diversion of our management's attention and resources.

Significant sales of our common stock could depress or reduce the market price of our common stock, cause our shares of common stock to trade below the prices at which they would otherwise trade, or impede our ability to raise future capital.

A small number of institutional investors and private equity funds hold a significant number of shares of our common stock and all of our shares of Series B Preferred Stock. Sales by these stockholders of a substantial number of common shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

We may sell securities in the future, if we determine it is appropriate or necessary to do so, which could cause a significant reduction in the market price of our common stock.

In addition to our outstanding common stock, as of December 31, 2022, options to purchase 1,175,339 shares of our common stock were outstanding. Upon the exercise of the stock options in accordance with their terms, the shares so acquired may be resold freely, subject to restrictions imposed on our affiliates under the SEC's Rule 144 and to our securities trading policy. Additionally, Ocumension holds 1,144,945 shares of our common stock, and the lock-up restrictions on those shares have expired. Moreover, as of March 24, 2023, if all of our outstanding Series B Preferred Stock were converted and all of our outstanding warrants to purchase common stock were exercised in full, we would have issued 11,428,572 shares of common stock (without giving effect to any limitation on conversions or exercise). If significant sales of our common stock occur in short periods, this could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms.

Actual or perceived significant sales of our common stock could depress or reduce the market price of our common stock, cause our shares of common stock to trade below the prices at which they would otherwise trade or impede our ability to raise future capital.

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

To the extent we raise additional capital by issuing equity securities; our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, whether in public or private offerings, investors may be diluted by subsequent sales. Those sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders. In addition, the Series B Preferred Stock is entitled to price-based anti-dilution protection in connection with certain financings, which has the potential to further dilute our other stockholders.

Pursuant to the 2019 Omnibus Incentive Plan, our board of directors is authorized to grant various types of equity-based awards, including stock options and RSUs, to our employees, directors and consultants. As of December 31, 2022, a total of 754,033 shares of our common stock were available for issuance under new awards granted under our 2019 Omnibus Incentive Plan.

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

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Further, the rights and preferences of our Series B Preferred Stock and our 2019 Loan Agreement also place limitations on our ability to declare or pay any dividend or distribution on any shares of capital stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Anti-takeover provisions in our charter and bylaws and in Delaware law could prevent or delay acquisition bids for us that stockholders might consider favorable and could entrench current management.

We are a Delaware corporation. The anti-takeover provisions of the Delaware General Corporation Law may deter, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders. In addition, our restated certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our restated certificate of incorporation and bylaws:

- authorize the issuance of "blank check" preferred stock that could be issued by our Board of Directors to thwart a takeover attempt;
- do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of our outstanding common stock to elect some directors;
- establish a classified Board of Directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election;
- require that directors only be removed from office for cause;
- provide that vacancies on the Board of Directors, including newly created directorships, may be filled only by a majority vote of directors then in office;
- contain certain protective provisions in favor of the holders of Series A Convertible Preferred Stock;
- limit who may call special meetings of stockholders;
- prohibit common stockholder action by written consent, requiring all actions of the holders of common stock to be taken at a meeting of the stockholders; and
- establish advance notice requirements for nominating candidates for election to the Board of Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to comply with various securities laws and regulations and Nasdaq listing requirements.

As a public company, we incur significant accounting, legal and other expenses. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and Nasdaq, has imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure controls and procedures, internal controls over financial reporting, and changes in corporate governance practices. Our management and other personnel are required to devote a substantial amount of time and expense to legal compliance.

In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time-consuming. We intend to continue investing in substantial resources to comply with evolving laws, regulations, and standards, and this investment may result in increased expenses and a diversion of management's time and attention from business operations to compliance activities. For example, U.S. and international regulators, investors and other stakeholders are increasingly focused on environmental, social, and governance (ESG) matters. New domestic and international laws and regulations relating to ESG matters, including climate change, cybersecurity, human capital, diversity and sustainability, are under consideration or being adopted, which may include specific, target-driven disclosure requirements or other obligations. Our compliance with such laws and regulations will require additional investments and implementation of new practices and reporting processes, all entailing additional compliance risk. If our efforts to comply with new or existing laws, regulations, and standards differ from the activities

intended by regulatory or governing bodies for any reason, regulatory authorities may initiate legal proceedings against us, our business may be harmed and the market price of our common stock could decline.

We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a smaller reporting company under Rule 12b-2 of the Securities Exchange Act of 1934. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on smaller reporting company exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 2. *PROPERTIES*

In our U.S. segment, our U.S. headquarters is located in Alpharetta, Georgia, consisting of approximately 14,900 square feet of office space. Our lease for this facility expires in December 2032 with an early termination option in December 2029 and an option to extend five years beyond December 2032.

In our international segment, we lease approximately 4,500 square feet of office space in Dublin, Ireland, approximately 1,000 square feet of office space in Berlin, Germany, and approximately 6,000 square feet of office space in Aldershot, U.K. Our leases for these facilities in Ireland and Germany expire in August 2024 and June 2024, respectively. Our lease for the U.K. facility expires in December 2024. We anticipate that following the expiration of these leases, we will be able to lease additional or alternative space at commercially reasonable terms. Additionally, we have an agreement to use approximately 400 square feet of office space in Lisbon, Portugal, which can be terminated with 90 days' notice.

We do not own any real estate.

ITEM 3. *LEGAL PROCEEDINGS*

From time to time, we may become subject to legal proceedings, claims, and litigation arising in the ordinary course of business. We currently are not a party to any threatened or pending material litigation and do not have contingency reserves established for any litigation liabilities. However, third parties might allege that we are infringing their patent rights or that we are otherwise violating their intellectual property rights, including trade names and trademarks. Such third parties may resort to litigation. We accrue contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

ITEM 4. *MINE SAFETY DISCLOSURES*

Not applicable.

PART II

ITEM 5. *MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*

Our common stock is traded on The Nasdaq Global Market (Nasdaq) under the symbol ALIM.

Stockholder Data

As of March 28, 2023, there were 26 holders of record of our common stock, and there were 7,227,094 shares of our common stock issued and outstanding. 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.

Dividends

We have not declared or paid any cash dividends on our common stock since our inception. We do not plan to pay dividends in the foreseeable future. Further, the rights and preferences of our Series B Preferred Stock and our 2019 Loan Agreement also place limitations on our ability to declare or pay any dividend or distribution on any shares of capital stock. We currently intend to retain earnings, if any, to finance our growth. Consequently, stockholders will need to sell shares of our common stock to realize a return on their investment, if any.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by ITEM 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Sales of Unregistered Securities

In 2022, we did not sell any shares of stock that were not registered under the Securities Act of 1933, as amended, other than those sales previously reported in a Current Report on Form 8-K.

ITEM 6. [*RESERVED.*]

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

The following discussion and analysis should be read in conjunction with our audited annual consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those described in Part I, Item 1A, "Risk Factors" and elsewhere in this Annual Report on Form 10-K. For further information regarding forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements and Projections" elsewhere in this Annual Report on Form 10-K.

Overview

Alimera Sciences, Inc., and its subsidiaries (we, our or us), is a commercial-stage, global pharmaceutical company developing and commercializing ILUVIEN for the treatment of diabetic macular edema (DME), a leading cause of blindness, and for non-infectious uveitis affecting the posterior segment of the eye (NIU-PS). ILUVIEN is its state-of-the-art, sustained release intravitreal implant that enables patients to maintain vision longer, and importantly, with fewer injections. We commercialize ILUVIEN in the U.S., Europe, China and Middle East. We are also studying ILUVIEN in a clinical trial, the New Day Study, where it is being evaluated for efficacy as baseline therapy in patients with early DME by comparing ILUVIEN to the current standard of care, anti-VEGF therapy. Alimera's mission is to be invaluable to patients, physicians and partners concerned with retinal health and maintaining better vision longer.

Recent Developments

Securities Purchase Agreement

On March 24, 2023, we entered into a Securities Purchase Agreement (the Purchase Agreement) with certain investors for the sale of up to 27,000 shares of our newly designated Series B Convertible Preferred Stock, par value $0.01 per share (the Series B Preferred Stock) and warrants (the Warrants) to purchase up to 5,714,286 shares of our common stock, for an aggregate purchase price of up to $27.0 million in two tranches. On March 24, 2023 (the Tranche 1 Closing Date), we issued and sold an aggregate of 12,000 shares of Series B Preferred Stock at a per-share purchase price of $1,000 (the Stated Value) and the Warrants

for aggregate gross proceeds of $12.0 million (the Tranche 1 Closing). The proceeds from the Tranche 1 Closing will be used to fund development and commercialization of our existing and pipeline drugs, maintenance of our credit facility and corporate purposes substantially related to the commercialization of our existing and pipeline drugs, as well as the Repurchase (as defined below).

At the closing of the second tranche (the Tranche 2 Closing), we will issue and sell an aggregate of 15,000 shares of Series B Preferred at a per-share purchase price equal to the Stated Value for aggregate gross proceeds of $15.0 million. The Tranche 2 Closing will only occur upon the mutual agreement of us and the holders of a majority of the outstanding Series B Preferred Stock (the Preferred Majority); provided that the closing shall occur no later than December 31, 2023, if at all. The proceeds from the Tranche 2 Closing, if any, will be used to fund potential in-licenses or acquisitions of new technologies, products or businesses in ophthalmology, subject to applicable Nasdaq listing rules. If Stockholder Approval (as defined below) is obtained prior to the Tranche 2 Closing, the securities issued and sold at the Tranche 2 Closing will be shares of common stock rather than shares of Series B Preferred.

Pursuant to the Purchase Agreement, each investor has certain participation rights in our future financings, and also has the right to designate a member of our Board of Directors (the Board) so long as such investor beneficially holds 50% or more of the shares of common stock (calculated on an as-converted basis) it acquired pursuant to the Purchase Agreement. Effective as of the Tranche 2 Closing, the investors will have the right to designate one additional individual mutually agreed upon by the investors for election to the Board, subject to applicable Nasdaq listing rules.

We intend to hold a meeting of our stockholders to approve the issuance of common stock upon conversion of the Series B Preferred Stock and exercise of the Warrants in excess of the Change of Control Cap and the Exchange Cap (each as defined and described below) (such meeting, the Stockholder Meeting and such approval, the Stockholder Approval). Prior to the conclusion of the Stockholder Meeting, the Series B Preferred Stock is not convertible into common stock. If Stockholder Approval is obtained, all of the outstanding Series B Preferred Stock will automatically convert into shares of common stock. If Stockholder Approval is not obtained at the Stockholder Meeting, following such meeting, each share of Series B Preferred Stock will be convertible, at the option of the holder, into shares of common stock, subject to the Change of Control Cap and the Exchange Cap.

The initial conversion price of the shares of Series B Preferred Stock issued at the Tranche 1 Closing is $2.10 (the Tranche 1 Conversion Price). The shares of Series B Preferred Stock issued at the Tranche 2 Closing, if any, will have an initial conversion price equal to the 30-day preceding volume-weighted average price of the common stock on Nasdaq, but in any event (i) no less than eighty percent (80%) of the Tranche 1 Conversion Price per share nor (ii) greater than two-times the Tranche 1 Conversion Price per share. In each case, the conversion price of the Series B Preferred Stock is subject to certain customary adjustments, including a weighted average anti-dilution adjustment.

Unless and until Stockholder Approval is obtained, the Series B Preferred Stock will not be convertible into common stock to the extent that such conversion would cause (i) the aggregate number of shares of common stock that would be issued pursuant to the Purchase Agreement and the transactions contemplated thereby to exceed 1,401,901 (19.99% of the voting power or number of shares of common stock, issued and outstanding immediately prior to the execution of the Purchase Agreement), which number will be reduced, on a share-for-share basis, by the number of shares of common stock issued or issuable pursuant to any transactions that may be aggregated with the transactions contemplated by the Purchase Agreement under applicable Nasdaq rules (the Exchange Cap); or (ii) the aggregate number of shares of common stock that would be issued pursuant to such conversion, when aggregated with any shares of common stock then beneficially owned by the holder (or group of holders required to be aggregated) of such shares, would result in (a) a “change of control” under applicable Nasdaq listing rules (the Change of Control Cap) or (b) such holder or a “person” or “group” to beneficially own in excess of 9.99% of the common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon such conversion (the Ownership Limitation).

The Series B Preferred Stock will be entitled to receive dividends and other distributions pro rata with the common stock. In addition, prior to conversion, dividends will accrue on the Series B Preferred at an annual rate of 6% of the Stated Value, accruing daily. The Series B Preferred Stock is not redeemable.

The Warrants have an exercise price equal to the Tranche 1 Conversion Price (as adjusted pursuant to the Certificate of Designation of the Series B Preferred Stock through the date of Stockholder Approval) and expire seven years from the date of the Tranche 1 Closing. The Warrants are exercisable upon the earlier of (a) a change of control and (b) March 24, 2024; provided that prior to Stockholder Approval, exercise of the Warrants is subject to the Ownership Limitation, the Change of Control Cap and the Exchange Cap. If we consummate the Tranche 2 Closing or a qualified financing transaction of at least $15.0 million prior to December 31, 2023, the number of shares underlying the Warrants will automatically be reduced to an aggregate of 1.0 million shares of common stock.

Repurchase and Elimination of Series A Convertible Preferred Stock

As a condition to closing the Transactions, we repurchased all 200,919 shares of common stock and 600,000 shares of our Series A Convertible Preferred Stock (the Series A Preferred) held by the holders thereof (the Repurchase), for an aggregate purchase price of approximately $1.25 million. The holders of the Series A Preferred were entitled to a liquidation preference before the holders of common stock would be entitled to receive any consideration in the event of our liquidation. As of December 31, 2022, the Series A Preferred aggregate liquidation preference was approximately $24 million. As a result of the Repurchase, no shares of the Series A Preferred remain outstanding and the liquidation preference is no longer in effect.

Fifth Amendment to Loan and Security Agreement and Exit Fee Agreement

On March 24, 2023, we entered into the Fifth Amendment (the Amendment) to our Loan and Security Agreement dated December 31, 2019, with SLR Investment Corp. (SLR) as collateral agent, and the lenders party thereto, including SLR as a lender (as amended from time to time, the 2019 Loan Agreement).

Pursuant to the Amendment, the lenders have agreed to, among other things, (i) an additional tranche of $2,500,000 to increase our existing term loan facility to $47.5 million, subject to certain closing conditions (the New Term Loan), and (ii) extend a $15.0 million additional term loan available to be funded at the lenders' sole discretion. The New Term Loan will bear interest at an annual rate equal to 5.15% plus the greater of (i) 4.60% and (ii) one-month SOFR, which will reset monthly. The Amendment extends the maturity date to April 30, 2028, and the interest-only period to April 30, 2025. The interest-only period may be extended an additional 12 months if we meet certain financial targets by March 31, 2025. In addition, the Amendment specifies the minimum net product revenue levels, calculated on a trailing six-month basis beginning with the six-month period ended March 31, 2023, and tested at the end of each calendar quarter, that we must achieve for each such period. We also agreed to grant to the collateral agent (for the benefit of the lenders) a first-priority security interest in all of our intellectual property.

We are obligated to pay additional fees under the Fifth Amendment Exit Fee Agreement (the New Exit Fee Agreement) dated as of March 24, 2023, with SLR as collateral agent, and the lenders party thereto. The New Exit Fee Agreement will survive the termination of the 2019 Loan Agreement and has a term of 10 years. We will be obligated to pay an exit fee of 1.5% of the original principal amount funded under the 2019 Loan Agreement upon the occurrence of an exit event, which generally means a change in control. If we have not already paid the exit fee, we will also be obligated to pay an equivalent fee upon achieving revenues of $82.5 million or more from the sale of ILUVIEN in the ordinary course of business, measured on a trailing 12-month basis.

ILUVIEN

Our only current product is ILUVIEN®, which has received marketing authorization and reimbursement in numerous countries for the treatment of diabetic macular edema (DME). In the U.S. and certain other countries outside Europe, ILUVIEN is indicated for the treatment of DME in patients that have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. In 17 countries in Europe, ILUVIEN is indicated for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. ILUVIEN is also now indicated in 17 European countries and reimbursed in nine countries in Europe for prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye (NIU-PS).

We market ILUVIEN directly in the U.S., Germany, the U.K., Portugal and Ireland. In addition, we have entered into various agreements under which distributors are providing or will provide regulatory, reimbursement and sales and marketing support for ILUVIEN in Austria, Belgium, the Czech Republic, Denmark, Finland, France, Italy, Luxembourg, the Netherlands, Norway, Spain, Sweden, Switzerland, Australia, New Zealand, China and several countries in the Western Pacific and several countries in the Middle East. As of December 31, 2022, we have recognized net product revenue from our international distributors in the Middle East, China, Austria, Belgium, Czech Republic, France, Italy, Luxembourg, Spain and the Netherlands.

Sources of Revenues

We generate revenue from ILUVIEN, our only product. In addition to generating revenue from product sales, we intend to seek to generate revenue from other sources such as upfront fees, milestone payments in connection with collaborative or strategic relationships, and royalties resulting from the licensing of ILUVIEN or any future product candidates and other intellectual property. Additionally, revenue from our international distributors fluctuates depending on the timing of the shipment of ILUVIEN to the distributors and the distributors' sales of ILUVIEN to their customers.

Our revenues for the fiscal years ended December 31, 2022 and 2021 were generated from (a) product sales primarily in the U.S., Germany and the U.K., (b) for 2021, the recognition of $1.0 million of deferred revenue associated with the termination of our Canadian distribution agreement with Knight Therapeutics, and (c) for 2021, the upfront license payment under the Ocumension License Agreement which resulted in license revenue of approximately $11.0 million. The upfront license payment under the Ocumension License Agreement was our only licensing revenue for 2021.

In the U.S., two large pharmaceutical distributors accounted for 63% and 55% of our consolidated product revenues for the years ended December 31, 2022 and 2021, respectively. These U.S.-based distributors purchase ILUVIEN from us, maintain inventories of ILUVIEN and sell on to physician offices, pharmacies and hospitals. Internationally, in countries where we sell direct, our customers are hospitals, clinics and pharmacies. We sometimes refer to physician offices, pharmacies, hospitals and clinics as end users. In international countries where we sell to distributors, these distributors purchase ILUVIEN from us and maintain inventories of ILUVIEN that they sell to their customers.

License Agreement with EyePoint Pharmaceuticals US, Inc.

In July 2017, we amended and restated our license agreement with EyePoint Pharmaceuticals US, Inc. (EyePoint) (the New Collaboration Agreement). Under the New Collaboration Agreement, we hold a worldwide license from EyePoint for the use of steroids, including FAc, in EyePoint's proprietary insert technology for the treatment of all ocular diseases, other than uveitis, outside of Europe, the Middle East and Africa. The New Collaboration Agreement converted our previous profit share obligation to a royalty payable on global net revenues of ILUVIEN.

The New Collaboration Agreement included a right to offset $15.0 million of future royalty payments (the Future Offset). As of December 31, 2022, the balance of the Future Offset was approximately $7.0 million, which is fully reserved. See Note 10 to the accompanying consolidated financial statements.

We will be able to recover the balance of the Future Offset as a reduction of future royalties that would otherwise be owed to EyePoint by reducing the royalty owed from 6% to 5.2% for net revenues and other related consideration up to $75.0 million annually and from 8% to 6.8% for net revenues and other related consideration in excess of $75.0 million on an annual basis.

During 2022 and 2021, we recognized approximately $2.8 million and $2.9 million of royalty expense, respectively, which amounts reflect the reductions in the royalty percentage noted above and the corresponding reductions in the Future Offset.

Transactions with Ocumension Therapeutics

On April 14, 2021, we entered into a transaction with Ocumension Therapeutics (Ocumension). In the Ocumension transaction, we received a total of $20.0 million in cash under two agreements:

- an Exclusive License Agreement (the Ocumension License Agreement) with a wholly owned subsidiary of Ocumension, pursuant to which we granted an exclusive license for the development and commercialization of our 190 microgram fluocinolone acetonide intravitreal implant in applicator under Ocumension's own branded label in China, East Asia, and the Western Pacific, in exchange for a nonrefundable upfront payment of $10.0 million and aggregated potential sales milestone payments of up to $89.0 million upon achievement by the Ocumension subsidiary of specified amounts of net sales of the licensed product in in the future. We recognized $11.0 million in license revenue from the Ocumension transaction (including the value of a warrant subscription agreement, which we received as consideration, to purchase 1,000,000 shares of Ocumension Therapeutics during a period of four years), in accordance with ASC 606, Revenue from Contracts with Customers, with the remaining approximate $300,000 in consideration received classified as deferred revenue that will be recognized over the remaining term of the license agreement once Ocumension begins to sell products. Revenue from the Ocumension License Agreement is included within net revenue in the accompanying consolidated statements of operations; and
- a Share Purchase Agreement with Ocumension, pursuant to which we offered and sold to Ocumension 1,144,945 shares of our common stock at a purchase price of $8.734044 per share, or $10.0 million in total.

