UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

or

o **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 **(State or other jurisdiction of incorporation or organization)**	**20-0028718** **(I.R.S. Employer Identification Number)**
6310 Town Square, Suite 400 **Alpharetta, GA** **(Address of principal executive offices)**	**30005** **(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 o No x

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 o No x

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 x No o

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 x No o

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	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
		Emerging growth company	o

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. o

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. o

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

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

As of June 30, 2023, 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 $14,369,959 based on the closing price per share of the registrant's Common Stock, on June 30, 2023, 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 6, 2024, there were 52,354,450 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 2024 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, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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,” “forecast,” “outlook,” “contemplates,” “predict,” “project,” “aim,” “seek,” “target,” “likely,” “remain,” “potential,” “continue,” “ongoing,” “will,” “will likely result,” “will continue,” “would,” “should,” “could,” or the variation 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,” “our,” the “registrant,” the “Company” or similar terms refer to Alimera Sciences, Inc. and its subsidiaries (as applicable).

The term “ILUVIEN®” and “YUTIQ®” are our registered trademarks. 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 global pharmaceutical company that specializes in the commercialization and development of prescription ophthalmic retinal pharmaceuticals. We are committed to improving the retinal health of patients through long term treatment of chronic retinal diseases. We believe these diseases are not well treated with current therapies and affect millions of people globally. Our vision is to be the place in retina and our mission is to be invaluable to patients, physicians and partners concerned with retinal health and maintaining better vision longer.

At Alimera, we internally developed and commercialized ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg, in the U.S. and internationally for the treatment of diabetic macular edema (“DME”), a leading cause of severe vision loss and blindness, and certain international markets for chronic non-infectious uveitis affecting the posterior segment of the eye (“NIU-PS”). We acquired exclusive commercialization rights to YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg, in May 2023 from EyePoint Pharmaceuticals, Inc. (“EyePoint Parent”) for the treatment and prevention of NIU-PS worldwide except for Europe, the Middle East, Africa, (known as ILUVIEN in Europe, the Middle East and Africa) and certain Asian countries including China. ILUVIEN and YUTIQ are state-of-the-art sustained release intravitreal implants that reduce disease recurrence and enable patients to maintain vision longer with fewer injections. We are continuing to study ILUVIEN and YUTIQ in trials. ILUVIEN is being evaluated as baseline therapy in naïve or near naïve patients with early DME in comparison with the current standard of care, anti-vascular endothelial growth factor (“VEGF”) therapy in the NEW DAY Study. YUTIQ is being further studied in the SYNCHRONICITY trial, a prospective, open-label clinical study evaluating the safety and efficacy of YUTIQ for the treatment and prevention of chronic NIU-PS and related intraocular inflammation. Both studies are described further below.

Business Strategy

We are committed to improving the retinal health of patients through long term treatment of chronic retinal diseases, because we believe these diseases are not sufficiently treated with current competing therapies and treatment regimens and represent a significant market opportunity. To fulfill our vision of becoming the place to be in retina, we provide a platform utilizing fluocinolone as an implant to become a leading therapy for DME and chronic NIU-PS patients because of its ability to control disease recurrence for up to three years and help patients see better, longer with fewer injections. We rely on our management’s experience and the breadth of our commercial resources in both the U.S. and internationally to maintain focus on the retinal space to commercialize our products. We intend to use those same strengths to acquire, obtain regulatory approval for and commercialize other potential retinal products. To implement our strategy, we intend to:

- Maximize the commercial success of ILUVIEN for treatment of DME in our current markets in which we have obtained regulatory approval and ILUVIEN is commercially available.
- Maximize the commercial success of ILUVIEN and YUTIQ for the treatment of chronic NIU-PS in the current markets in which we have obtained regulatory approval and ILUVIEN and YUTIQ is commercially available.
- Leverage the opportunity to cross sell