Results of Operations - Year ended December 31, 2022 compared to year ended December 31, 2021

	Years Ended December 31,	
	2022	**2021**
	(In thousands, except share and per share data)	
REVENUE:		
PRODUCT REVENUE, NET	$ 54,129	$ 47,981
LICENSE REVENUE	—	11,048
NET REVENUE	54,129	59,029
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(7,977)	(7,030)
GROSS PROFIT	46,152	51,999
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	16,228	13,778
GENERAL AND ADMINISTRATIVE EXPENSES	12,871	12,774
SALES AND MARKETING EXPENSES	25,987	23,069
DEPRECIATION AND AMORTIZATION	2,706	2,579

OPERATING EXPENSES	57,792	52,200
LOSS FROM OPERATIONS	(11,640)	(201)
INTEREST EXPENSE AND OTHER	(5,881)	(5,413)
UNREALIZED FOREIGN CURRENCY GAIN, NET	92	416
GAIN ON EXTINGUISHMENT OF DEBT	—	1,792
CHANGE IN FAIR VALUE OF WARRANT ASSET	(650)	(528)
NET LOSS BEFORE TAXES	(18,079)	(3,934)
PROVISION FOR TAXES	(28)	(438)
NET LOSS	(18,107)	(4,372)
NET LOSS PER SHARE — Basic and diluted	$ (2.59)	$ (0.66)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	6,996,850	6,595,237

Revenue

Product revenue, net, associated with ILUVIEN sales, increased by approximately $6.1 million, or 13%, to approximately $54.1 million for 2022, compared to approximately $48.0 million in 2021. The increase was primarily attributable to increased unit sales volume.

Net revenue decreased by approximately $4.9 million, or 8%, to approximately $54.1 million for 2022, compared to approximately $59.0 million for 2021. The 2022 decrease was primarily attributable to (a) the $11.0 million of recognized license revenue from our transactions with Ocumension and (b) the recognition of $1.0 million in deferred product revenue associated with the termination of our Canadian distribution agreement with Knight Therapeutics, both of which were recognized during the year ended December 31, 2021. These decreases were partially offset by an increase of approximately $7.1 million of net product revenue associated with ILUVIEN sales in 2022, as described above.

Cost of Goods Sold, Excluding Depreciation and Amortization, and Gross Profit

Gross profit is affected by costs of goods sold, which includes costs of manufactured goods sold and royalty payments to EyePoint under the New Collaboration Agreement. Additionally, cost of goods sold by our international distributors fluctuates depending on the revenue share attributable to the respective contract.

Cost of goods sold, excluding depreciation and amortization increased by approximately $1.0 million, or 14%, to approximately $8.0 million for 2022, compared to approximately $7.0 million for 2021. The increase was primarily attributable to our increased net product revenue in 2022 as compared to 2021.

Gross profit decreased by approximately $5.8 million, or 11%, to approximately $46.2 million for 2022, compared to approximately $52.0 million for 2021. Gross margin was 85% and 88% for 2022 and 2021, respectively. While the license revenue we recognized in 2021 had no product cost of goods sold associated with it, we did have additional royalty expense that reduced our total gross margin for 2021. The decrease in gross profit in 2022 was attributable to the decrease in net revenue of $4.9 million and the increase in cost of goods sold of $1.0 million.

Research, Development and Medical Affairs Expenses

Currently, our research, development and medical affairs expenses are primarily focused on activities that support ILUVIEN and include salaries and related expenses for research and development and medical affairs personnel, expenses related to clinical trials including the NEW DAY Study, and expenses tied to physician engagement by our medical sciences liaisons. Our research, development and medical affairs expenses also include costs related to symposia development for physician education, and costs related to compliance with FDA, EEA or other regulatory requirements.

Research, development and medical affairs expenses increased by approximately $2.4 million, or 17%, to approximately $16.2 million for 2022, compared to approximately $13.8 million for 2021. The increase was primarily attributable to increases of approximately $1.0 million in inserter component manufacturing costs, $720,000 of personnel and travel costs, $520,000 of clinical study costs related to increased enrollment in our NEW DAY Study and $130,000 in scientific communication costs.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and administrative functions, including finance, accounting, information technology and human resources. Other significant costs include facilities costs and professional fees for accounting and legal services, including legal services associated with obtaining and maintaining patents. We expect to continue to incur significant costs to comply with the corporate governance, internal control and similar requirements applicable to public companies.

General and administrative expenses increased by approximately $100,000 , or 1%, to approximately $12.9 million for 2022, compared to approximately $12.8 million for 2021.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation for employees for commercial promotion of ILUVIEN, including the assessment of the commercial opportunity, development of market awareness, pursuit of reimbursement approval and commercialization generally, including launch plans in new markets. Other costs include third party service fees, professional fees associated with developing marketing strategies for ILUVIEN and maintaining public relations.

Sales and marketing expenses increased by approximately $2.9 million, or 13%, to approximately $26.0 million for 2022, compared to approximately $23.1 million for 2021. The increase was primarily attributable to increases of approximately $1.9 million in marketing costs, including costs to attend conventions, costs related to our direct to patient marketing campaign and costs associated with customer engagement which has contributed to our increase net product revenue and $1.2 million of added personnel costs, including commissions, and travel expenses.

Operating Expenses

Primarily as a result of the changes in expenses described above, total operating expenses increased by approximately $5.6 million, or 11%, to approximately $57.8 million for 2022, compared to approximately $52.2 million for 2021.

Interest Expense and Other

Interest expense and other consists primarily of interest and amortization of deferred financing costs and debt discounts associated with our outstanding debt under the 2019 Loan Agreement.

Interest expense and other increased by approximately $500,000 or 9%, to approximately $5.9 million for 2022, compared to $5.4 million for 2021. The increase was primarily attributable to the increasing interest rate on the 2019 Loan Agreement. For more detailed information, see Note 12 of our notes to consolidated financial statements below.

Basic and Diluted Net Loss Applicable to Common Stockholders per Share of Common Stock

We follow FASB ASC, *Earnings Per Share* (ASC 260), which requires the reporting of both basic and diluted earnings per share (EPS). Because our preferred stockholders participate in dividends equally with common stockholders (if we were to declare and pay dividends), we use the two-class method to calculate EPS. However, our preferred stockholders are not contractually obligated to share in losses.

Basic EPS is computed by dividing net loss available to stockholders by the weighted average number of shares outstanding for the period. Diluted EPS is calculated in accordance with ASC 260 by adjusting weighted average shares outstanding for the dilutive effect of common stock options, restricted stock units and warrants. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be anti-dilutive.

Weighted average shares outstanding increased by approximately 400,000 shares to approximately 7.0 million for 2022 compared to approximately 6.6 million for 2021. The increase was primarily attributable to an increase in our common shares outstanding, including the issuance of 1,144,945 common shares in accordance with the Share Purchase Agreement with Ocumension in April 2021, which were outstanding for the full year ended December 31, 2022.

Results of Operations - Segment Review

The following selected unaudited financial and operating data are derived from our consolidated financial statements. The results and discussions that follow reflect how executive management monitors the performance of our reporting segments.

Our U.S. and International segments represent the sales and marketing, general and administrative and research and development activities dedicated to the respective geographies. The Operating Cost segment primarily represents the general and administrative and research and development activities not specifically associated with the U.S. or International segments and includes expenses such as executive management; information technology administration and support; legal; compliance; clinical studies; and business development. In monitoring performance, aligning strategies and allocating resources, our CODM manages and evaluates our U.S., International and Operating Cost segments based on segment income or loss from operations adjusted for certain non-cash items, such as stock-based compensation expense and depreciation and amortization. Therefore, we classify within Other (a) the non-cash expenses included in research, development and medical affairs expenses; general and administrative expenses; and sales and marketing expenses; and (b) depreciation and amortization.

Each of our U.S., International and Operating Cost segments is separately managed and is evaluated primarily upon segment income or loss from operations. Other is presented to reconcile to our consolidated totals. For that reconciliation, please see Note 19 of the accompanying consolidated financial statements. We do not report balance sheet information by segment because our CODM does not review that information. We allocate certain operating expenses among our reporting segments based on activity-based costing methods. These activity-based costing methods require us to make estimates that

affect the amount of each expense category that is attributed to each segment. Changes in these estimates will directly affect the amount of expense allocated to each segment and therefore the operating profit of each reporting segment.

U.S. Segment

	Years Ended December 31,	
	2022	2021
	(In thousands)	
REVENUE:		
PRODUCT REVENUE, NET	$ 34,202	$ 26,740
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(4,165)	(3,298)
GROSS PROFIT	30,037	23,442
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	5,036	3,628
GENERAL AND ADMINISTRATIVE EXPENSES	1,238	969
SALES AND MARKETING EXPENSES	17,898	15,348
OPERATING EXPENSES	24,172	19,945
SEGMENT INCOME FROM OPERATIONS	$ 5,865	$ 3,497

U.S. Segment - Year ended December 31, 2022 compared to year ended December 31, 2021

Product Revenue, net. Product revenue, net increased by approximately $7.5 million, or 28%, to approximately $34.2 million for 2022, compared to approximately $26.7 million for 2021. The increase was primarily attributable to our end user demand, which increased 23% in 2022 to 4,053 units compared to 3,287 units for 2021 as we focused on increasing face-to-face interactions with customers across multiple formats and the publication of our PALADIN Study. End user demand represents units purchased by physicians and pharmacies from our distributors.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately $900,000, or 27%, to approximately $4.2 million for 2022 compared to approximately $3.3 million for 2021. The increase was primarily attributable to our increased product demand.

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately $1.4 million, or 39%, to approximately $5.0 million for 2022, compared to approximately $3.6 million for 2021. The increase was primarily attributable to increases of approximately $1.1 million in personnel and travel costs and $170,000 in scientific communication costs.

General and administrative expenses. General and administrative expenses decreased by approximately $230,000, or 24%, to approximately $1.2 million for 2022, compared to approximately $970,000 for 2021.

Sales and marketing expenses. Sales and marketing expenses increased by approximately $2.6 million, or 17%, to approximately $17.9 million for 2022, compared to approximately $15.3 million for 2021. The increase was primarily attributable to increases of approximately $1.4 million in marketing costs, including costs to attend conventions, and costs related to our direct to patient marketing campaign and $1.1 million in added personnel costs including increased commissions and travel expenses.

International Segment

	Years Ended December 31,	
	2022	2021
	(In thousands)	
REVENUE:		
PRODUCT REVENUE, NET	$ 19,927	$ 21,241
LICENSE REVENUE	—	11,048
NET REVENUE	19,927	32,289
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(3,812)	(3,732)
GROSS PROFIT	16,115	28,557
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	3,470	4,197
GENERAL AND ADMINISTRATIVE EXPENSES	1,740	1,322
SALES AND MARKETING EXPENSES	7,356	6,953
OPERATING EXPENSES	12,566	12,472
SEGMENT INCOME FROM OPERATIONS	$ 3,549	$ 16,085

International Segment - Year ended December 31, 2022 compared to year ended December 31, 2021

Net Revenue. Net revenue decreased by approximately $12.4 million, or 38%, to approximately $19.9 million for 2022, compared to approximately $32.3 million for 2021. International net revenue in 2021 was composed of $21.2 million in product revenue and $11.0 million in license revenue from the Ocumension transaction, which was recognized in 2021, but not in 2022.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately $100,000, or 3%, to approximately $3.8 million for 2022, compared to approximately $3.7 million for 2021.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately $700,000, or 17%, to approximately $3.5 million for 2022, compared to approximately $4.2 million for 2021. The decrease was primarily attributable to decreases of approximately $320,000 in consultant costs including pharmacovigilance consultants and $250,000 in personnel costs.

General and administrative expenses. General and administrative expenses increased by approximately $400,000, or 31%, to approximately $1.7 million for 2022, compared to approximately $1.3 million for 2021. The increase was primarily attributable to a recovery of value added tax expense during 2021.

Sales and marketing expenses. Sales and marketing expenses increased by approximately $400,000, or 6%, to approximately $7.4 million for 2022, compared to approximately $7.0 million for 2021. The increase was primarily attributable to increases of approximately $480,000 in marketing costs, including costs to attend conventions and $150,000 in personnel costs including increased commissions and travel expenses, partially offset by a decrease of approximately $140,000 in market access costs.

Operating Cost Segment

	Years Ended December 31,	
	2022	2021
	(In thousands)	
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	$ 7,657	$ 5,850
GENERAL AND ADMINISTRATIVE EXPENSES	9,258	9,828
SALES AND MARKETING EXPENSES	523	529
OPERATING EXPENSES	17,438	16,207
SEGMENT LOSS FROM OPERATIONS	$ (17,438)	$ (16,207)

Operating Cost Segment - Year ended December 31, 2022 compared to year ended December 31, 2021

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately $1.8 million, or 31%, to approximately $7.7 million for 2022, compared to approximately $5.9 million for 2021. The increase was primarily attributable to increases of approximately $1.0 million in inserter component manufacturing costs and $520,000 of clinical study costs, including costs associated with our NEW DAY Study.

General and administrative expenses. General and administrative expenses decreased by approximately $500,000 or 5%, to approximately $9.3 million for 2022, compared to approximately $9.8 million for 2021. The decrease was primarily attributable to decreases of $370,000 of professional fees and $270,000 in personnel and travel expenses.

Sales and marketing expenses. Sales and marketing expenses decreased by approximately $10,000, or 2%, to approximately $520,000 for 2022, compared to approximately $530,000 for 2021. These costs are tied to executive management of our global sales and marketing.

Other

	Years Ended December 31,	
	2022	2021
	(In thousands)	
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	$ 65	$ 103
GENERAL AND ADMINISTRATIVE EXPENSES	635	655
SALES AND MARKETING EXPENSES	210	239
DEPRECIATION AND AMORTIZATION	2,706	2,579
OPERATING EXPENSES	3,616	3,576
SEGMENT LOSS FROM OPERATIONS	$ (3,616)	$ (3,576)

Other - Year ended December 31, 2022 compared to year ended December 31, 2021

In monitoring performance, aligning strategies and allocating resources, our CODM manages and evaluates our U.S., International and Operating Cost segments based on segment income or loss from operations adjusted for certain non-cash items, such as stock-based compensation expense and depreciation and amortization. Therefore, we classify within Other (a) the non-cash expenses included in research, development and medical affairs expenses, general and administrative expenses, and sales and marketing expenses; and (b) depreciation and amortization. Other is presented to reconcile to our consolidated totals.

Operating expenses. Operating expenses in Other was approximately $3.6 million for both of the years ended 2022, and 2021.

Depreciation and amortization. Depreciation and amortization was approximately $2.7 million for 2022 and approximately $2.6 million for 2021.

Liquidity and Capital Resources

Overview

Since inception, we have incurred recurring losses, negative cash flow from operations and have accumulated a deficit in stockholders' equity of $415.4 million as of December 31, 2022. As of December 31, 2022, we had approximately $5.3 million in cash and cash equivalents. In mid-April 2021 we received a total of $20.0 million in cash from the Ocumension transaction described above. We have used and plan to continue to use these funds to continue to commercialize ILUVIEN, to fund our NEW DAY Study and for general corporate purposes, which may include working capital, debt maintenance, capital expenditures, other clinical trial expenditures, acquisitions of new technologies, products or businesses in ophthalmology, and investments.

Since January 2020, we have primarily funded our operations through cash from our product sales, the net proceeds of the 2019 Loan Agreement (discussed below) and the $20.0 million in funds we obtained in April 2021 as a result of the Ocumension transaction.

The 2019 Loan Agreement does not include a revolving loan feature and has been fully advanced by the lenders. We currently have no additional borrowing capacity, and the 2019 Loan Agreement generally prohibits any additional debt unless we obtain the prior consent of the lenders.

Indebtedness

Loans from SLR Investment Corp. (SLR, formerly known as Solar Capital Ltd.).

In December 2019, we refinanced our previously outstanding debt facility by entering into a $45.0 million loan and security agreement (the 2019 Loan Agreement) with SLR, as Agent, and the parties signing the loan agreement from time to time as Lenders, including SLR in its capacity as a Lender (collectively, the Lenders). Under the 2019 Loan Agreement, we borrowed $42.5 million on December 31, 2019 and borrowed the remaining $2.5 million on February 21, 2020, totaling $45.0 million. The 2019 Loan Agreement has been amended on multiple occasions.

On February 22, 2022, we entered into a Third Amendment to the 2019 Loan Agreement (the Third Amendment), which, among other things:

(a) specified the minimum revenue amount, calculated on a trailing six-month basis and tested at the end of each calendar quarter in 2022, that we must achieve for each such period (the Third Revenue Covenant);

(b) consented to our maintaining a lower minimum revenue amount under the Third Revenue Covenant for the trailing six month period ended December 31, 2021 than previously required under the 2019 Loan Agreement (and waived any event of default that may have occurred or may be deemed to have occurred as a result of our lower revenue amount for that period); and

(c) required that the Third Revenue Covenant be tested at March 31, 2023 and at the last day of each quarter thereafter, with the minimum revenue amount equal to a percentage of our projected revenues in accordance with an annual plan submitted by us to the Collateral Agent by January 15 of such year, such plan to be thereafter approved by the Board and the Collateral Agent in its sole discretion no later than February 28 of such year.

On December 7, 2022, we entered into a Fourth Amendment to the 2019 Loan Agreement (the Fourth Amendment), which, among other things:

(a) extended the amortization date from January 1, 2023 to April 1, 2023, provided that such date could be further extended to July 1, 2023 upon our request and in consultation with the Lenders, in each of the Lenders' sole discretion;

(b) specified the minimum revenue amount, calculated on a trailing six-month basis and tested at the end of each calendar quarter in 2023, that we must achieve for each such period (the Fourth Revenue Covenant); and

(c) required that the Fourth Revenue Covenant be tested at March 31, 2024 and at the last day of each quarter thereafter, with the minimum revenue amount equal to a percentage of our projected revenues in accordance with an annual plan submitted by us to the Collateral Agent by January 15th of such year, such plan to be thereafter approved by the Board and the Collateral Agent in its sole discretion no later than February 28 of such year.

On March 24, 2023, we entered into a Fifth Amendment to the 2019 Loan Agreement, as described under "—Recent Developments".

Interest on the 2019 Loan Agreement is payable at an annual rate equal to 5.15% plus the greater of (i) 4.60% and (ii) one-month SOFR, which will reset monthly. The 2019 Loan Agreement provides for interest only payments until April 30, 2025, which may be extended an additional 12 months if we meet certain financial targets by March 31, 2025, followed by monthly payments of principal and interest through the loan maturity date of April 30, 2028.

The Federal Reserve raised interest rates seven times in 2022, and has indicated it may continue to do so to combat the effects of inflation, which is currently higher than it has been since the early 1980s. An increase in SOFR would increase our interest costs. Significant increases in our interest costs could materially and adversely affect our results of operations and our ability to pay amounts due under the 2019 Loan Agreement, and any increase in the interest we pay would reduce our cash available for working capital, acquisitions, and other uses.

During 2022, we maintained compliance with the Third Revenue Covenant at each reportable date. We expect to comply with the Fourth Revenue Covenant throughout 2023. If we fail to comply with the Fourth Revenue Covenant and the lenders do not provide a consent and waiver, acceleration of the maturity of the loan is one of the remedies available to the lenders. If the lenders accelerate the maturity of the loan, we would be forced to find alternative financing or enter into an alternative agreement with the lenders. We cannot be sure that alternative financing will be available when needed or that, if available, the alternative financing could be obtained on terms that are not significantly detrimental to us or our stockholders.

Paycheck Protection Program Loan.

On April 22, 2020, we received an approximately $1.8 million loan (the PPP Loan) under the Paycheck Protection Program established by the U.S. Small Business Administration as part of the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act. The PPP Loan was unsecured and was evidenced by a note in favor of HSBC Bank USA, National Association (HSBC) as the lender. On July 21, 2020, we submitted an application to HSBC for forgiveness of the PPP Loan. The PPP Loan was forgiven in its entirety, including interest, on April 16, 2021.

$20.0 million Ocumension Transaction

On April 14, 2021, we entered into a Share Purchase Agreement with Ocumension Therapeutics, pursuant to which we offered and sold to Ocumension 1,144,945 shares of our common stock, at a purchase price of $8.734044 per share, for aggregate gross proceeds of $10.0 million. The number of shares sold was equal to 19.9% of the number of shares of common stock outstanding immediately before the closing. In addition, we received a nonrefundable upfront license payment of $10.0 million pursuant to the Ocumension License Agreement. Under that agreement, we granted an exclusive license for the development and commercialization of our 190 microgram fluocinolone acetonide intravitreal implant in applicator under Ocumension's own branded label in China, East Asia and the Western Pacific.

Year-end Cash Position

As of December 31, 2022, we had approximately $5.3 million in cash and cash equivalents, a decrease of $11.2 from the $16.5 million in cash and cash equivalents as of December 31, 2021. In April 2021, we received gross proceeds of $20.0 million in cash from the Ocumension transaction. As we have previously disclosed, we have used some of these proceeds to invest in targeted spending programs in both the U.S. and international markets to drive reengagement with physicians and accelerate our growth. While we believe many of these investments have proven to be successful, we also realize that continuing to spend at those levels in current market conditions is not sustainable. To conserve our cash, we are curtailing some of our spending to address the slower than expected revenue growth coming out of the pandemic, and we expect to continue to monitor our ongoing spending programs closely.

In March 2023, we issued and sold an aggregate of 12,000 shares of Series B Preferred Stock at a per-share purchase price of $1,000 and the warrants to purchase common stock for aggregate gross proceeds of $12.0 million.

We may need to raise alternative or additional financing to fund our operations and support growth. We cannot be sure that additional financing will be available when needed or that, if available, the additional financing could be obtained on terms that are not significantly detrimental to us or our stockholders. In addition, our ability to access any existing or future capital is also dependent on market conditions. For example, in March 2023, the Federal Deposit Insurance Corporation (FDIC) took control and was appointed receiver of Silicon Valley Bank (SVB) and Signature Bank (Signature). As of the date of this report, we do not

have direct exposure to SVB or Signature, but we cannot predict the broader impact or follow-on effects of these insolvencies. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened. If we were to raise additional funds by issuing equity securities, substantial dilution to existing stockholders could result, and the terms of any new equity securities may have a preference over our common stock. If we were to attempt to raise additional funds through strategic collaboration agreements, we may not be successful in obtaining those agreements, or in receiving milestone or royalty payments under them. If we were to attempt to raise additional funds through debt financing, we would be required to obtain the permission or participation of SLR (and, in certain cases, the consent of the holders of our Series B Preferred Stock), which we might not be able to obtain. Our recurring losses and any potential needs to raise capital create substantial doubt about our ability to continue as a going concern for the next 12 months following the issuance of the financial statements for the filing of this Annual Report on Form 10-K.

Sources and Uses of Cash in 2022 and 2021

For 2022, net cash used in our operations was approximately $10.0 million. The cash used in our operations was primarily due to our net loss of $18.1 million, an increase of $860,000 in accounts receivable, a decrease of $380,000 in long-term liabilities and $90,000 of unrealized foreign currency gains. These cash decreases were partially offset by $2.7 million of non-cash depreciation and amortization, a $2.1 million increase in accounts payable, accrued expenses and other current liabilities, $1.2 million of non-cash interest expense associated with the amortization of our debt discount, $970,000 decrease in prepaid and other current assets, $910,000 of non-cash stock-based compensation expense and a $650,000 change in fair value of warrant asset.

For 2021, net cash used in our operations was approximately $3.2 million. The cash used in our operations was primarily due to our net loss of $4.4 million, a $2.2 million increase in accounts receivable, a gain on extinguishment of debt of $1.8 million, $970,000 of non-cash consideration received as revenue, a decrease of $750,000 in long-term liabilities and $420,000 of unrealized foreign currency gains. These cash decreases were partially offset by $2.6 million of non-cash depreciation and amortization, a $2.0 million increase in accounts payable, accrued expenses and other current liabilities, $1.0 million of non-cash stock-based compensation expense, $960,000 of non-cash interest expense associated with the amortization of our debt discount and a $530,000 change in fair value of warrant asset.

For 2022, net cash used in our investing activities was approximately $260,000, which was primarily due to capital expenditures associated with purchases of office furniture and equipment for our U.S. headquarters and purchases of new IT equipment.

For 2021, net cash used in our investing activities was approximately $620,000, which was primarily due to capital expenditures associated with relocating our U.S. headquarters and purchases of new IT equipment.

For 2022, net cash used in our financing activities was approximately $300,000, which was primarily due to $110,000 in payments of debt costs and payments of $290,000 in finance lease obligation, partially offset by $90,000 in proceeds from the issuance of common stock and $20,000 in proceeds from stock options exercised.

For 2021, net cash provided by our financing activities was approximately $9.8 million, which was primarily due to $10.1 million of proceeds from the issuance of common stock, including the $10.0 million common stock sale to Ocumension, partially offset by $220,000 of payments of finance lease obligations.

Other Contractual Obligations and Commitments

The NEW DAY Study. In January 2020, we began entering into agreements with contract research organizations (CROs) and physician clinics in connection with a multicenter, single masked, randomized and controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its advantages over the current standard of care of repeat anti-VEGF injections (the NEW DAY Study). The NEW DAY Study is planned to enroll approximately 300 treatment-naïve, or almost naïve, DME patients in approximately 40 sites around the U.S. For 2022 and 2021, we incurred approximately $4.3 million and $3.8 million, respectively, of expense associated with the NEW DAY Study. In connection with the NEW DAY Study, we expect to incur approximately an additional $6.8 million of expense associated with this study through 2024.

Manufacturing Services Agreement with Alliance. In February 2016, we and Alliance Medical Products Inc., a Siegfried Company (Alliance), a third-party manufacturer, amended and restated the parties' existing agreement for the manufacture of the ILUVIEN implant, the assembly of the ILUVIEN applicator and the packaging of the completed ILUVIEN commercial product. Under the amended and restated Alliance agreement, its term was extended by five years, at which point the agreement became automatically renewable for successive one-year periods unless either party delivers notice of non-renewal to the other party at least 12 months before the end of the term or any renewal term. We are responsible for supplying the ILUVIEN applicator and the active pharmaceutical ingredient, and we must order at least 80% of the ILUVIEN units required in the covered territories from Alliance.

Manufacturing Services Agreement with Cadence. On October 30, 2020, we entered into a Manufacturing Services Agreement (the Cadence Agreement) with Cadence, Inc., for the manufacture of certain component parts of the ILUVIEN applicator (the components) at its facility near Pittsburgh, Pennsylvania. Under the Cadence Agreement, we will pay certain per-unit prices based on regularly scheduled shipments of a minimum number of components. The initial term of the Cadence Agreement expires on October 30, 2025. After the expiration of the initial term, the Cadence Agreement will automatically renew for separate but successive one-year terms unless either party provides written notice to the other party that it does not intend to renew the Cadence Agreement at least 24 months before the end of the term. The Cadence Agreement may be terminated by either party under certain circumstances. We have transferred the manufacturing of component parts of the ILUVIEN inserter to Cadence and have spent cash resources to purchase new equipment, to update clean room facilities and to assist in the regulatory approval process. In connection with the Cadence Agreement, we expect to be invoiced approximately $650,000 in 2023.

Critical Accounting Policies and Critical Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP) The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates. For a description of the accounting policies are the most critical to understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use to prepare our consolidated financial statements, see Note 2 of the accompanying consolidated financial statements.

Revenue Recognition

Net Product Revenue

We sell our products to major pharmaceutical distributors, pharmacies, hospitals and wholesalers (collectively, our Customers). In addition to distribution agreements with Customers, we enter into arrangements with healthcare providers and payors that provide for government-mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of our products. All of our current contracts have a single performance obligation, as the promise to transfer the individual goods is not separately identifiable from other promises in the contracts and is, therefore, not distinct.

We recognize revenues from product sales when the Customer obtains control, typically upon delivery. We accrue for fulfillment costs when the related revenue is recognized. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues.

License Revenue

We enter into agreements in which we license certain rights to our products to partner companies that act as distributors. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer.

Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. We determine standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, we estimate the standalone selling price taking into account available information such as market conditions related to the performance obligations.

We will recognize sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606 – *Revenue from Contracts with Customers*. For those milestone payments which are contingent on the occurrence of particular future events, we determine that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the expected value method. As such, we assess each milestone to determine the probability of and substance behind achieving each milestone. Given the inherent uncertainty associated with these future events, we will not recognize revenue from such milestones until there is a high probability of occurrence, which typically occurs near or upon achievement of the event.

Estimates of Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for reserves related to statutory rebates to state Medicaid and other government agencies; commercial rebates and fees to Managed Care Organizations (MCOs), Group Purchasing Organizations (GPOs), distributors and specialty pharmacies; product returns; sales discounts (including trade discounts); distributor costs; wholesaler chargebacks; and allowances for patient assistance programs relating to sales of our products.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales. Our estimates take into consideration historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and Customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration included in the net sales price is limited to the amount that is probable not to result in a significant reversal in the amount of the cumulative revenue recognized in a future period. If actual results vary, we may adjust these estimates, which could have an effect on earnings in the period of adjustment.

With respect to our international contracts with third party distributors, certain contracts have elements of variable consideration, and management reviews those contracts on a regular basis and makes estimates of revenue based on historical ordering patterns and known market events and data. The amount of variable consideration included in net sales in each period can vary depending on the terms of these contracts and the probability of reversal in future periods.

Income Taxes

We recognize deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of our assets and liabilities in accordance with ASC 740, *Income Taxes*. We evaluate the positive and negative evidence bearing upon the realizability of our deferred tax assets on an annual basis. Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to the realization of our U.S. deferred tax assets resulting from our history of operating losses, we have established a valuation allowance against our U.S. deferred tax asset balances to reduce the net carrying value to an amount that is more likely than not to be realized. As a result, we have fully reserved against the U.S. deferred tax asset balances. The valuation allowances are based on our estimates of taxable income in the jurisdictions in which we operate and the period over which deferred tax assets will be recoverable. If actual results differ from these estimates or we adjust these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact our financial position and results of operations.

Our deferred tax assets primarily consist of net operating loss (NOL) carry-forwards. As of December 31, 2022, we had federal NOL carry-forwards of approximately $147.2 million and state NOL carry-forwards of approximately $107.7 million, respectively, subject to further limitation based upon the final results of our analyses under Internal Revenue Code Sections 382 and 383. Except for the NOLs generated after 2017, the U.S. federal NOLs not fully utilized will expire at various dates between 2029 and 2037; most state NOL carry-forwards will expire at various dates between 2022 and 2042. Under the Tax Cuts and Jobs Act of 2017, U.S. federal NOLs and some state NOLs generated after 2017 will carry forward indefinitely.

Sections 382 and 383 of the Internal Revenue Code limit the annual use of NOL carry-forwards and tax credit carry-forwards, respectively, following an ownership change. NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (Section 382) (or comparable provisions of state law) if certain changes in ownership were to occur. We periodically evaluate our NOL carry-forwards and whether certain changes in ownership have occurred that would limit our ability to utilize a portion of our NOL carry-forwards. If we determine that significant ownership changes have occurred since we generated our NOL carry-forwards, we may be subject to annual limitations on the use of these NOL carry-forwards under Section 382 (or comparable provisions of state law). We have determined that a Section 382 change in ownership occurred in late 2015. As a result of this change in ownership, we estimated that approximately $18.6 million of our federal NOLs and approximately $382,000 of federal tax credits generated prior to the change in ownership will not be utilized in the future. We are currently in the process of refining and finalizing these calculations, and upon finalization, will determine if a write-off is necessary. Any future changes in our ownership or sale of our stock, including our March 2023 financing, could further limit the use of our NOLs in the future. The reduction to our NOL deferred tax asset due to the annual Section 382 limitation and the NOL carryforward period would result in an offsetting reduction in valuation allowance recorded against the NOL deferred tax asset.

If we were to determine that we are able to realize any of our net deferred tax assets in the future, we would adjust the valuation allowance to increase net income in the period in which we make that determination. We believe that the most significant uncertainty affecting the determination of our valuation allowance will be our estimation of the extent and timing of future net income, if any.

We considered our income tax positions for uncertainty in accordance with ASC 740. The balance of unrecognized tax benefits as of December 31, 2022 and December 31, 2021 are approximately $112,000 and $88,000, respectively. Both balances relate to research and development tax credits. In accordance with ASC 740-10, such attributes are reduced to the amount that is expected to be recognized in the future. We do not accrue interest or penalties, as there is no risk of additional tax liability due to significant NOLs available. We do not expect any decreases to the unrecognized tax benefits within the next twelve months due to any lapses in statute of limitations. Tax years from 2019 to 2021 remain subject to examination in California, Georgia, Kentucky, New Jersey, Tennessee, Texas and on the federal level, provided that assessment of NOL carry-forwards available for use can be examined for all years since 2009. The statute of limitations on these years will close when the NOLs expire or when the statute closes on the years in which we use the NOLs.

New Accounting Pronouncements

See Note 2 of our notes to consolidated financial statements below for a description of recent accounting pronouncements, including the expected dates of adoption and expected effects on results of operations and financial condition, if known.

Foreign Exchange

Our international operations are subject to certain opportunities and risks, including currency fluctuations and governmental actions. The impact of fluctuations in foreign currency exchange rates decreased our net product revenue for year ended December 31, 2022 by approximately $2.4 million.

Non-GAAP Financial Measure

Adjustments in net product revenue to exclude fluctuations in foreign currency exchange rates result in a non-GAAP financial measure, as defined in Regulation G promulgated under the Securities Exchange Act of 1934, as amended. We report our financial results in compliance with GAAP but believe that adjusting our net product revenue to exclude fluctuations in foreign currency exchange rates provides a useful comparative framework for investors to access our operating performance. We use this non-GAAP financial measure in the management of our business. Net product revenue for the year ended December 31, 2022 has been adjusted in certain instances in this report to exclude the impact of fluctuations in foreign currency exchange rates in the comparisons to GAAP net product revenue for the year ended December 31, 2021. See the table below entitled "Reconciliation of GAAP Net Product Revenue to Non-GAAP Adjusted Net Product Revenue." GAAP net product revenue is the most directly comparable GAAP financial measure to adjusted net product revenue.

This non-GAAP financial measure, as presented, may not be comparable to a similarly titled measure reported by other companies because not all companies adjust revenue for currency fluctuations in an identical manner. Therefore, this non-GAAP financial measure is not necessarily an accurate measure of comparison between companies.

The presentation of this non-GAAP financial measure is not intended to be considered in isolation or as a substitute for guidance prepared in accordance with GAAP. The principal limitation of this non-GAAP financial measure is that it excludes significant elements required by GAAP to be recorded in Alimera's financial statements. In addition, this non-GAAP financial measure is subject to inherent limitations because it reflects the exercise of judgment by management in determining it.

RECONCILIATION OF GAAP NET PRODUCT REVENUE TO NON-GAAP ADJUSTED NET PRODUCT REVENUE

Amounts presented for the year ended December 31, 2021 is our reported amount we prepared in accordance with GAAP

	Years Ended December 31,	
	2022	2021
	(unaudited)	
GAAP NET PRODUCT REVENUE	$ 54,129	$ 47,981
Adjustment to net product revenue:		
Foreign currency fluctuations, net	2,447	—
NON-GAAP ADJUSTED NET PRODUCT REVENUE	$ 56,576	$ 47,981

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

Because we are allowed to comply with the disclosure obligations applicable to a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act, with respect to this Annual Report on Form 10-K, we are not required to provide the information required by this Item.

ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

The consolidated financial statements and related consolidated financial statement schedules required to be filed are indexed on page 59 and are incorporated herein.

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

Under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, we evaluated the effectiveness of the design and operation of our "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2022.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officer and effected by our board of directors, management and other personnel, 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 and includes those policies and procedures that:

pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Under the supervision and with the participation of management, including our principal executive and financial officers, we assessed our internal control over financial reporting as of December 31, 2022, based on criteria for effective internal control over financial reporting established in the 2013 Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on this assessment, our management concluded that we maintained effective internal control over financial reporting as of December 31, 2022.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the fourth quarter of 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. *OTHER INFORMATION*

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

The information required by this item regarding our executive officers will be presented under the caption "Executive Officers" in our Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022 (the 2023 Proxy Statement) and is incorporated herein by reference.

The information required by this item regarding our directors will be presented under the caption "Proposal 1: Election of Directors" in our 2023 Proxy Statement and is incorporated herein by reference.

With regard to the information required by this item regarding compliance with Section 16 of the Exchange Act of 1934, as amended, we will provide disclosure of delinquent Section 16(a) reports, if any, under the caption "Security Ownership of Certain Beneficial Owners and Management - Delinquent Section 16(a) Reports" in our 2023 Proxy Statement and such disclosure, if any, is incorporated herein by reference.

The information required by this item regarding our audit committee will be presented under the caption "Corporate Governance - Board Committee - Audit Committee" in our 2023 Proxy Statement and is incorporated herein by reference.

The information required by this item regarding our code of ethics will be presented under the caption "Corporate Governance - Code of Business Conduct" in our 2023 Proxy Statement and is incorporated herein by reference.

ITEM 11. *EXECUTIVE COMPENSATION*

The information required by this item regarding executive compensation will be presented under the caption "Executive Compensation" in our 2023 Proxy Statement and is incorporated herein by reference.

The information required by this item regarding director compensation will be presented under the caption "Corporate Governance - Director Compensation" in our 2023 Proxy Statement and is incorporated herein by reference.

The information required by this item regarding our compensation committee will be presented under the caption "Corporate Governance - Compensation Committee Interlocks and Insider Participation" in our 2023 Proxy Statement and is incorporated herein by reference.

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

The information required by this item regarding security ownership and certain beneficial owners and management will be presented under the caption "Security Ownership of Certain Beneficial Owners and Management" in our 2023 Proxy Statement and is incorporated herein by reference.

Equity Compensation Plan Information

The following table provides information, as of December 31, 2022, with respect to shares of our common stock that may be issued, subject to certain vesting requirements, under (a) existing awards under our 2010 Equity Incentive Plan (2010 Plan), and (b) existing and future awards under our 2019 Omnibus Incentive Plan (2019 Plan). The following table also provides information, as of December 31, 2022, with respect to shares of our common stock that we may sell to our employees under our 2010 Employee Stock Purchase Plan (ESPP).

	A	B	C
Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A))
Equity compensation plans approved by security holders	1,248,933 (1)	$ 19.03	766,228 (2)
Equity compensation plans not approved by security holders	—	—	—
Total	1,248,993	$ 19.03	766,228

(1) Of these shares, 551,834 were subject to stock options then outstanding under the 2010 Plan, 623,505 were subject to stock options then outstanding under the 2019 Plan, and 73,594 were outstanding but unvested shares of restricted stock then outstanding under the 2019 Plan.

(2) Represents 754,033 shares of common stock available for issuance under our 2019 Plan and 12,195 shares of common stock available for issuance under our ESPP. No shares are available for future issuance under the 2010 Plan. In addition, our ESPP provides for annual increases in the number of shares available for issuance thereunder equal to such number of shares necessary to restore the number of shares reserved thereunder to 32,961 shares of our common stock. As such, on January 1, 2023, an additional 20,766 shares became available for future issuance under our ESPP. These additional shares from the annual increase under the ESPP are not included in the table above.

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

The information required by this item regarding certain relationships and related persons transactions will be presented under the caption “Certain Relationships and Related Persons Transactions” in our 2023 Proxy Statement and is incorporated herein by reference.

The information required by this item regarding director independence will be presented under the caption “Corporate Governance - Independent Directors” in our 2023 Proxy Statement and is incorporated herein by reference.

ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES*

The information required by this item regarding aggregate fees billed to us by our independent registered public accounting firm’s fees will be presented under the caption “Proposal 2: Ratification of Selection of Independent Registered Public Accounting Firm - Independent Registered Public Accounting Firm’s Fees” in our 2023 Proxy Statement and is incorporated herein by reference.

The information required by this item regarding our audit committee’s pre-approval policies and procedures will be presented under the caption “Proposal 2: Ratification of Selection of Independent Registered Public Accounting Firm - Pre-Approval Policies and Procedures of the Audit Committee” in our 2023 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. *EXHIBITS AND FINANCIAL STATEMENTS SCHEDULES*

(a) The following documents are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K:

1. *Financial Statements*. See Index to Financial Statements under Item 8 of this Annual Report on Form 10-K.

2. *Financial Statement Schedules.* All schedules have been omitted because the information required to be presented in them is not applicable or is shown in the financial statements or related notes.

3. *Exhibits.* We have filed, or incorporated into this Annual Report on Form 10-K by reference, the exhibits listed on the accompanying Exhibit Index immediately following the financial statements contained in this Annual Report on Form 10-K.

(b) *Exhibits.* See Item 15(a)(3) above.

(c) *Financial Statement Schedules.* See Item 15(a)(2) above.

ITEM 16. *FORM 10-K SUMMARY*

None.

ALIMERA SCIENCES, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Alimera Sciences, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Alimera Sciences, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2022, and 2021, the related consolidated statements of operations, comprehensive loss, changes in stockholders' deficit, and cash flows for the years then ended and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 5 to the consolidated financial statements, the Company has incurred recurring losses, negative cash flows from operations, and has an accumulated deficit of $415,388,000 as of December 31, 2022. These conditions, along with the other matters as set forth in Note 5, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 5. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

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

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

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

Critical audit matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2012.

Atlanta, Georgia
March 31, 2023

ALIMERA SCIENCES, INC.

CONSOLIDATED BALANCE SHEETS

AS OF DECEMBER 31, 2022 AND 2021

	December 31,	
	2022	2021
	(In thousands, except share and per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,274	$ 16,510
Restricted cash	30	34
Accounts receivable, net	19,612	19,128
Prepaid expenses and other current assets	2,892	3,809
Inventory (Note 6)	1,605	2,679
Total current assets	29,413	42,160
NON-CURRENT ASSETS:		
Property and equipment, net	2,525	2,783
Right of use assets, net	1,395	1,710
Intangible asset, net	8,957	10,897
Deferred tax asset	129	137
Warrant asset	183	833
TOTAL ASSETS	$ 42,602	$ 58,520
CURRENT LIABILITIES:		
Accounts payable	$ 10,088	$ 8,706
Accrued expenses (Note 9)	3,998	3,617
Notes payable	25,313	—
Finance lease obligations	333	269
Total current liabilities	39,732	12,592
NON-CURRENT LIABILITIES:		
Notes payable (Note 12)	18,683	43,080
Other non-current liabilities	4,995	5,453
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' DEFICIT:		
Preferred stock, $.01 par value — 10,000,000 shares authorized at December 31, 2021 and 2020:		
Series A Convertible Preferred Stock, 1,300,000 authorized and 600,000 issued and outstanding at December 31, 2022 and 2021; liquidation preference of $24,000 at December 31, 2022 and 2021	19,227	19,227
Common stock, $.01 par value — 150,000,000 shares authorized, 6,995,513 shares issued and outstanding at December 31, 2022 and 6,935,154 shares issued and outstanding at December 31, 2021 (Note 2)	70	69
Additional paid-in capital	378,238	377,229
Accumulated deficit	(415,388)	(397,281)
Accumulated other comprehensive loss — foreign currency translation adjustments	(2,955)	(1,849)
TOTAL STOCKHOLDERS' DEFICIT	(20,808)	(2,605)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 42,602	$ 58,520

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

	Years Ended December 31,	
	2022	**2021**
	(In thousands, except share and per share data)	
REVENUE:		
PRODUCT REVENUE, NET	$ 54,129	$ 47,981
LICENSE REVENUE	—	11,048
NET REVENUE	54,129	59,029
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(7,977)	(7,030)
GROSS PROFIT	46,152	51,999
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	16,228	13,778
GENERAL AND ADMINISTRATIVE EXPENSES	12,871	12,774
SALES AND MARKETING EXPENSES	25,987	23,069
DEPRECIATION AND AMORTIZATION	2,706	2,579
OPERATING EXPENSES	57,792	52,200
LOSS FROM OPERATIONS	(11,640)	(201)
INTEREST EXPENSE AND OTHER	(5,881)	(5,413)
UNREALIZED FOREIGN CURRENCY GAIN, NET	92	416
GAIN ON EXTINGUISHMENT OF DEBT	—	1,792
CHANGE IN FAIR VALUE OF WARRANT ASSET	(650)	(528)
NET LOSS BEFORE TAXES	(18,079)	(3,934)
INCOME TAX PROVISION	(28)	(438)
NET LOSS	(18,107)	(4,372)
NET LOSS PER SHARE — Basic and diluted (Note 2)	$ (2.59)	$ (0.66)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	6,996,850	6,595,237

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

	Years Ended December 31,	
	2022	2021
	(In thousands)	
NET LOSS	$ (18,107)	$ (4,372)
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustments	(1,106)	(1,296)
TOTAL OTHER COMPREHENSIVE LOSS	(1,106)	(1,296)
COMPREHENSIVE LOSS	$ (19,213)	$ (5,668)

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT

FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

	Common Stock		Series A Convertible Preferred Stock		Additional Paid-In	Common Stock		Accumulated Other	
	Shares	Amount	Shares	Amount	Capital	Warrants	Accumulated Deficit	Comprehensive Loss	Total
	(In thousands, except share data)								
BALANCE — December 31, 2020	5,719,367	$ 57	600,000	$ 19,227	$ 365,830	$ 370	$ (392,909)	$ (553)	$ (7,978)
Issuance of common stock, net issuance costs	1,223,323	12	—	—	9,990	—	—	—	10,002
Forfeitures of restricted stock	(13,933)		—	—	—	—	—	—	—
Stock option exercises	6,397				42	—	—	—	42
Expiration of common warrants	—	—	—	—	370	(370)	—	—	—
Stock-based compensation expense	—	—	—	—	997	—	—	—	997
Net loss	—	—	—	—	—	—	(4,372)	—	(4,372)
Foreign currency translation adjustments	—	—	—	—	—	—	—	(1,296)	(1,296)
BALANCE — December 31, 2021	6,935,154	69	600,000	19,227	377,229	—	(397,281)	(1,849)	(2,605)
Issuance of common stock, net issuance costs	78,266	1	—	—	84	—	—	—	85
Forfeitures of restricted stock	(20,469)	—	—	—	—	—	—	—	—
Stock option exercises	2,562	—	—	—	15	—	—	—	15
Stock-based compensation expense	—	—	—	—	910	—	—	—	910
Net loss	—	—	—	—	—	—	(18,107)	—	(18,107)
Foreign currency translation adjustments	—	—	—	—	—	—	—	(1,106)	(1,106)
BALANCE — December 31, 2022	6,995,513	$ 70	600,000	$ 19,227	$ 378,238	$ —	$ (415,388)	$ (2,955)	$(20,808)

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

	Years Ended December 31,	
	2022	2021
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (18,107)	$ (4,372)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,706	2,579
Non-cash consideration received as revenue	—	(973)
Unrealized foreign currency transaction gain	(92)	(416)
Amortization of debt discount and deferred financing costs	1,153	964
Deferred tax expense	116	610
Stock-based compensation expense	910	997
Gain on extinguishment of debt	—	(1,792)
Change in fair value of warrant asset	650	528
Changes in assets and liabilities:		
Accounts receivable	(863)	(2,206)
Prepaid expenses and other current assets	973	(404)
Inventory	1,010	(19)
Accounts payable	1,468	1,485
Accrued expenses and other current liabilities	483	540
Other long-term liabilities	(382)	(745)
Net cash used in operating activities	(9,975)	(3,224)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(255)	(621)
Net cash used in investing activities	(255)	(621)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock	85	10,084
Common stock issuance costs	—	(82)
Proceeds from exercise of stock options	15	42
Payment of debt costs	(113)	—
Payments on finance lease obligations	(289)	(221)
Net cash (used in) provided by financing activities	(302)	9,823
EFFECT OF EXCHANGE RATES ON CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(708)	(676)
NET CHANGE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(11,240)	5,302
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH — Beginning of year	16,544	11,242
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH — End of year	$ 5,304	$ 16,544
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	$ 4,489	$ 4,302
Cash paid for income taxes	$ 232	$ 112
Supplemental schedule of noncash investing and financing activities:		
Property and equipment acquired under finance leases	$ 259	$ —
Property and equipment acquired under operating leases	$ 7	$ 1,255
Note payable end of term payment accrued but unpaid	$ 2,250	$ 2,250

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS

Alimera Sciences, Inc., together with its wholly-owned subsidiaries (the Company), is a pharmaceutical company that specializes in the commercialization and development of ophthalmic pharmaceuticals. The Company was formed on June 4, 2003 under the laws of the State of Delaware.

The Company presently focuses on diseases affecting the retina, because the Company believes these diseases are not well treated with current therapies and affect millions of people globally. The Company's only product is ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg, which has received marketing authorization and reimbursement in 24 countries for the treatment of diabetic macular edema (DME). In the U.S. and certain other countries outside Europe, ILUVIEN is indicated for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. In 17 countries in Europe, ILUVIEN is indicated for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. In addition, ILUVIEN has received marketing authorization in 17 European countries, and reimbursed in nine countries for the prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment (NIU-PS).

The Company markets ILUVIEN directly in the U.S., Germany, the U.K., Portugal and Ireland. In addition, the Company has entered into various agreements under which distributors are providing or will provide regulatory, reimbursement and sales and marketing support for ILUVIEN in Austria, Belgium, the Czech Republic, Denmark, Finland, France, Italy, Luxembourg, the Netherlands, Norway, Spain, Sweden, Switzerland, Australia, New Zealand and several countries in the Middle East. In addition, the Company has granted an exclusive license to Ocumension Therapeutics for the development and commercialization of the Company's 0.19mg fluocinolone acetonide intravitreal injection in China, East Asia and the Western Pacific. As of December 31, 2022, the Company has recognized sales of ILUVIEN to its international distributors in the Middle East, China, Austria, Belgium, Czech Republic, France, Italy, Luxembourg, Spain and the Netherlands.

Effects of the COVID-19 Pandemic

The public health crisis caused by the COVID-19 pandemic and the measures being taken by governments, businesses, and the public at large to limit the COVID-19 pandemic's spread have had, and the Company expects will continue to have to some degree, certain negative effects on, and present certain risks to, the Company's business. These limitations and other effects of the COVID-19 pandemic have had an adverse impact on the Company's revenues beginning late in the first quarter of 2020 and this adverse impact has continued to a lesser degree through the date of this report in some of the Company's key markets in Europe that have now begun to recover. As the COVID-19 pandemic continued, the Company's liquidity and financial condition were adversely affected as well. These COVID-19 pandemic-related factors may continue to adversely affect the Company's revenue, liquidity and financial condition, and the extent and duration of that effect is uncertain, particularly if SARS-CoV-2 variants emerge that may increase the transmissibility of the coronavirus or be more deadly, or both. This uncertainty could in the future affect certain estimates the Company uses to prepare its financial results, including impairment of intangible assets, the income tax provision and realizability of certain receivables and the prospective compliance with the Company's covenants in its loan agreement.

In response to the COVID-19 pandemic, the Company has implemented measures to mitigate the impact of the pandemic on its financial position and operations. The Company is continuing to monitor the effects of the SARS-CoV-2 variants and to increase its engagement with its customers to mitigate any loss of revenue in the affected markets.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The preparation of the Company's consolidated financial statements requires the Company to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements and accompanying notes. Although these estimates are based on the Company's knowledge of current events and actions the Company may undertake in the future, actual results may ultimately differ from these estimates and assumptions. Furthermore, when testing assets for impairment in future periods, if management uses different assumptions or if different conditions occur, impairment charges may result.

Use of Estimates in Financial Statements

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America and, as such, include amounts based on informed estimates and judgments of management. Actual results could differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of Alimera Sciences, Inc. and its wholly-owned subsidiaries. All significant inter-company balances have been eliminated in consolidation.

Cash, Cash Equivalents and Restricted Cash

Cash equivalents include highly liquid investments that are readily convertible into cash and have a maturity of 90 days or less when purchased. Generally, cash, cash equivalents and restricted cash held at financial institutions are in excess of federally insured limits. Cash, cash equivalents and restricted cash were $5,304,000 and $16,544,000 as of December 31, 2022 and 2021, respectively, with approximately 72% and 46% of these balances, respectively, held in U.S.-based financial institutions.

Revenue

See Note 3 for expanded disclosures regarding the Company's revenues and how the Company accounts for revenue.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are generated through sales primarily to major pharmaceutical distributors, pharmacies, hospitals and wholesalers. The Company does not require collateral from its customers for accounts receivable. The carrying amount of accounts receivable is reduced by an allowance for doubtful accounts that reflects management's best estimate of the amounts that will not be collected. In addition to reviewing delinquent accounts receivable, management considers many factors in estimating its general allowance, including historical data, experience, customer types, credit worthiness and economic trends. From time to time, management may adjust its assumptions for anticipated changes in any of those or other factors expected to affect collectability. A provision for doubtful accounts is charged to operations when management determines the accounts may become uncollectable. The Company writes off accounts receivable when management determines they are uncollectable and credits payments subsequently received on such receivables to bad debt expense in the period received. As of December 31, 2022 and 2021, the Company had no reserve for doubtful accounts. During the twelve months ended December 31, 2022, the Company had no write-offs for doubtful accounts. During the twelve months ended December 31, 2021, the Company wrote off less than $10,000 for doubtful accounts.

Inventory

Inventories are stated at the lower of cost or net realizable value with cost determined under the first in, first out (FIFO) method. Included in inventory costs are component parts, work-in-progress and finished goods. The Company relies on third party manufacturers for the production of all inventory and does not capitalize any internal costs. The Company periodically reviews inventories for excess, obsolete or expiring inventory and writes down obsolete or otherwise unmarketable inventory to its estimated net realizable value.

Intangible Assets

The cost of intangible assets with determinable useful lives is amortized to reflect the pattern of economic benefits consumed, which approximates a straight-line basis, over the estimated periods benefited. The Company estimated the useful life of its intangible asset at approximately thirteen years (see Note 8).

Warrant Asset

Based on the terms of the Company's warrant agreement with Ocumension Therapeutics, the Company has the right to exercise the warrants at its option and classifies it as a non-current asset. The Company recognizes the warrants at fair value and includes any changes in value on the Company's statement of operations (see Note 11).

Property and Equipment

Property and equipment are stated at cost. Additions and improvements are capitalized while repairs and maintenance are expensed. Depreciation is provided on the straight-line method over the useful life of the related assets beginning when the asset is placed in service. The estimated useful lives of the individual assets are as follows: furniture, fixtures and manufacturing equipment, five years; automobiles, three years or the related lease life; software and information technology hardware, three years; and office equipment and leasehold improvements are amortized over the shorter of their estimated useful lives or the related lease life.

Impairment

Property and equipment and definite lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When indicators of impairment are present, the Company evaluates the carrying amount of such assets in relation to the operating performance and future estimated undiscounted net cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. The assessment of the recoverability of assets will be impacted if estimated future operating cash flows are not achieved. The Company recorded no impairment during the years ended December 31, 2022 and 2021.

Income Taxes

The Company provides for income taxes based on pretax income and applicable tax rates available in the various jurisdictions in which it operates. Significant judgment is required in determining the provision for income taxes and income tax assets and liabilities, including evaluating uncertainties in the application of accounting principles and complex tax laws. Deferred income taxes are recorded for the expected tax consequences of temporary differences between the bases of assets and liabilities, as well as for loss and tax credit carryforwards for financial reporting purposes and amounts recognized for income tax purposes. A valuation allowance is recorded to reduce the Company's deferred tax assets to the amount of future tax benefit that is more likely than not to be realized.

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits (UTBs) is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. The Company recognizes both accrued interest and penalties, where appropriate, related to UTBs in income tax expense.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses were $5, 363,000 and $4,607,000 for 2022 and 2021, respectively.

Advertising Expenses

The Company expenses the cost of advertising including digital and print media directed to patients and healthcare professionals, as incurred. Advertising expenses, recorded in sales and marketing expenses were $1,816,000 and $1,905,000 for 2022 and 2021, respectively.

Stock-Based Compensation

The Company has stock-based compensation plans under which various types of equity-based awards are granted, including restricted stock, restricted stock units (RSUs) and stock options. The fair values of restricted stock, RSUs and stock option awards, which are subject only to service conditions with graded vesting, are recognized as compensation expense, generally on a straight-line basis over a service period, net of estimated forfeitures.

Compensation expense is recognized for all share-based awards based on the grant date fair value in accordance with the provisions of the Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) 718, *Compensation — Stock Compensation* (ASC 718). The fair values for the options are estimated at the dates of grant using a Black-Scholes option-pricing model.

Additionally, the Company sponsors an employee stock purchase plan (ESPP) under which U.S.-based employees may elect payroll withholdings to fund purchases of the Company's stock at a discount. The Company estimates the fair value of the option to purchase shares of the Company's common stock using the Black-Scholes valuation model and recognizes compensation expense in accordance with the provisions of ASC 718-50, *Employee Share Purchase Plans*.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash and cash equivalents and current assets and liabilities approximate their fair value because of their short maturities. The weighted average interest rate of the Company's notes payable approximates the rate at which the Company could obtain alternative financing; therefore, the carrying amount of the note approximates the fair value. The Company uses the Black-Scholes option pricing model and assumptions that consider, among

other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value of options granted.

Foreign Currency Translation

The U.S. dollar is the functional currency of Alimera Sciences, Inc. The Euro is the functional currency for the Company's subsidiaries operating outside of the U.S.

The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using applicable exchange rates. The U.S. dollar effects that arise from translating net assets of these subsidiaries at changing rates are recognized in accumulated other comprehensive loss and is the only adjustment recognized in accumulated other comprehensive loss.

The Company's foreign currency assets and liabilities are remeasured into U.S. dollars at end-of-period exchange rates, except for nonmonetary balance sheet accounts, which are remeasured at historical exchange rates. Revenue and expenses are remeasured at average exchange rates in effect during each period, except for those expenses related to the non-monetary balance sheet amounts, which are remeasured at historical exchange rates. Gains or losses from foreign currency remeasurement are included in income. Equity is translated at historical rates and the resulting cumulative translation adjustments are included as a component of accumulated other comprehensive income.

Earnings Per Share (EPS)

The Company follows ASC 260, *Earnings Per Share* (ASC 260), which requires the reporting of both basic and diluted earnings per share. Because the Company's preferred stockholders participate in dividends equally with common stockholders (if the Company were to declare and pay dividends), the Company uses the two-class method to calculate EPS. However, the Company's preferred stockholders are not contractually obligated to share in losses.

Basic EPS is computed by dividing net (loss) income available to stockholders by the weighted average number shares outstanding for the period. Diluted EPS is calculated in accordance with ASC 260 by adjusting weighted average shares outstanding for the dilutive effect of common stock options, restricted stock units and warrants. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be anti-dilutive.

Common stock equivalent securities that would potentially dilute basic EPS in the future, but were not included in the computation of diluted EPS because they were either classified as participating or would have been anti-dilutive, were as follows:

	Years Ended December 31,	
	2022	**2021**
Series A convertible preferred stock	601,504	601,504
Stock options	1,175,339	1,075,795
Total	1,776,843	1,677,299

Reporting Segments

See Note 19 for expanded disclosures regarding the Company's reporting segments and how the Company's Chief Executive Officer (CEO), who is the chief operating decision maker (CODM), reviews its segments.

Adoption of New Accounting Standard

In August 2020, the FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This standard simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The standard requires entities to provide expanded disclosures about the terms and features of convertible instruments and amends certain guidance in ASC 260 on the computation of EPS for convertible instruments and contracts on an entity's own equity. The standard became effective for the Company on January 1, 2022. The adoption of this guidance did not have a material impact on the Company's financial statements.

Accounting Standards Issued but Not Yet Effective

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (ASC 326): Measurement of Credit Losses on Financial Instruments*. This ASU replaces the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a

broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. The standard becomes effective for the Company on January 1, 2023. The Company does not anticipate the adoption of this ASU will have a material impact on its financial statements.

In March 2020, the FASB issued ASU 2020-04, Reference Rate Reform (ASC 848) - Facilitation of the Effects of Reference Rate Reform on Financial Reporting. This standard provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The standard is available until December 31, 2022. In December 2022, the FASB issued ASU No. 2022-06 which extended the period of time preparers can utilize the reference rate reform relief guidance in Topic 848. The guidance ensures the relief in Topic 848 covers the period of time during which a significant number of modifications may take place and the ASU defers the sunset date of Topic 848 from December 31, 2022 to December 31, 2024. The Company does not anticipate the adoption of this ASU will have a material impact on its financial statements.

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805) – Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*. The amendments in this ASU require that an acquirer recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with Topic 606, Revenue from Contracts with Customers. The amendments in this ASU are effective for fiscal years beginning after December 15, 2022 with early adoption permitted. The Company does not anticipate the adoption of this ASU will have a material impact on its financial statements.

3. REVENUE RECOGNITION

Overview

The Company recognizes revenue when a customer obtains control of the related good or service. The amount recognized reflects the consideration the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, Revenue from Contracts with Customers, the Company performs the following steps as outlined in the guidance: (1) identify the contract with the customer, (2) identify the performance obligations within the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when the entity satisfies a performance obligation. At the inception of a contract, the contract is evaluated to determine if it falls within the scope of ASC 606, followed by the Company's assessment of the goods or services promised within each contract, assessment of whether the promised good or service is distinct and determination of the performance obligations. The Company then recognizes revenue based on the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions related to the performance obligations.

Net Product Sales

The Company sells its products to major pharmaceutical distributors, pharmacies, hospitals and wholesalers (collectively, its Customers). In addition to distribution agreements with Customers, the Company enters into arrangements with healthcare providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products. The Company recognizes revenues from product sales at a point in time when the Customer obtains control, typically upon delivery. The Company accrues for fulfillment costs when the related revenue is recognized. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues.

Estimates of Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for reserves related to statutory rebates to State Medicaid and other government agencies; commercial rebates and fees to Managed Care Organizations (MCOs), Group Purchasing Organizations (GPOs), distributors, and specialty pharmacies; product returns; sales discounts (including trade discounts); distributor costs; wholesaler chargebacks; and allowances for patient assistance programs relating to the Company's sales of its products.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales. Management's estimates take into consideration historical experience, current contractual and statutory requirements, specific known market events and

trends, industry data, and Customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration included in the net sales price is limited to the amount that is probable not to result in a significant reversal in the amount of the cumulative revenue recognized in a future period. If actual results vary, the Company may adjust these estimates, which could have an effect on earnings in the period of adjustment.

With respect to the Company's international contracts with third party distributors, certain contracts have elements of variable consideration, and management reviews those contracts on a regular basis and makes estimates of revenue based on historical ordering patterns and known market events and data. The amount of variable consideration included in net sales in each period could vary depending on the terms of these contracts and the probability of reversal in future periods.

Consideration Payable to Customers

Distribution service fees are payments issued to distributors for compliance with various contractually-defined inventory management practices or services provided to support patient access to a product. Distribution service fees reserves are based on the terms of each individual contract and are classified within accrued expenses and are recorded as a reduction of revenue.

Product Returns

The Company's policies provide for product returns in the following circumstances: (a) expiration of shelf life on certain products; (b) product damaged while in the Customer's possession; and (c) following product recalls. Generally, returns for expired product are accepted three months before and up to one year after the expiration date of the related product, and the related product is destroyed after it is returned. The Company may, at its option, either refund the sales price paid by the Customer by issuing a credit or exchanging the returned product for replacement inventory. The Company typically does not provide cash refunds. The Company estimates the proportion of recorded revenue that will result in a return by considering relevant factors, including historical returns experience, the estimated level of inventory in the distribution channel, the shelf life of products and product recalls, if any.

The estimation process for product returns involves, in each case, several interrelating assumptions, which vary for each Customer. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue from product sales in the period the related revenue is recognized, and because this returned product cannot be resold, there is no corresponding asset for product returns. Through the date of this report, product returns have been minimal.

License Revenue

The Company enters into agreements in which it licenses certain rights to its products to partner companies that act as distributors. The terms of these arrangements may include payment to the Company of one or more of the following: non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer.

Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions related to the performance obligations.

The Company will recognize sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606. For those milestone payments which are contingent on the occurrence of particular future events, the Company determines that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the expected value method. As such, the Company assesses each milestone to determine the probability of and substance behind achieving each milestone. Given the inherent uncertainty associated with these future events, the Company will not recognize revenue from such milestones until there is a high probability of occurrence, which typically occurs near or upon achievement of the event.

Customer Payment Obligations

The Company receives payments from its Customers based on billing schedules established in each contract, which vary across the Company's locations, but generally range between 30 to 120 days. Occasionally, the Company offers extended payment terms or payment term discounts to certain customers. 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 is that the Customer will pay for the product or services within one year or less of receiving those products or services.

4. LEASES

The Company evaluates all of its contracts to determine whether it is or contains a lease at inception. The Company reviews its contracts for options to extend, terminate or purchase any right of use assets and accounts for these, as applicable, at inception of the contract. Upon adoption of ASC 842, the Company elected the transition package of three practical expedients permitted within the standard. In accordance with the package of practical expedients, the Company did not reassess initial direct costs, lease classification, or whether its contracts contain or are leases. The Company made an accounting policy election not to recognize right of use assets and liabilities for leases with a term of 12 months or less, or those that do not meet the Company's capitalization threshold, unless the leases include options to renew or purchase the underlying asset that are reasonably certain to be exercised. Lease costs associated with those leases are recognized as incurred. The Company has also chosen the practical expedient that allows it to combine lease and non-lease components as a single lease component.

Lease renewal options are not recognized as part of the lease liability until the Company determines it is reasonably certain it will exercise any applicable renewal options. The Company has determined it is not reasonably certain it will exercise any applicable renewal options. The Company has not recorded any liability for renewal options in these consolidated financial statements. The useful lives of leased assets as well as leasehold improvements, if any, are limited by the expected lease term.

Operating Leases

The Company's operating lease activities primarily consist of leases for office space in the U.S., the U.K., Ireland, Portugal and Germany. Most of these leases include options to renew, with renewal terms generally ranging from one to eight years. The exercise of lease renewal options is at the Company's sole discretion. Certain of the Company's operating lease agreements include variable lease costs that are based on common area maintenance and property taxes. The Company expenses these payments as incurred. The Company's operating lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Supplemental balance sheet information as of December 31, 2022 and December 31, 2021 for the Company's operating leases is as follows:

	December 31,	
	2022	2021
	(In thousands)	
NON-CURRENT ASSETS:		
Right of use assets, net	$ 1,395	$ 1,710
Total lease assets	$ 1,395	$ 1,710
CURRENT LIABILITIES:		
Accrued expenses (Note 9)	$ 768	$ 220
NON-CURRENT LIABILITIES:		
Other non-current liabilities	2,267	2,735
Total lease liabilities	$ 3,035	$ 2,955

The Company's operating lease costs for the years ended December 31, 2021 and 2022 were $512,000 and $538,000, respectively, and are included in general and administrative expenses in its consolidated statements of operations.

As of December 31, 2022, a schedule of maturity of lease liabilities under all of the Company's operating leases is as follows:

Years Ending December 31	(In thousands)
2023	$ 699
2024	672
2025	474
2026	488
2027	503
Thereafter	1,052
Total	3,888
Less amount representing interest	(853)
Present value of minimum lease payments	3,035

Less current portion	(768)
Non-current portion	$ 2,267

Cash paid for operating leases was $253,000 during the year ended December 31, 2022. No right-of-use assets were obtained in connection with operating leases for the year ended December 31, 2022.

As of December 31, 2022, the weighted average remaining lease terms of the Company's operating leases was 6.9 years. The weighted average discount rate used to determine the lease liabilities was 9.5%. When available, the Company uses the rate implicit in the lease or sublease to discount lease payments to present value; however, most of the Company's leases do not provide a readily determinable implicit rate. Therefore, the Company must estimate its incremental borrowing rate to discount the lease payments based on information available at lease commencement. The incremental borrowing rate is defined as the rate of interest that the Company would have to pay to borrow, on a collateralized basis and over a similar term, an amount equal to the lease payments in a similar economic environment. In using the Company's incremental borrowing rate, management has elected to utilize a portfolio approach and apply the rates to a portfolio of leases with similar underlying assets and terms. Upon adoption of the new lease standard, discount rates used for existing leases were established.

Finance Leases

The Company's finance lease activities primarily consist of leases for office equipment and automobiles. The property and equipment is capitalized at the lesser of fair market value or the present value of the minimum lease payments at the inception of the leases using the Company's incremental borrowing rate. The Company's finance lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Supplemental balance sheet information as of December 31, 2022 and December 31, 2021 for the Company's finance leases is as follows:

	December 31,	
	2022	2021
	(In thousands)	
NON-CURRENT ASSETS:		
Property and equipment, net	$ 366	$ 392
Total lease assets	$ 366	$ 392
CURRENT LIABILITIES:		
Finance lease obligations	$ 333	$ 269
NON-CURRENT LIABILITIES:		
Other non-current liabilities	131	225
Total lease liabilities	$ 464	$ 494

Depreciation expense associated with property and equipment under finance leases was approximately $285,000 and $396,000 for the years ended December 31, 2022 and 2021, respectively. Interest expense associated with finance leases was $43,000 and $58,000 for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, a schedule of maturity of lease liabilities under finance leases, together with the present value of minimum lease payments, is as follows:

Years Ending December 31	**(In thousands)**
2023	$ 338
2024	110
2025	70
Total	518
Less amount representing interest	(54)
Present value of minimum lease payments	464
Less current portion	(333)
Non-current portion	$ 131

Cash paid for finance leases was $289,000 during the year ended December 31, 2022. No property and equipment was obtained during the year ended December 31, 2022 in exchange for finance leases.

As of December 31, 2022, the weighted average remaining lease terms of the Company's financing leases was 0.7 years. The weighted average discount rate used to determine the financing lease liabilities was 9.7%. When available, the Company uses the rate implicit in the lease or sublease to discount lease payments to present value; however, most of the Company's leases do not provide a readily determinable implicit rate. Therefore, the Company must estimate its incremental borrowing rate to discount the lease payments based on information available at lease commencement. The incremental borrowing rate is defined as the rate of interest that the Company would have to pay to borrow, on a collateralized basis and over a similar term, an amount equal to the lease payments in a similar economic environment. In using the Company's incremental borrowing rate, management has elected to utilize a portfolio approach and applies the rates to a portfolio of leases with similar underlying assets and terms.

5. GOING CONCERN

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company has incurred recurring losses, negative cash flow from operations and has accumulated a deficit of $415,388,000 from the Company's inception through December 31, 2022. As of December 31, 2022, the Company had approximately $5,274,000 in cash and cash equivalents. The Company's ability to achieve profitability and positive cash flow depends on its ability to increase revenue and contain its expenses.

Further, the Company must maintain compliance with the debt covenants of its Loan and Security Agreement dated December 31, 2019 with SLR and certain other lenders (as amended, the 2019 Loan Agreement). (See Note 12.) In management's opinion, the uncertainty regarding future revenues raises substantial doubt about the Company's ability to continue as a going concern without access to additional debt and/or equity financing, over the course of the next twelve months. Additionally, if the Company were unable to comply with the Revenue Covenant at any time over the course of the next year, the lenders have the right to accelerate the maturity of the loan which would raise substantial doubt about the Company's ability to continue as a going concern without access to alternative debt and/or equity financing, over the course of the next twelve months.

To meet the Company's future working capital needs, in March 2023, the Company consummated an equity financing and amended the 2019 Loan Agreement. (See Notes 12 and 21) However, the Company may need to raise additional debt and/or equity financing. While the Company has historically been able to raise additional capital through issuance of equity and/or debt financing and has implemented a plan to control its expenses to satisfy its obligations due within one year from the date of issuance of these financial statements, the Company cannot guarantee that it will be able to maintain debt compliance, raise additional equity, contain expenses, or increase revenue. Accordingly, there is substantial doubt about the Company's ability to continue as a going concern within one year after these financial statements are issued.

6. INVENTORY

Inventory consisted of the following:

	December 31,	
	2022	2021
	(In thousands)	
Component parts (1)	$ 152	$ 200
Work-in-process (2)	560	1,416
Finished goods	893	1,063
Total inventory	$ 1,605	$ 2,679

(1) Component parts inventory consisted of manufactured components of the ILUVIEN applicator.

(2) Work-in-process consisted of completed units of ILUVIEN that are undergoing, but have not completed, quality assurance testing as required by U.S. or EEA regulatory authorities.

7. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31,	
	2022	2021
	(In thousands)	
Furniture and fixtures	$ 427	$ 226
Office equipment	509	461
Finance leases	1,127	974
Software	1,228	1,236
Leasehold improvements	1,364	1,380
Manufacturing equipment	1,931	1,936
Total property and equipment	6,586	6,213
Less accumulated depreciation and amortization	(4,061)	(3,430)
Property and equipment — net	$ 2,525	$ 2,783

Depreciation and amortization expense associated with property and equipment totaled $766,000 and $639,000 for the years ended December 31, 2022 and 2021, respectively.

8. INTANGIBLE ASSET

As a result of the U.S. Food and Drug Administration's (FDA) approval of ILUVIEN in September 2014, the Company was required to pay in October 2014 a milestone payment of $25,000,000 (the EyePoint Milestone Payment) to EyePoint Pharmaceuticals US, Inc. (EyePoint), formerly known as pSivida US, Inc. (see Note 10).

The gross carrying amount of the intangible asset is $25,000,000, which is being amortized over approximately 13 years from the acquisition date. The net book value of the intangible asset was $8,957,000 and $10,897,000 as of December 31, 2022 and 2021, respectively, and amortization expense was $1,940,000 for each of the years ended December 31, 2022 and 2021, respectively.

The estimated remaining amortization as of December 31, 2022 is as follows (in thousands):

Years Ending December 31	
2023	$ 1,940
2024	1,946
2025	1,940
2026	1,940
2027	1,191
Total	$ 8,957

9. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
	2022	2021
	(In thousands)	
Accrued compensation expenses	$ 2,294	$ 2,182
Accrued rebate and other revenue reserves	709	658
Accrued lease liabilities (note 4)	768	220
Other accrued expenses	227	557
Total accrued expenses	$ 3,998	$ 3,617

10. LICENSE AGREEMENTS

EyePoint Agreement

In February 2005, the Company entered into an agreement with EyePoint for the use of fluocinolone acetonide (FAc) in EyePoint's proprietary insert technology. This agreement was subsequently amended a number of times (as amended, the EyePoint Agreement). The EyePoint Agreement provides the Company with a worldwide exclusive license to utilize certain underlying technology used in the development and commercialization of ILUVIEN.

Second Amended and Restated Collaboration Agreement

On July 10, 2017, the Company and EyePoint entered into a Second Amended and Restated Collaboration Agreement (the New Collaboration Agreement), which amended and restated the EyePoint Agreement.

Before entering into the New Collaboration Agreement, the Company held the worldwide license from EyePoint for the use of EyePoint's proprietary insert technology for the treatment of all ocular diseases other than uveitis. The New Collaboration Agreement expanded the license to include uveitis, including NIU-PS, in Europe, the Middle East and Africa and also allows the Company to pursue an indication for NIU-PS for ILUVIEN in those territories.

The New Collaboration Agreement converted the Company's obligation to share 20% of its net profits to a royalty payable on global net revenues of ILUVIEN. The Company began paying a 2% royalty on net revenues and other related consideration to EyePoint on July 1, 2017. This royalty amount increased to 6% effective December 12, 2018. Pursuant to the New Collaboration Agreement the Company is required to pay an additional 2% royalty on global net revenues and other related consideration in excess of $75,000,000 in any year. During 2022 and 2021, the Company recognized approximately $2,808,000 and $2,949,000 of royalty expense, respectively, which is included in cost of goods sold, excluding depreciation and amortization. As of December 31, 2022, approximately $727,000 of this royalty expense was included in the Company's accounts payable.

In connection with a previous agreement with EyePoint, the Company was entitled to recover commercialization costs that were incurred prior to profitability of ILUVIEN and offset a portion of future payments owed to EyePoint in connection with sales of ILUVIEN with those accumulated commercialization costs. (The Company's future rights to recover these amounts from EyePoint are referred to as the Future Offset.) Following the signing of the New Collaboration Agreement, the Company retained a right to recover up to $15,000,000 of the Future Offset. Due to the uncertainty of future net profits, the Company has fully reserved the Future Offset in the accompanying consolidated financial statements. In March 2019, pursuant to the New Collaboration Agreement, the Company forgave $5,000,000 of the Future Offset in connection with the approval of ILUVIEN for NIU-PS in the U.K. As of December 31, 2022, the balance of the Future Offset was approximately $6,987,000, which is fully reserved. The Company will be able to recover the balance of the Future Offset as a reduction of future royalties that would otherwise be owed to EyePoint by reducing the royalty from 6% to 5.2% for net revenues and other related consideration up to $75,000,000 annually and from 8% to 6.8% for net revenues and other related consideration in excess of $75,000,000 on an annual basis.

Possible Reversion of the Company's License Rights to EyePoint

The Company's license rights to EyePoint's proprietary delivery device could revert to EyePoint if the Company were to:

(i) fail twice to cure its breach of an obligation to make certain payments to EyePoint following receipt of written notice thereof;

(ii) fail to cure other breaches of material terms of the EyePoint Agreement within 30 days after notice of such breaches or such longer period (up to 90 days) as may be reasonably necessary if the breach cannot be cured within such 30-day period;

(iii) file for protection under the bankruptcy laws, make an assignment for the benefit of creditors, appoint or suffer appointment of a receiver or trustee over its property, file a petition under any bankruptcy or insolvency act or have any such petition filed against it and such proceeding remains undismissed or unstayed for a period of more than 60 days; or

(iv) notify EyePoint in writing of its decision to abandon its license with respect to a certain product using EyePoint's proprietary insert technology.

On December 17, 2020, EyePoint, entered into a royalty purchase agreement (the SWK Agreement) with SWK Funding, LLC (SWK). In its Current Report on Form 8-K filed on December 18, 2020, EyePoint stated that pursuant to the SWK Agreement, EyePoint sold its interest in royalties that the Company is obligated to pay EyePoint under the New Collaboration Agreement. EyePoint reported that it had received a one-time $16,500,000 payment from SWK and, in return, SWK became

entitled to receive future royalties that the Company is obligated to pay to EyePoint under the New Collaboration Agreement. The Company is not a party to the SWK Agreement.

Ocumension License Agreement

On April 14, 2021, the Company entered into an exclusive license agreement (the License Agreement) with Ocumension (Hong Kong) Limited (Ocumension HK), a wholly owned subsidiary of Ocumension Therapeutics, for the development and commercialization under Ocumension HK's own brand name(s), either directly or through its affiliates or approved third-party sublicensees, of the Company's 190 microgram fluocinolone acetonide intravitreal implant in applicator (the Product; currently marketed in the United States, Europe, and the Middle East as ILUVIEN®) for the treatment and prevention of eye diseases in humans, other than uveitis, in a specified territory. The Territory is defined as the People's Republic of China, including Hong Kong SAR and Macau SAR, region of Taiwan, South Korea, Brunei, Cambodia, East Timor, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

The Company received a nonrefundable upfront payment of $10,000,000 from Ocumension HK and may in the future receive additional sales-based milestone payments totaling up to $89,000,000 upon the achievement by Ocumension HK of certain specified sales milestones during the term of the License Agreement. The Company's receipt of future milestone payments depends upon whether Ocumension HK is able to successfully complete product development and commercialization in the Territory, which requires, among other things, obtaining necessary regulatory approvals and appropriate reimbursement pricing in the various countries and jurisdictions in the Territory, a process that may take several years. In 2021, the Company recognized $11,048,000 in license revenue from the Ocumension transaction (including the value of a warrant subscription agreement, which Alimera received as consideration, for Alimera to purchase 1,000,000 shares of Ocumension Therapeutics during a period of four years), in accordance with ASC 606, Revenue from Contracts with Customers, with the remaining approximate $300,000 in consideration classified as deferred revenue that will be recognized over the remaining term of the license agreement once Ocumension begins to sell products.

The term of the License will continue (a) until the 10th anniversary of the latest first commercial sale of the Product in any country or jurisdiction in the Territory or (b) for as long as Ocumension HK is commercializing the Product in any part of the Territory, whichever is later. The term is subject to the Company's right to partially terminate the Agreement beginning on the 10th anniversary of the effective date with respect to any country or jurisdiction in the Territory in which Ocumension has not achieved at the time of termination first commercial sale and is not continuing to commercialize the Product. Ocumension will purchase Product from the Company at a fixed transfer price without royalty obligation on future sale (other than milestone payments as described above). Ocumension HK is responsible for all costs of development and commercialization in the Territory.

When the Company entered into the license agreement, it also entered into a share purchase agreement and a warrant subscription agreement, which are discussed in Note 11.

11. OTHER AGREEMENTS WITH OCUMENSION

Share Purchase Agreement

On April 14, 2021, the Company entered into a Share Purchase Agreement with Ocumension Therapeutics, pursuant to which the Company offered and sold to Ocumension 1,144,945 shares of common stock (the Shares), at a purchase price of $8.734044 per Share. The number of Shares sold was equal to 19.9% of the number of shares of common stock outstanding immediately before the closing.

The aggregate gross proceeds from the sale of the Shares were $10,000,000. The Company has used the net proceeds from the sale of the Shares to continue to commercialize ILUVIEN and for general corporate purposes, which may include working capital, capital expenditures, other clinical trial expenditures, acquisitions of new technologies, products or businesses in ophthalmology, and investments.

Pursuant to the Share Purchase Agreement and subject to certain limited exceptions, Ocumension was prohibited from selling, transferring, or otherwise disposing of the Shares for a year following the closing date.

Ocumension is entitled to certain purchase rights if the Company elects to offer or sell new securities in either a private or public offering.

Warrant Subscription Agreement

On April 14, 2021, the Company entered into the warrant agreement with Ocumension Therapeutics pursuant to which Ocumension agreed to issue to the Company 1,000,000 non-transferable warrants granting the Company the right for a period of

four years to subscribe to up to an aggregate of 1,000,000 shares of Ocumension stock at the subscription price of HK$23.88 per warrant share (or US$3.07 per warrant share as converted to U.S. Dollars at the exchange rate on April 9, 2021 of 0.12853 U.S. Dollars per HK$), subject to adjustment. (The converted rate is for illustrative purposes only; if the Company exercises the warrants, it will pay the subscription price of HK$23.88 per warrant share in HK$.) The warrants were issued on August 13, 2021, pursuant to the terms of the warrant agreement. The warrants are not and will not be listed on any stock exchange.

12. LOAN AGREEMENTS

Loan Agreements with SLR Investment Corp. (formerly Solar Capital Ltd.)

On January 5, 2018, the Company entered into a $40,000,000 loan and security agreement with Solar Capital Ltd., as Collateral Agent, and the parties signatory thereto from time to time as Lenders, including Solar Capital Ltd. in its capacity as a Lender (the 2018 Loan Agreement). On December 31, 2019, the Company refinanced the 2018 Loan Agreement by entering into a $45,000,000 loan and security agreement (the 2019 Loan Agreement) with SLR Investment Corp. (SLR, f/k/a Solar Capital Ltd.), as Agent, and the parties signing the Loan Agreement from time to time as Lenders, including SLR in its capacity as a Lender (collectively, the Lenders). The Company amended the 2019 Loan Agreement on March 24, 2023 (the Fifth Amendment) and entered into a related exit fee agreement with the Lenders. (See Note 21) Pursuant to the Fifth Amendment, the Lenders agreed to, among other things, (i) an additional tranche of $2,500,000 to increase the Company's existing term loan facility to $47,500,000, subject to certain closing conditions, and (ii) extend a $15,000,000 additional term loan available to be funded at the Lender's sole discretion.

Interest on the 2019 Loan Agreement prior to the Fifth Amendment was payable at an annual rate the greater of (i) one-month LIBOR or (ii) 1.78%, plus 7.65% per annum. As of December 31, 2022, the interest rate on the 2019 Loan Agreement was approximately 11.82%. Interest on the 2019 Loan Agreement following the Fifth Amendment is payable at an annual rate equal to 5.15% plus the greater of (i) 4.60% and (ii) one-month SOFR, which will reset monthly. The 2019 Loan Agreement provides for interest only payments until April 30, 2025, which may be extended an additional 12 months if the Company meets certain financial targets by March 31, 2025, followed by monthly payments of principal and interest through the loan maturity date of April 30, 2028.

2018 Exit Fee Agreement

Notwithstanding the repayment of the outstanding loan under the 2018 Loan Agreement, the Company remains obligated to pay additional fees under the Exit Fee Agreement (2018 Exit Fee Agreement) dated as of January 5, 2018 by and among the Company, SLR, as Agent, and the Lenders. The 2018 Exit Fee Agreement survived the termination of the 2018 Loan Agreement upon the repayment of the outstanding loan under the 2018 Loan Agreement and has a term of 10 years. The Company is obligated to pay up to, but no more than, $2,000,000 in fees under the 2018 Exit Fee Agreement.

Specifically, the Company is obligated to pay an exit fee of $2,000,000 on a "change in control" (as defined in the 2018 Exit Fee Agreement). To the extent that the Company has not already paid the $2,000,000 fee, the Company is also obligated to pay a fee of $1,000,000 on achieving each of the following milestones:

first, if the Company achieves revenues of $80,000,000 or more from the sale of its ILUVIEN product in the ordinary course of business to third party customers, measured on a trailing 12-month basis during the term of the agreement, tested at the end of each month; and

second, if the Company achieves revenues of $100,000,000 or more from the sale of its ILUVIEN product in the ordinary course of business to third party customers, measured in the same manner.

2019 Exit Fee Agreement

The Company is also obligated to pay additional fees under the Exit Fee Agreement dated as of December 31, 2019 by and among the Company, SLR as Agent, and the Lenders (2019 Exit Fee Agreement). The 2019 Exit Fee Agreement will survive the termination of the 2019 Loan Agreement and has a term of 10 years. The Company will be obligated to pay a $675,000 exit fee upon the occurrence of an exit event, which generally means a change in control, as defined in the 2019 Exit Fee Agreement.

Third Amendment to 2019 Loan Agreement

On February 22, 2022, the Company entered into a Third Amendment to the 2019 Loan Agreement (the Third Amendment), which, among other things:

(a) specified the minimum revenue amount, calculated on a trailing six-month basis and tested at the end of each calendar quarter in 2022, that the Company must achieve for each such period (the Revenue Covenant);

(b) consented to the Company maintaining a lower minimum revenue amount under the Revenue Covenant for the trailing six month period ended December 31, 2021 than previously required under the Loan Agreement (and waived any event of default that may have occurred or may be deemed to have occurred as a result of the Company's lower revenue amount for that period); and

(c) required that the Revenue Covenant be tested at March 31, 2023 and at the last day of each quarter thereafter, with the minimum revenue amount equal to a percentage of the Company's projected revenues in accordance with an annual plan submitted by the Company to Collateral Agent by January 15 of such year, such plan to be thereafter approved by the Company's board of directors and Collateral Agent in its sole discretion no later than February 28 of such year.

Fourth Amendment to 2019 Loan Agreement

On December 7, 2022, the Company entered into a Fourth Amendment to the 2019 Loan Agreement (the Fourth Amendment), which, among other things:

(a) extends the amortization date from January 1, 2023 to April 1, 2023, provided that such date may be further extended to July 1, 2023 upon the Company's request and in consultation with the Lenders, in each of the Lenders' sole discretion;

(b) specifies the minimum revenue amount, calculated on a trailing six-month basis and tested at the end of each calendar quarter in 2023, that the Company must achieve for each such period (the Revenue Covenant); and

(c) requires that the Revenue Covenant be tested at March 31, 2024 and at the last day of each quarter thereafter, with the minimum revenue amount equal to a percentage of Alimera's projected revenues in accordance with an annual plan submitted by the Company to the Collateral Agent by January 15th of such year, such plan to be thereafter approved by Alimera's board of directors and the Collateral Agent in its sole discretion no later than February 28 of such year.

Fifth Amendment to 2019 Loan Agreement

On March 24, 2023, the Company entered into a Fifth Amendment to the 2019 Loan Agreement (the Fifth Amendment and the 2019 Loan Agreement as so amended, the Amended Loan Agreement), under which the Lenders have agreed to, among other things:

(a) an additional tranche of $2,500,000 to increase the Company's existing term loan facility to $47,500,000, subject to certain closing conditions (the New Term Loan);

(b) extend a $15,000,000 additional term loan available to be funded at the Lender's sole discretion;

(c) annual interest rate equal to 5.15% plus the greater of (i) 4.60%, and (ii) one-month SOFR, which will reset monthly, on the New Term Loan;

(d) extend the maturity date to April 30, 2028 and the interest-only period to April 30, 2025, which may be extended an additional 12 months if the Company meets certain financial targets by March 31, 2025

(e) specify the minimum revenue amount, calculated on a trailing six-month basis beginning with the six month period ended March 31, 2023, and tested at the end of each calendar quarter, that the Company must achieve for each such period (the Revenue Covenant)

The Company expects to comply with the Revenue Covenant at the next reportable date, which is March 31, 2023, and the remainder of the Revenue Covenants through one year after these financial statements are issued.

Fifth Amendment Exit Fee Agreement

On March 24, 2023, the Company entered into the Fifth Amendment Exit Fee Agreement (the New Exit Fee Agreement), which will survive the termination of the Amended Loan Agreement and has a term of 10 years. The Company will be obligated to pay an exit fee of 1.5% of the original principal amount funded under the Amended Loan Agreement upon the occurrence of an exit event, which generally means a change in control, as defined in the New Exit Fee Agreement. If the Company has not already paid the exit fee under the New Exit Fee Agreement, the Company is also obligated to pay an equivalent fee upon achieving revenues of $82,500,000 or more from the sale of ILUVIEN in the ordinary course of business to third party customers, measured on a trailing 12-month basis during the term of the New Exit Fee Agreement, tested at the end of each month. The Company's

existing exit fee agreements remain in effect. The fees payable pursuant to the Company's existing exit fee agreements and the New Exit Fee Agreement will not exceed $3,387,500 in total.

Modification of Debt

In accordance with the guidance in ASC 470-50, *Debt*, the Company entered into and accounted for the Third Amendment and the Fourth Amendment as modifications and expensed, as they were incurred, an insignificant amount of legal costs associated with third parties as costs of modifications. The Company capitalized approximately $113,000 of costs as additional deferred financing costs in connection with the Fourth Amendment. The Company did not capitalize any costs associated with the Third Amendment.

Paycheck Protection Program Loan

On April 22, 2020, the Company received a $1,778,000 loan (the PPP Loan) under the Paycheck Protection Program established by the U.S. Small Business Administration as part of the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act. The PPP Loan was unsecured and was evidenced by a note in favor of HSBC Bank USA, National Association (HSBC) as the lender. On July 21, 2020, the Company submitted an application to HSBC for forgiveness of the PPP Loan. The PPP Loan was forgiven in its entirety, including interest, on April 16, 2021. As a result of forgiveness, the Company recognized a gain on extinguishment of debt of $1,792,000 during 2021.

Fair Value of Debt

The weighted average interest rates of the Company's notes payable approximate the rate at which the Company could obtain alternative financing. Therefore, the carrying amount of the notes approximated their fair value at December 31, 2022 and December 31, 2021.

13. COMMITMENTS AND CONTINGENCIES

2019 Loan Agreement

Under the 2019 Loan Agreement (see Note 12), as of December 31, 2022, the Company was obligated to make future minimum principal payments as follows:

Years Ending December 31	(In thousands)
2023	$ 28,421
2024	16,579
Total	45,000
Less unamortized debt discount and deferred financing costs	(1,004)
Less current portion	(25,313)
Non-current portion	$ 18,683

At each of December 31, 2022 and 2021, the Company had $458,000 and $365,000, respectively, of accrued and unpaid interest payable under the 2019 Loan Agreement.

Significant Agreements

In February 2016, the Company and Alliance Medical Products Inc., a Siegfried Company (Alliance), a third-party manufacturer, amended and restated the parties' existing agreement for the manufacture of the ILUVIEN implant, the assembly of the ILUVIEN applicator and the packaging of the completed ILUVIEN commercial product. Under the amended and restated Alliance agreement, its term was extended by five years, at which point the agreement became automatically renewable for successive one-year periods unless either party delivers notice of non-renewal to the other party at least 12 months before the end of the term or any renewal term. The Company is responsible for supplying the ILUVIEN applicator and the active pharmaceutical ingredient, and the Company must order at least 80% of the ILUVIEN units required in the covered territories from Alliance. Although the Company has approval to sell ILUVIEN in Canada, it does not currently have plans to pursue commercialization there. The Company holds total equipment of $1,043,000 at Alliance as of December 31, 2022.

In October 2020, the Company entered into a Manufacturing Services Agreement with Cadence, Inc. (the Cadence Agreement), under which Cadence has replaced the prior manufacturer. In 2021, Cadence began manufacturing certain component parts of the ILUVIEN applicator (the components) at its facility near Pittsburgh, Pennsylvania. Under the Cadence Agreement, the Company pays certain per-unit prices based on regularly scheduled shipments of a minimum number of

components. The initial term of the Cadence Agreement expires on October 30, 2025. After the expiration of the initial term, the Cadence Agreement will automatically renew for separate but successive one-year terms unless either party provides written notice to the other party that it does not intend to renew the Cadence Agreement at least 24 months before the end of the term. The Cadence Agreement may be terminated by either party under certain circumstances. The Company has transferred the manufacturing of component parts of the ILUVIEN inserter to Cadence and has spent cash resources to purchase new equipment, to update clean room facilities and to assist in the regulatory approval process. The Company holds total equipment of $802,000 at Cadence as of December 31, 2022.

In January 2020, the Company began entering into agreements with contract research organizations (CROs) and physician clinics in connection with a multicenter, single masked, randomized and controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its advantages over using the current standard of care of repeat anti-VEGF injections (the NEW DAY Study). The NEW DAY Study is planned to enroll 300 treatment-naïve, or almost naïve, DME patients in approximately 40 sites around the U.S. For the years ended December 31, 2022 and 2021, the Company incurred $4,345,000 and $3,824,000, respectively, of expense associated with the NEW DAY Study. As of December 31, 2022, the Company expects to incur approximately an additional $6,809,000 of expense associated with the study through December 31, 2024.

Employment Agreements

The Company is party to employment agreements with four executives. The agreements generally provide for annual salaries, bonuses and benefits and for the “at-will” employment of such executives. Effective February 1, 2023, the Company is party to four employment agreements with these four executives with annual salaries ranging from $355,000 to $580,000. If any of these individual employment agreements are terminated by the Company without cause, or by the employee for good reason, as defined in the applicable agreement, the Company will be liable for one year to 18 months of salary and benefits to that individual employee. Certain other employees have general employment contracts that include stipulations regarding confidentiality, Company property, severance in an event of change of control and miscellaneous items.

14. PREFERRED STOCK

Series A Convertible Preferred Stock

In October 2012, the Company closed its preferred stock financing in which it sold units consisting of 1,000,000 shares of Series A Convertible Preferred Stock (Series A Preferred Stock) and warrants (which expired on October 1, 2017) to purchase 300,000 shares of Series A Preferred Stock for gross proceeds of $40,000,000, prior to the payment of approximately $560,000 of related issuance costs. The powers, preferences and rights of the Series A Preferred Stock are set forth in the certificate of designation for the Series A Preferred Stock filed by the Company with the Delaware Secretary of State as part of the Company’s certificate of incorporation. As of December 31, 2022, there were 600,000 shares of Series A Convertible Preferred Stock issued and outstanding.

The Company repurchased all of its outstanding Series A Preferred Stock on March 24, 2023. Following such repurchase, the Company filed a certificate of elimination of the Series A Preferred Stock with the Secretary of State of the State of Delaware. (See Note 21.)

15. STOCK INCENTIVE PLANS

The Company has stock option and stock incentive plans that provide for grants of shares to employees and grants of options to employees and directors to purchase shares of the Company’s common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. Awards that can be granted under these plans include stock options, restricted stock units (RSUs) and restricted stock. The Company also has an employee stock purchase plan (see Note 18). Options granted to employees typically become exercisable over a four-year vesting period and have a ten-year contractual term. Initial options granted to directors typically vest over a four-year period and have a ten-year contractual term. Annual option grants to directors typically vest in full on the date of the Company’s next annual meeting of shareholders and have a ten-year contractual term. As of December 31, 2022, a total of 754,033 shares of the Company’s common stock were available for issuance under new awards granted under the Company’s 2019 Omnibus Incentive Plan.

A summary of stock option transactions under the plans are as follows:

	Years Ended December 31,			
	2022		2021	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options outstanding at beginning of period	1,075,795	$ 23.35	939,379	$ 26.72
Grants	287,800	4.96	228,805	5.63
Forfeitures	(185,694)	22.26	(85,992)	14.25
Exercises	(2,562)	5.85	(6,397)	6.59
Options outstanding at year end	1,175,339	19.03	1,075,795	23.35
Options exercisable at year end	878,115	23.62	809,837	28.76
Weighted average per share fair value of options granted during the year	$ 3.33		$ 3.65	

The following table provides additional information related to outstanding stock options, fully vested stock options, and stock options expected to vest as of December 31, 2022:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
				(In thousands)
Outstanding	1,175,339	$ 19.03	5.68 years	$ —
Exercisable	878,115	23.62	4.72 years	—
Outstanding, vested and expected to vest	1,139,482	19.46	5.58 years	—

The Company estimated the fair value of options granted using the Black-Scholes option pricing model. Use of a valuation model requires the Company to make certain assumptions with respect to selected model inputs. Changes in these input variables would affect the amount of expense associated with equity-based compensation. Expected volatility is based on the historical volatility of the Company's common shares over the expected term of the stock option grant. To estimate the expected term, the Company utilizes the "simplified" method for "plain vanilla" options as discussed within the SEC's Statement of Accounting Bulletin 110. The Company intends to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior will be more widely available. The risk-free interest rate is based on U.S. Treasury Daily Treasury Yield Curve Rates corresponding to the expected life assumed at the date of grant. Dividend yield is zero as there are no payments of dividends made or expected. The weighted-average assumptions used for option grants were as follows:

	Years Ended December 31,	
	2022	2021
Risk-free interest rate	1.46%	0.66%
Volatility factor	76.97%	74.47%
Grant date fair value of common stock options	$ 3.33	$ 3.65
Weighted-average expected life	6.02 years	6.03 years
Assumed forfeiture rate	10.00%	10.00%

Employee stock-based compensation expense related to stock options recognized in accordance with ASC 718 was as follows:

	Years Ended December 31,	
	2022	2021
	(In thousands)	
Sales and marketing	$ 174	$ 199
Research, development and medical affairs	93	77
General and administrative	553	595
Total employee stock-based compensation expense related to stock options	$ 820	$ 871

As of December 31, 2022, there was approximately $1,005,000 of total unrecognized compensation cost related to outstanding stock option awards that will be recognized over a weighted average period of 2.50 years. The total fair value of shares vested during 2022 was approximately $844,000.

The total estimated fair value of options granted during the years ended December 31, 2022 and 2021 was $957,000 and $835,000, respectively. The total estimated intrinsic value of options exercised was $3,000 for the year ended December 31, 2022. The total estimated intrinsic value of options exercised was $23,000 for the year ended December 31, 2021.

Restricted Stock

A summary of restricted stock transactions under the plans are as follows:

	Years Ended December 31,			
	2022		2021	
	Restricted Stock & RSUs	Weighted Average Grant Date Fair Value	RSUs	Weighted Average Grant Date Fair Value
Restricted stock & RSUs outstanding at beginning of period	46,250	$ 5.65	30,086	$ 3.12
Grants of restricted stock & RSUs	57,500	4.96	55,500	5.73
Vested shares of restricted stock & RSUs	(9,687)	5.01	(25,403)	3.12
Forfeitures	(20,469)	6.42	(13,933)	5.15
Restricted stock & RSUs outstanding at year end	73,594	4.98	46,250	5. 65

As of December 31, 2022, there was approximately $288,000 of total unrecognized compensation cost related to outstanding restricted stock that will be recognized over a weighted average period of 2.69 years.

Employee stock-based compensation expense related to restricted stock recognized in accordance with ASC 718 was $56,000 and $81,000 for the years ended December 31, 2022, and 2021, respectively.

16. CONCENTRATIONS AND CREDIT RISK

For the years ended December 31, 2022 and 2021, there were three customers within the U.S. segment. Two of these customers, which are large pharmaceutical distributors, accounted for approximately 63% and 55%, respectively, of the Company's total consolidated product revenues. These two customers accounted for approximately 71% and 68% of the Company's consolidated accounts receivable as of December 31, 2022 and 2021, respectively.

For the year ended December 31, 2022, one of the Company's third-party manufacturers of ILUVIEN comprised approximately 13% of the Company's total purchases, and there were no other vendors that comprised more than 10% of the Company's total purchases. For the year ended December 31, 2021, one of the Company's third-party manufacturers of ILUVIEN comprised approximately 12% of the Company's total purchases, and there were no other vendors that comprised more than 10% of the Company's total purchases. The Company relies on a single manufacturer for the ILUVIEN intravitreal implant, a single manufacturer for the ILUVIEN applicator and a single active pharmaceutical ingredient manufacturer for ILUVIEN's active pharmaceutical ingredient.

17. INCOME TAXES

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act (the CARES Act) was enacted and signed into law. In addition to other provisions, the CARES Act contains modifications to Net Operating Loss (NOL) carryback rules. For each of the twelve months ended December 31, 2022 and 2021, there were no material impacts to the tax provision related to the CARES Act.

The components of net loss before taxes are as follows:

	Years Ended December 31,	
	2022	2021
	(In thousands)	
United States	$ (11,000)	$ (10,241)
Foreign	(7,079)	6,307
Loss before provision for income taxes	$ (18,079)	$ (3,934)

In accordance with ASC 740, the Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of assets and liabilities at the enacted tax rates in effect for the year in which the differences are expected to reverse. The Company records a valuation allowance against the net deferred tax asset to reduce the net carrying value to an amount that is more likely than not to be realized.

The provision for income taxes consists of the following components:

	Years Ended December 31,	
	2022	2021
	(In thousands)	
Current expense (benefit):		
Federal	$ —	$ —
State	—	—
Foreign	144	(172)
Current income tax expense (benefit)	144	(172)
Deferred expense (benefit):		
Federal	—	—
State	—	—
Foreign	(116)	610
	(116)	610
Valuation allowance	—	—
Deferred income tax expense (benefit)	(116)	610
Total income tax expense	$ 28	$ 438

The following summarizes activity related to the Company's valuation allowance:

	Years Ended December 31,	
	2022	2021
	(In thousands)	
Valuation allowance at beginning of period	$ (48,855)	$ (38,882)
Increase in valuation allowance	(4,310)	(9,973)
Valuation allowance at end of period	$ (53,165)	$ (48,855)

Worldwide net deferred tax assets and liabilities are as follows:

	December 31,	
	2022	2021
Deferred tax assets	(In thousands)	
Depreciation and amortization	$ 94	$ 27
Intangible assets	6,841	7,692
Other deferred tax assets	91	829
NOL carry-forwards	41,800	35,335
Equity compensation	2,749	3,347
Collaboration agreement receivable reserves	1,719	1,762
Valuation allowance	(53,165)	(48,855)
Total deferred tax assets	$ 129	$ 137

A reconciliation from the federal statutory rate to the total provision for income taxes is as follows:

	Years Ended December 31,			
	2022		2021	
	Amount	Percent	Amount	Percent
	(in thousands, except percentages)			
Federal tax benefit at statutory rate	$ (3,797)	21.0%	$ (826)	21.0%
State tax — net of federal benefit	(379)	2.1	(24)	0.6
Permanent items	718	(4.0)	240	(6.1)
Foreign rate differential	(1,680)	9.3	(1,374)	34.9
Deferred rate change	—	—	(215)	5.5
Tax effect of intellectual property migration	—	—	(8,547)	217.2
Tax credits and true-ups	856	(4.8)	1,211	(30.7)
Increase in valuation allowance	4,310	(23.8)	9,973	(253.5)
Total tax expense	$ 28	(0.2)%	$ 438	(11.1)%

A rollforward of the Company's uncertain tax positions is as follows:

	Years Ended December 31,	
	2022	2021
	(In thousands)	
Balance of uncertain tax positions at beginning of period	$ 88	$ 65
Gross increases - tax positions in current period	24	29
Gross decreases - tax positions in prior period	—	(6)
Balance of uncertain tax positions at end of period	$ 112	$ 88

Included in the balance of unrecognized tax benefits as of December 31, 2022 and 2021 are approximately $112,000 and $88,000, respectively, of tax benefits related to research and development tax credits. In accordance with ASC 740-10, such attributes are reduced to the amount that is expected to be recognized in the future. The Company does not accrue interest or penalties, as there is no risk of additional tax liability due to significant NOLs available. The Company does not expect any decreases to the unrecognized tax benefits within the next twelve months due to any lapses in statute of limitations. Tax years from 2019 to 2021 remain subject to examination in California, Georgia, Kentucky, Tennessee, Texas and on the federal level, with the exception of the assessment of NOL carry-forwards available for utilization, which can be examined for all years since 2009. The statute of limitations on these years will close when the NOLs expire or when the statute closes on the years in which the NOLs are utilized.

Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to the realization of U.S. deferred tax assets due to the history of operating losses, a valuation allowance has been established against the entire net U.S. deferred tax asset balance. The valuation allowance is based on management's estimates of taxable income in the jurisdictions in which the Company operates and the period over which deferred tax assets will be recoverable. If actual results differ from these estimates or the Company adjusts these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact the Company's financial position and results of operations.

As of December 31, 2022 and 2021, the Company had federal net operating loss (NOL) carry-forwards of approximately $147.2 million and $143.2 million, and state NOL carry-forwards of approximately $107.7 million and $106.7 million, respectively, subject to further limitation based upon the final results of the Company's analyses of Internal Revenue Code Sections 382 and 383. These NOLs are available to reduce future income unless otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2029 and 2037, the Company's federal NOL created in 2018 and onward will carry forward indefinitely and the state NOL carry-forwards will expire at various dates between 2022 and 2042.

Sections 382 and 383 of the Internal Revenue Code limit the annual use of NOL carry-forwards and tax credit carry-forwards, respectively, following an ownership change. NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (Section 382) (or comparable provisions of state law) if certain changes in ownership were to occur. The Company periodically evaluates its NOL carry-forwards and whether certain changes in ownership have occurred that would limit the Company's ability to utilize a portion of its NOL carry-forwards. If it is determined that significant ownership changes have occurred since the Company generated its NOL carry-forwards, the Company may be subject to annual limitations on the use of these NOL carry-forwards under Section 382 (or comparable provisions of state law). The Company has determined that a Section 382 change in ownership occurred in late 2015. As a result of this change in ownership, the Company estimated that approximately $18.6 million of the Company's federal NOLs and approximately $382,000 of federal tax credits generated prior to the change in ownership will not be utilized in the future. The Company is currently in the process of refining and finalizing

these calculations, and upon finalization, will determine if a write-off is necessary. Any future changes in the Company's ownership or sale of its stock, including the Company's March 2023 financing, could further limit the use of its NOLs in the future. The reduction to the Company's NOL deferred tax asset due to the annual Section 382 limitation and the NOL carryforward period would result in an offsetting reduction in valuation allowance recorded against the NOL deferred tax asset.

Effective January 1, 2022, for U.S. tax purposes research and development costs, including software development costs, are required to be capitalized and will be deductible over five years for costs incurred domestically and over fifteen years for costs incurred in a foreign country. Additionally, the first year of amortization requires that amortization begin with the midpoint of the taxable year. As of December 31, 2022, the Company has recorded a deferred tax asset of approximately $969,000 related to capitalized research and development costs. This deferred tax asset is fully reserved with a valuation allowance.

As of December 31, 2022, the Company's U.K. subsidiary is in a net deferred tax asset position primarily due to the step up in tax basis for intangible assets created by the transfer of intellectual property from the Netherlands to the U.K. Based upon the expected pattern of reversal of deferred taxes, it is not more likely than not that these deferred tax assets will be realized. As such, a full valuation allowance is placed against the net deferred tax assets of the U.K. subsidiary. The Company's Irish subsidiary has a deferred tax asset for net operating loss carryforwards. The Company expects this net operating loss carryforward to be fully realizable in the future based upon the Company's control of the transfer pricing arrangements. A valuation allowance is not recorded on the deferred tax assets of the Ireland subsidiary. Deferred tax considerations for all other foreign entities are immaterial to the financial statements.

The Company anticipates that its foreign subsidiaries will be profitable and have earnings in the future. Once the foreign subsidiaries have earnings, the Company intends to indefinitely reinvest in its foreign subsidiaries all undistributed earnings and original investments in such subsidiaries. As a result, the Company does not expect to record deferred tax liabilities in the future related to excesses of book over tax basis in the stock of its foreign subsidiaries in accordance with ASC 740-30-25.

18. EMPLOYEE BENEFIT PLANS

The Company has a salary deferral 401(k) plan that covers substantially all U.S. employees of the Company. The Company matches participant contributions subject to certain plan limitations. Compensation expense associated with the Company's matching plan totaled $412,000 and $431,000 for the years ended December 31, 2022 and 2021, respectively. The Company may also make an annual discretionary profit-sharing contribution. No such discretionary contributions were made during the years ended December 31, 2022 and 2021, respectively.

In 2010, the Company established an Employee Stock Purchase Plan (the ESPP). Under the ESPP, eligible employees can participate and purchase common stock semi-annually through accumulated payroll deductions. The compensation committee of the Company's board of directors administers the ESPP. Under the ESPP, eligible employees may purchase stock at 85% of the lower of the fair market value of a share of common stock on the offering date or the exercise date. The ESPP provides for two six-month purchase periods generally starting on the first trading day on or after October 31 and April 30 of each year. Eligible employees may contribute up to 15% of their eligible compensation. A participant may purchase a maximum of 500 shares of common stock per purchase period. The value of the shares purchased in any calendar year may not exceed $25,000.

The ESPP was effective upon the completion of the Company's initial public offering in 2010, at which time a total of 32,961 shares of the Company's common stock were made available for sale. As of January 1 of each year, the number of available shares is automatically restored to the original level. A total of 20,766 and 22,878 shares of the Company's common shares were acquired through the ESPP during the years ended December 31, 2022 and 2021, respectively. As such, on January 1, 2023 and 2022 an additional 20,766 and 22,878, respectively, shares became available for future issuance under the ESPP. In accordance with ASC 718-50, the ability to purchase stock at 85% of the lower of the fair market value of a share of common stock on the offering date or the exercise date represents an option. The Company estimates the fair value of such options at the inception of each offering period using the Black-Scholes valuation model. In connection with the ESPP, the Company recorded $34,000 and $45,000 of compensation expense for the years ended December 31, 2022 and 2021, respectively.

19. SEGMENT INFORMATION

For the years ended December 31, 2022 and 2021, two customers within the U.S. segment that are large pharmaceutical distributors accounted for 63% and 55% of the Company's consolidated product revenues, respectively. These same two customers within the U.S. segment accounted for approximately 71% and 68% of the Company's consolidated accounts receivable at December 31, 2022 and 2021, respectively.

During the first quarter of 2021, the Chief Executive Officer (CEO), who is the chief operating decision maker (CODM), changed the manner in which the CODM monitors performance, aligns strategies and allocates resources, which resulted in a change in the operating segments. The Company's operations are now managed as three operating segments: U.S., International and Operating Cost. The Company determined that each of these operating segments represented a reportable segment.

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Previously, the Company was managed as two operating segments: U.S. and International. In monitoring performance, aligning strategies and allocating resources, the Company's CODM manages and evaluates our U.S., International and Operating Cost segments based on segment income or loss from operations adjusted for certain non-cash items, such as stock-based compensation expense and depreciation and amortization. Therefore, the Company classifies within Other (a) the non-cash expenses included in research, development and medical affairs expenses; general and administrative expenses; and sales and marketing expenses; and (b) depreciation and amortization.

The Company's U.S. and International segments represent the sales and marketing, general and administrative and research and development activities dedicated to the respective geographies. The Operating Cost segment primarily represents the general and administrative and research & development activities not specifically associated with the U.S. or International segments and includes expenses such as executive management; information technology administration and support; legal; compliance; clinical studies; and business development.

Each of the Company's U.S., International and Operating Cost segments is separately managed and is evaluated primarily upon segment income or loss from operations. Other is presented to reconcile to the Company's consolidated totals. The Company does not report balance sheet information by segment because the Company's CODM does not review that information. The Company allocates certain operating expenses among its reporting segments based on activity-based costing methods. These activity-based costing methods require the Company to make estimates that affect the amount of each expense category that is attributed to each segment. Changes in these estimates will directly affect the amount of expense allocated to each segment and therefore the operating profit of each reporting segment.

The following table presents a summary of the Company's reporting segments for the years ended December 31, 2022 and 2021:

	Year Ended December 31, 2022				
	U.S.	International	Operating Cost	Other	Consolidated
			(In thousands)		
REVENUE:					
PRODUCT REVENUE, NET	$ 34,202	$ 19,927	$ —	$ —	$ 54,129
LICENSE REVENUE	—	—	—	—	—
NET REVENUE	34,202	19,927	—	—	54,129
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(4,165)	(3,812)	—	—	(7,977)
GROSS PROFIT	30,037	16,115	—	—	46,152
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	5,036	3,470	7,657	65	16,228
GENERAL AND ADMINISTRATIVE EXPENSES	1,238	1,740	9,258	635	12,871
SALES AND MARKETING EXPENSES	17,898	7,356	523	210	25,987
DEPRECIATION AND AMORTIZATION	—	—	—	2,706	2,706
OPERATING EXPENSES	24,172	12,566	17,438	3,616	57,792
SEGMENT INCOME (LOSS) FROM OPERATIONS	5,865	3,549	(17,438)	(3,616)	(11,640)
OTHER INCOME AND EXPENSES, NET				(6,439)	(6,439)
NET LOSS BEFORE TAXES					$ (18,079)

	Year Ended December 31, 2021				
	U.S.	International	Operating Cost	Other	Consolidated
			(In thousands)		
REVENUE:					
PRODUCT REVENUE, NET	$ 26,740	$ 21,241	$ —	$ —	$ 47,981
LICENSE REVENUE	—	11,048	—	—	11,048
NET REVENUE	26,740	32,289	—	—	59,029

COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(3,298)	(3,732)	—	—	(7,030)
GROSS PROFIT	23,442	28,557	—	—	51,999
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	3,628	4,197	5,850	103	13,778
GENERAL AND ADMINISTRATIVE EXPENSES	969	1,322	9,828	655	12,774
SALES AND MARKETING EXPENSES	15,348	6,953	529	239	23,069
DEPRECIATION AND AMORTIZATION	—	—	—	2,579	2,579
OPERATING EXPENSES	19,945	12,472	16,207	3,576	52,200
SEGMENT INCOME (LOSS) FROM OPERATIONS	3,497	16,085	(16,207)	(3,576)	(201)
OTHER INCOME AND EXPENSES, NET				(3,733)	(3,733)
NET LOSS BEFORE TAXES					$ (3,934)

20. FAIR VALUE

The Company applies ASC 820, Fair Value Measurements, in determining the fair value of certain assets and liabilities. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the “exit price”) in an orderly transaction between market participants at the measurement date.

In determining fair value, the Company uses various valuation approaches. The hierarchy of those valuation approaches is broken down into three levels based on the reliability of inputs as follows:

Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. An active market for the asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis. The valuation under this approach does not entail a significant degree of judgment.

Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include: quoted prices for similar assets or liabilities in active markets, inputs other than quoted prices that are observable for the asset or liability, (e.g., interest rates and yield curves observable at commonly quoted intervals or current market) and contractual prices for the underlying financial instrument, as well as other relevant economic measures.

Level 3 inputs are unobservable inputs for the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

The following fair value table presents information about the Company’s assets and liabilities measured at fair value on a recurring basis:

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Warrant asset (1)	$ —	$ 183	$ —	$ 183
Assets measured at fair value	$ —	$ 183	$ —	$ 183

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Warrant asset (1)	$ —	$ 833	$ —	$ 833

Assets measured at fair value	$ —	$ 833	$ —	$ 833

(1) The Company uses the Black-Scholes pricing model and assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. Changes in this value each reporting period are reported in the consolidated statement of operations.

21. SUBSEQUENT EVENTS

Securities Purchase Agreement

On March 24, 2023, the Company entered into a Securities Purchase Agreement (the Purchase Agreement) with certain investors for the sale of up to 27,000 shares of the Company's newly designated Series B Convertible Preferred Stock, par value $0.01 per share (the Series B Preferred Stock) and warrants (the Warrants) to purchase up to 5,714,286 shares of the Company's common stock, for an aggregate purchase price of up to $27,000,000 in two tranches. On March 24, 2023 (the Tranche 1 Closing Date), the Company issued and sold an aggregate of 12,000 shares of Series B Preferred Stock at a per-share purchase price of $1,000 (the Stated Value) and the Warrants for aggregate gross proceeds of $12,000,000 (the Tranche 1 Closing). The proceeds from the Tranche 1 Closing will be used to fund development and commercialization of the Company's existing and pipeline drugs, maintenance of the Company's credit facility and corporate purposes substantially related to the commercialization of the Company's existing and pipeline drugs, as well as the Repurchase (as defined below).

At the closing of the second tranche (the Tranche 2 Closing), the Company will issue and sell an aggregate of 15,000 shares of Series B Preferred at a per-share purchase price equal to the Stated Value for aggregate gross proceeds of $15,000,000. The Tranche 2 Closing will only occur upon the mutual agreement of the Company and the holders of a majority of the outstanding Series B Preferred Stock (the Preferred Majority); provided that the closing shall occur no later than December 31, 2023, if at all. The proceeds from the Tranche 2 Closing, if any, will be used to fund potential in-licenses or acquisitions of new technologies, products or businesses in ophthalmology, subject to applicable Nasdaq listing rules.

The initial conversion price of the shares of Series B Preferred Stock issued at the Tranche 1 Closing is $2.10 (the Tranche 1 Conversion Price). The shares of Series B Preferred Stock issued at the Tranche 2 Closing, if any, will have an initial conversion price equal to the 30-day preceding volume-weighted average price of the common stock on Nasdaq, but in any event (i) no less than eighty percent (80%) of the Tranche 1 Conversion Price per share nor (ii) greater than two-times the Tranche 1 Conversion Price per share. In each case, the conversion price of the Series B Preferred Stock is subject to certain customary adjustments, including a weighted average anti-dilution adjustment.

Unless and until stockholder approval to issue the common stock underlying the Series B Preferred Stock is obtained, the Series B Preferred Stock will not be convertible into common stock to the extent that such conversion would cause (i) the aggregate number of shares of common stock that would be issued pursuant to the Purchase Agreement and the transactions contemplated thereby to exceed 1,401,901 (19.99% of the voting power or number of shares of common stock, issued and outstanding immediately prior to the execution of the Purchase Agreement), which number will be reduced, on a share-for-share basis, by the number of shares of common stock issued or issuable pursuant to any transactions that may be aggregated with the transactions contemplated by the Purchase Agreement under applicable Nasdaq rules (the Exchange Cap); or (ii) the aggregate number of shares of common stock that would be issued pursuant to such conversion, when aggregated with any shares of common stock then beneficially owned by the holder (or group of holders required to be aggregated) of such shares, would result in (a) a "change of control" under applicable Nasdaq listing rules (the Change of Control Cap) or (b) such holder or a "person" or "group" to beneficially own in excess of 9.99% of the common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon such conversion (the Ownership Limitation).

The Series B Preferred Stock will be entitled to receive dividends and other distributions pro rata with the common stock. In addition, prior to conversion, dividends will accrue on the Series B Preferred at an annual rate of 6% of the Stated Value, accruing daily. The Series B Preferred Stock is not redeemable.

The Warrants have an exercise price equal to the Tranche 1 Conversion Price (as adjusted pursuant to the Certificate of Designation of the Series B Preferred Stock through the date of Stockholder Approval) and expire seven years from the date of the Tranche 1 Closing. The Warrants are exercisable upon the earlier of (a) a change of control and (b) March 24, 2024; provided that prior to Stockholder Approval, exercise of the Warrants is subject to the Ownership Limitation, the Change of Control Cap and the Exchange Cap. If the Company consummates the Tranche 2 Closing or a qualified financing transaction of at least

$15,000,000 prior to December 31, 2023, the number of shares underlying the Warrants will automatically be reduced to an aggregate of 1,000,000 shares of common stock.

Repurchase and Elimination of Series A Convertible Preferred Stock

As a condition to entering into the Purchase Agreement, the Company repurchased all 200,919 shares of common stock and 600,000 shares of its Series A Preferred Stock held by the holders thereof (the Repurchase), for an aggregate purchase price of approximately $1,252,000. The holders of the Series A Preferred Stock were entitled to a liquidation preference before the holders of common stock would be entitled to receive any consideration in the event of the Company's liquidation. As of December 31, 2022, the Series A Preferred Stock aggregate liquidation preference was $24,000,000. As a result of the Repurchase, no shares of the Series A Preferred Stock remain outstanding and the liquidation preference is no longer in effect.

Fifth Amendment to Loan and Security Agreement and Exit Fee Agreement

On March 24, 2023, the Company entered into the Fifth Amendment. Pursuant to the Fifth Amendment, the lenders have agreed to, among other things, (i) an additional tranche of $2,500,000 to increase the existing term loan facility to $47,500,000, subject to certain closing conditions (the New Term Loan), and (ii) extend a $15,000,000 additional term loan available to be funded at the lenders' sole discretion. The New Term Loan will bear interest at an annual rate equal to 5.15% plus the greater of (i) 4.60% and (ii) one-month SOFR, which will reset monthly. The Fifth Amendment extends the maturity date to April 30, 2028, and the interest-only period to April 30, 2025. The interest-only period may be extended an additional 12 months if the Company meets certain financial targets by March 31, 2025. In addition, the Fifth Amendment specifies the minimum net product revenue levels, calculated on a trailing six-month basis beginning with the six-month period ended March 31, 2023, and tested at the end of each calendar quarter, that the Company must achieve for each such period. The Company also agreed to grant to the collateral agent (for the benefit of the lenders) a first-priority security interest in all of its intellectual property.

The Company is obligated to pay additional fees under the Fifth Amendment Exit Fee Agreement (the New Exit Fee Agreement) dated as of March 24, 2023, with SLR as collateral agent, and the lenders party thereto. The New Exit Fee Agreement will survive the termination of the 2019 Loan Agreement and has a term of 10 years. The Company will be obligated to pay an exit fee of 1.5% of the original principal amount funded under the 2019 Loan Agreement upon the occurrence of an exit event, which generally means a change in control. If the Company has not already paid the exit fee, it will also be obligated to pay an equivalent fee upon achieving revenues of $82,500,000 or more from the sale of ILUVIEN in the ordinary course of business, measured on a trailing 12-month basis.

EXHIBIT INDEX

Exhibit Number	Exhibit Title
3.1	Restated Certificate of Incorporation of Registrant, as amended on various dates (filed as Exhibit 3.1 to the Registrant's Annual Report on Form 10-K, as filed on March 2, 2020, and incorporated herein by reference)
3.2	Amended and Restated Bylaws of the Registrant, as amended (filed as Exhibit 3.2 to the Registrant's Annual Report on Form 10-K, as filed on March 2, 2020, and incorporated herein by reference)
3.3	Certificate of Designation of Series B Convertible Preferred Stock (filed as Exhibit 3.1 to the Registrant's Form 8-K, as filed March 27, 2023, and incorporated herein by reference)
3.4	Certificate of Elimination of Series A Convertible Preferred Stock (filed as Exhibit 3.2 to the Registrant's Form 8-K, as filed March 27, 2023, and incorporated herein by reference)
3.5	Certificate of Elimination of Series C Convertible Preferred Stock (filed as Exhibit 3.3 to the Registrant's Form 8-K, as filed March 27, 2023, and incorporated herein by reference)
4.1	Description of Securities (filed as Exhibit 4.2 to the Registrant's Form 10-K, as filed March 23, 2022, and incorporated herein by reference)
10.1†	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.2.A†	2010 Equity Incentive Plan (filed as Exhibit 10.9 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
10.2.B†	Form of Notice of Stock Option Grant and Stock Option Agreement under 2010 Equity Incentive Plan (filed as Exhibit 10.30 to Registrant's Annual Report on Form 10-K, as filed on March 25, 2011, and incorporated herein by reference)
10.2.C†	UK Sub-Plan of the 2010 Equity Incentive Plan of Alimera Sciences, Inc. (filed as Exhibit 10.38 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 7, 2012, and incorporated herein by reference and replaced by Exhibit 10.3.G)
10.2.D†	Form of UK Sub-Plan Notice of Stock Option Grant and Stock Option Agreement (filed as Exhibit 10.39 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 7, 2012, and incorporated herein by reference)
10.2.E†	(2017) UK Sub-Plan of the 2010 Equity Incentive Plan of Alimera Sciences, Inc. (filed as Exhibit 10.46 to the Registrant's Annual Report on Form 10-K, as filed on March 3, 2017, and incorporated herein by reference)

10.3.A†	2010 Employee Stock Purchase Plan (filed as Exhibit 10.10 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
10.3.B†	Amendment No. 1 to 2010 Employee Stock Purchase Plan (filed as Exhibit 10.7.A to the Registrant's Annual Report on Form 10-K, as filed March 13, 2015, and incorporated herein by reference)
10.3.C†	Amendment No. 2 to 2010 Employee Stock Purchase Plan (filed as Exhibit 99.3 to the Registrant's Registration Statement on Form S-8, as filed November 2, 2020, and incorporated herein by reference)
10.4.A†	Alimera Sciences, Inc. 2019 Omnibus Incentive Plan, as amended pursuant to stockholder approval on June 15, 2021 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on June 16, 2021, and incorporated herein by reference)
10.4.B†	Form of Stock Option Agreement under the Alimera Sciences, Inc. 2019 Omnibus Incentive Plan (filed as Exhibit 10.61 to the Registrant's Current Report on Form 8-K, as filed on June 19, 2019, and incorporated herein by reference)
10.4.C†	Form of Restricted Stock Agreement under the Alimera Sciences, Inc. 2019 Omnibus Incentive Plan (filed as Exhibit 10.5.C to the Registrant's Quarterly Report on Form 10-Q, as filed May 6, 2020, and incorporated herein by reference)
10.4.D†	Form of Restricted Stock Unit Agreement under the Alimera Sciences, Inc. 2019 Omnibus Incentive Plan (filed as Exhibit 10.5.D to the Registrant's Quarterly Report on Form 10-Q, as filed May 6, 2020, and incorporated herein by reference)
10.4.E†	UK Sub-Plan to the Alimera Sciences, Inc. 2019 Omnibus Incentive Plan (filed as Exhibit 99.5 to the Registrant's Registration Statement on Form S-8, as filed on October 29, 2021 and incorporated herein by reference)
10.4.F†	Form of UK Sub-Plan Stock Option Agreement (filed as Exhibit 99.6 to the Registrant's Registration Statement on Form S-8, as filed on October 29, 2021 and incorporated herein by reference)
10.5†	Alimera Sciences, Inc. 2019 Non-Employee Director Compensation Program (filed as Exhibit 10.62 to the Registrant's Current Report on Form 8-K, as filed July 19, 2019, and incorporated herein by reference)
10.6.A†	Amended and Restated Employment Agreement, effective as of October 23, 2014, by and between the Registrant and David Holland (filed as Exhibit 10.39 to the Registrant's Annual Report on Form 10-K, as filed on March 13, 2015, and incorporated herein by reference)
10.6.B†	Amended and Restated Employment Agreement, dated as of January 2, 2019, by and between Alimera Sciences, Inc. and Richard S. Eiswirth, Jr. (filed as Exhibit 10.58 to the Registrant's Current Report on Form 8-K, as filed May 8, 2019, and incorporated herein by reference)
10.6.C†	Contract of Employment dated November 3, 2012 by and between the Registrant and Philip Ashman (filed as Exhibit 10.40 to the Registrant's Annual Report on Form 10-K, as filed on March 28, 2013, and incorporated herein by reference)
10.6.D†	Change in Control Severance Agreement between Alimera Sciences, Inc., and Philip J. Ashman, Ph.D. as of July 16, 2021 (filed as Exhibit 10.7.H to the Registrant's Quarterly Report on Form 10-Q, as filed November 5, 2021 and incorporated herein by reference)
10.6.E†	Employment Agreement, dated as of January 9, 2023, by and between Alimera Sciences, Inc. and Russell L. Skibsted (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed January 10, 2023, and incorporated herein by reference)
10.7‡	First Amended and Restated Commercial Contract Manufacturing Agreement dated as of February 5, 2016 by and between Alimera Sciences, Inc. and Alliance Medical Products, Inc. d.b.a. Siegfried Irvine (filed as Exhibit 10.41 to the Registrant's Quarterly Report on Form 10-Q, as filed on May 6, 2016, and incorporated herein by reference)
10.8**	Manufacturing Services Agreement between Alimera Sciences, Inc. and Cadence, Inc. dated October 30, 2020 (including related Supplier Quality Agreement) (filed as Exhibit 10.16 to the Registrant's Quarterly Report on Form 10-Q, as filed November 3, 2020, and incorporated herein by reference)
10.9‡	Second Amended and Restated Collaboration Agreement by and between pSivida US Inc. and Alimera Sciences, Inc. dated July 10, 2017 (filed as Exhibit 10.23 to pSivida Corp.'s Annual Report on Form 10-K for the year ended June 30, 2017 (SEC File No. 000-51122), as filed September 13, 2017, and incorporated herein by reference)
10.10.A	Exit Fee Agreement dated as of January 5, 2018 by and among Alimera Sciences, Inc., Solar Capital Ltd. as collateral agent, and the Lenders (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, as filed January 8, 2018, and incorporated herein by reference)
10.10.B**	Loan and Security Agreement dated as of December 31, 2019, by and among Alimera Sciences, Inc., Solar Capital Ltd., as collateral agent, and the parties signatory thereto from time to time as Lenders, including Solar in its capacity as a Lender (filed as Exhibit 10.65 to the Registrant's Current Report on Form 8-K, as filed January 6, 2020, and incorporated herein by reference)

10.10.C	Exit Fee Agreement dated as of December 31, 2019, by and among Alimera Sciences, Inc., Solar Capital Ltd. as collateral agent, and the Lenders (filed as Exhibit 10.66 to the Registrant's Current Report on Form 8-K, as filed January 6, 2020, and incorporated herein by reference)
10.10.D	Consent to Loan and Security Agreement dated as of April 21, 2020 by and among Alimera Sciences, Inc., Solar Capital Ltd., as collateral agent, and the Lenders parties thereto, including Solar Capital Ltd. in its capacity as a Lender (filed as Exhibit 10.14.D to the Registrant's Current Report on Form 8-K, as filed April 23, 2020, and incorporated herein by reference)
10.10.E	First Amendment to Loan and Security Agreement dated as of May 1, 2020, by and among Alimera Sciences, Inc., Solar Capital Ltd., as Collateral Agent, and the parties signatory thereto as Lenders, including Solar in its capacity as a Lender (filed as Exhibit 10.14E to the Registrant's Current Report on Form 8-K, as filed May 1, 2020, and incorporated herein by reference)
10.10.F	Second Amendment to Loan and Security Agreement dated as of March 30, 2021, by and among Alimera Sciences, Inc., SLR Investment Corp. (f/k/a Solar Capital Ltd.), as Collateral Agent, and the parties signatory thereto as Lenders, including SLR in its capacity as a Lender (filed as Exhibit 10.14.F to the Registrant's Quarterly Report on Form 10-Q, as filed May 7, 2021, and incorporated herein by reference)
10.10.G	Third Amendment to Loan and Security Agreement dated as of February 22, 2022, by and among Alimera Sciences, Inc., SLR Investment Corp, as Collateral Agent, and the parties signatory thereto as Lenders, including SLR in its capacity as a Lender (filed as Exhibit 10.11.G to the Registrant's Quarterly Report on Form 10-Q, as filed May 12, 2022, and incorporated herein by reference)
10.11.A	Share Purchase Agreement by and between Ocumension Therapeutics and Alimera Sciences, Inc., dated as of April 14, 2021 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K as filed on April 14, 2021 and incorporated herein by reference)
10.11.B**	Voting and Investor Rights Agreement by and between Alimera Sciences, Inc. and Ocumension Therapeutics, dated as of April 14, 2021 (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K as filed on April 14, 2021 and incorporated herein by reference)
10.11.C	Warrant Subscription Agreement by and between Alimera Sciences, Inc. and Ocumension Therapeutics, dated as of April 14, 2021 (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K as filed on April 14, 2021 and incorporated herein by reference)
10.11.D**	Exclusive License Agreement by and between and Ocumension (Hong Kong) Limited, dated as of April 14, 2021 (filed as Exhibit 10.4 to the Registrant's Current Report on Form 8-K as filed on April 14, 2021 and incorporated herein by reference)
10.12* **	Fourth Amendment to Loan and Security Agreement dated as of December 7, 2022, by and among Alimera Sciences, Inc., SLR Investment Corp, as Collateral Agent, and the parties signatory thereto as Lenders, including SLR in its capacity as a Lender
21.1*	List of subsidiaries of the Registrant (including jurisdiction of organization and names under which subsidiaries do business)
23.1*	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350
101	The following financial information from The Registrant's Annual Report on Form 10-K for the year ended December 31, 2022, formatted in iXBRL (Inline Extensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2022 and 2021, (ii) Consolidated Statements of Operations for the years ended December 31, 2022 and 2021, (iii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2022 and 2021, (iv) Consolidated Statements of Changes in Stockholders' Deficit for the years ended December 31, 2022 and 2021, and (v) Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

† Management contracts and compensatory plans and arrangements required to be filed as exhibits pursuant to Item 15(b) of Form 10-K.

‡ Confidential treatment has been granted with respect to certain portions of this document.

** Certain confidential information contained in this agreement has been omitted because it is (i) material and (ii) something the company actually treats as confidential.

* Filed herewith.

Signatures

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in Alpharetta, Georgia, on March 31, 2023.

ALIMERA SCIENCES, INC.

By: /s/ Richard S. Eiswirth, Jr.
Name: Richard S. Eiswirth, Jr.
Title: President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Richard S. Eiswirth, Jr. and Russell L. Skibsted, and each of them, as his or her true and lawful attorneys-in-fact, proxies, and agents, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, 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, proxies, and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, proxies, and agents, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this Annual Report on Form 10-K 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/ Richard S. Eiswirth, Jr. Richard S. Eiswirth, Jr.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2023
/s/ Russell L. Skibsted Russell L. Skibsted	Chief Financial Officer and Senior Vice President (Principal Financial and Accounting Officer)	March 31, 2023
/s/ C. Daniel Myers C. Daniel Myers	Chairman of the Board of Directors	March 31, 2023
/s/ Michael Kaseta Michael Kaseta	Director	March 31, 2023
/s/ Garheng Kong Garheng Kong, M.D., Ph.D.	Director	March 31, 2023
/s/ Adam Morgan Adam Morgan	Director	March 31, 2023
/s/ Erin Parsons Erin Parsons	Director	March 31, 2023
/s/ Peter J. Pizzo, III Peter J. Pizzo, III	Director	March 31, 2023
/s/ John Snisarenko John Snisarenko	Director	March 31, 2023

Certain information in this document has been omitted pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is both (i) not material and (ii) is the type that the company treats as private or confidential, and has been marked with "[***]" to indicate where omissions have been made.

Exhibit 10.12

FOURTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **FOURTH AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of December 7, 2022, by and among SLR Investment Corp., a Maryland corporation, ("**SLR**"), as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**"), the lenders party hereto including SLR in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and Alimera Sciences, Inc., a Delaware corporation ("**Borrower**").

W I T N E S S E T H:

WHEREAS, Borrower, the Lenders, and Collateral Agent are parties to that certain Loan and Security Agreement, dated as of December 31, 2019 (as amended by the First Amendment to Loan and Security Agreement, dated as of May 1, 2020, by that certain Second Amendment to Loan and Security Agreement dated as of March 30, 2021, by that certain Third Amendment to Loan and Security Agreement dated as of February 22, 2022, and as further amended, restated, supplemented or otherwise modified from time to time prior to the date hereof, the "**Loan and Security Agreement**").

WHEREAS, Borrower has requested certain amendments to the Loan and Security Agreement as more fully set forth herein and Collateral Agent and the Lenders are willing to agree to such request, subject to and in accordance with the terms and conditions set forth in this Amendment.

NOW, THEREFORE, in consideration of the premises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, the Lenders, and Collateral Agent hereby agree as follows:

1. DEFINITIONS; INTERPRETATION.

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

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

2. AMENDMENTS TO LOAN AND SECURITY AGREEMENT.

(a) The Loan and Security Agreement shall be amended as follows:

(i) Section 1.4. Section 1.4 of the Loan Agreement is hereby amended and restated by amending and restating the following definition in its entirety as follows:

> "**Amortization Date**" is April 1, 2023; provided that the Amortization Date may, upon Borrower's request and in consultation with the Lenders, be extended to July 1, 2023 in each of the Lenders' sole discretion. Notwithstanding the foregoing or any other provision herein, after December 31, 2021, the Amortization Date shall be the first Payment Date following any Event of Default under Section 8.2(a) due to the failure to comply with Section 7.13.

(ii) Section 7.13. Section 7.13(a) of the Loan and Security Agreement is hereby amended and restated in its entirety as follows:

> (a) **Minimum Revenue Amount**. Permit revenues (under GAAP) from the sale in the ordinary course of business to third party customers of ILUVIEN by Borrower, on a trailing six (6) month basis, tested at November 30, 2020 (the "**Interim Revenue Testing Date**") for the trailing six (6) month period then ended and subsequently tested at the end of each quarter

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thereafter, to be less than the applicable Minimum Revenue Amount set forth below for such testing date:

Testing Date:	Minimum Revenue Amount:
November 30, 2020	$[***]
December 31, 2020	$[***]
March 31, 2021	$[***]
June 30, 2021	$[***]
September 30, 2021	$[***]
December 31, 2021	$[***]
March 31, 2022	$[***]
June 30, 2022	$[***]
September 30, 2022	$[***]
December 31, 2022	$[***]
March 31, 2023	$[***]
June 30, 2023	$[***]
September 30, 2023	$[***]
December 31, 2023	$[***]
March 31, 2024 and the last day of each quarter thereafter	[***]% of projected revenues in accordance with an annual plan submitted by Borrower to Collateral Agent by January 15th of such year (i.e., January 15, 2024 for the 2024 quarterly covenants), such plan to be thereafter approved by Borrower's board of directors and Collateral Agent in its sole discretion no later than February 28 of such year.

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

3. **CONDITIONS TO EFFECTIVENESS**. This Amendment shall become effective upon satisfaction of each of the conditions specified below:

(a) **This Amendment**. Collateral Agent shall have received one or more counterparts of this Amendment, duly executed, completed and delivered by Collateral Agent, each Lender and Borrower;

(b) **Fees and Expenses**. Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 9, (ii) all other fees, costs and expenses, if any, due and payable as of the date of this Amendment under the Loan and Security Agreement, and (iii) an amendment fee of $112,500 to the Collateral Agent for and on behalf of the Lenders (the "**Amendment Fee**"), which Amendment Fee shall be received by Collateral Agent within three (3) Business Days of the date hereof;

(c) **Representations and Warranties; No Default**. As of the date of this Amendment, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 of this Amendment shall be true and correct on and as of the date of this Amendment as though made on and as of such date; and

(ii) There exist no Default or Events of Default; and

(d) Collateral Agent shall have received all other documents and instruments as Collateral Agent or any Lender may reasonably deem necessary or appropriate to effectuate the intent and purpose of this Amendment.

For the avoidance of doubt, the Amendment Fee shall be fully earned on the date so paid, non-refundable for any reason and payable to the Lenders in accordance with their respective Pro Rata Shares.

4. REPRESENTATIONS AND WARRANTIES. To induce Collateral Agent and the Lenders to enter into this Amendment, Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof, *provided, further*, that to the extent such representations and warranties by their terms expressly relate only to a prior date such representations and warranties shall be true and correct as of such prior date; (b) that there has not been and there does not exist a Material Adverse Change; (c) reserved; (d) Collateral Agent and the Lenders have and shall continue to have valid, enforceable and perfected first-priority liens, subject only to Permitted Liens, on and security interests in the Collateral and all other collateral heretofore granted by Borrower to Collateral Agent and the Lenders pursuant to the Loan Documents or otherwise granted to or held by Collateral Agent and the Lenders; (e) the agreements and obligations of Borrower contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of Borrower, enforceable against Borrower in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; and (f) the execution, delivery and performance of this Amendment by Borrower will not (i) conflict with Borrower's organizational documents, including its Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable material order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or any of its property or assets may be bound or affected, and (iv) constitute an event of default under any material agreement by which Borrower or any of its properties is bound, the termination or noncompliance with which could reasonably be expected to have a Material Adverse Change. For the purposes of this Section, each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

5. LOAN DOCUMENTS OTHERWISE NOT AFFECTED; REAFFIRMATION; NO NOVATION.

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

(b) Borrower hereby expressly (1) reaffirms, ratifies and confirms its Obligations under the Loan and Security Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 4 of the Loan and Security Agreement, (3) reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, and with effect from (and including) the date hereof, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the consent and waiver expressly referenced herein; and (y) secures all Obligations under the Loan and Security Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan and Security Agreement, and (5) agrees that the Loan and Security Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

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

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

7. **RELEASE**. In consideration of the agreements of Collateral Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Collateral Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan and Security Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

8. **NO RELIANCE**. Borrower hereby acknowledges and confirms to Collateral Agent and the Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

9. **COSTS AND EXPENSES**. Borrower agrees to pay to Collateral Agent within ten (10) days of its receipt of an invoice (or on the date hereof to the extent invoiced on or prior to the date hereof), the out-of-pocket costs and expenses of Collateral Agent and the Lenders party hereto, and the fees and disbursements of counsel to Collateral Agent and the Lenders party hereto (including reasonable allocated costs of internal counsel), in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the date hereof or after such date.

10. **BINDING EFFECT**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

11. **GOVERNING LAW**. THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAW OTHER THAN THE LAW OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE.

12. **COMPLETE AGREEMENT; AMENDMENTS**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

13. **SEVERABILITY OF PROVISIONS**. Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

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

15. **LOAN DOCUMENTS**. This Amendment and the documents related thereto shall constitute Loan Documents.

16. **ELECTRONIC EXECUTION OF CERTAIN OTHER DOCUMENTS**. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by Collateral Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

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IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed and delivered as of the day and year specified at the beginning hereof.

BORROWER:

ALIMERA SCIENCES, INC.

By: /s/ Rick Eiswirth
Name: Rick Eiswirth
Title: President and Chief Executive Officer

[Signature Page to Fourth Amendment to Loan and Security Agreement]
[Signature Page to Fourth Amendment to Loan and Security Agreement]

COLLATERAL AGENT AND LENDER: SLR

INVESTMENT CORP.

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

[Signature Page to Fourth Amendment to Loan and Security Agreement]
[Signature Page to Fourth Amendment to Loan and Security Agreement]

LENDERS:

SUNS SPV LLC

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND SPV LLC

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND BDC SPV LLC

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CORPORATE LENDING FUND SPV LLC

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP SF DEBT FUND LP

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP CAYMAN DEBT MASTER FUND SPV LLC

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SLR CP SF DEBT FUND SPV LLC

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

[Signature Page to Fourth Amendment to Loan and Security Agreement]
[Signature Page to Fourth Amendment to Loan and Security Agreement]

Exhibit 21.1

Alimera Sciences, Inc.
List of Subsidiaries

Name of Wholly-Owned Subsidiary	Jurisdiction of Organization	Name under which the subsidiary conducts business
Alimera Sciences Limited	United Kingdom	Alimera Sciences Limited
Alimera Sciences Opthamologie GmbH	Germany	Alimera Sciences Opthamologie GmbH
Alimera Sciences Europe Limited	Ireland	Alimera Sciences Europe Limited

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 31, 2023, with respect to the consolidated financial statements included in the Annual Report of Alimera Sciences, Inc. on Form 10-K for the year ended December 31, 2022. We consent to the incorporation by reference of said reports in the Registration Statements of Alimera Sciences, Inc. on Forms S-8 (File No. 333-166822, File No. 333-173095, File No. 333-180567, File No. 333-187600, File No. 333-194381, File No. 333-201606, File No. 333-209035, File No. 333-215451, File No. 333-222508, File No. 333-229280, File No. 333-232206, File No. 333-249811, File No. 333-260617 and File No. 333-263784) and on Form S-3 (File No. 333-249804).

/s/ GRANT THORNTON LLP

Atlanta, Georgia
March 31, 2023

Exhibit 31.1

CERTIFICATION

I, Richard S. Eiswirth, Jr., certify that:

1. I have reviewed this annual report on Form 10-K of Alimera Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statements 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 consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 31, 2023

/s/ Richard S. Eiswirth, Jr.
Richard S. Eiswirth, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Russell L. Skibsted, certify that:

1. I have reviewed this annual report on Form 10-K of Alimera Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statements 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 consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 31, 2023

/s/ Russell L. Skibsted
Russell L. Skibsted
Chief Financial Officer and Senior Vice President
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

In connection with the Annual Report of Alimera Sciences, Inc. (the "Registrant") on Form 10-K for the annual period ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard S. Eiswirth, Jr., President, Chief Executive Officer, and Director of the Registrant, and Russell L. Skibsted, Chief Financial Officer of the Registrant, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their respective knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 31, 2023

/s/ Richard S. Eiswirth, Jr.
Richard S. Eiswirth, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 31, 2023

/s/ Russell L. Skibsted
Russell L. Skibsted
Chief Financial Officer and Senior Vice President
(Principal Financial and Accounting Officer)

This certification is made solely for the purposes of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose. A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the United States Securities and Exchange Commission or its staff upon request.

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 Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.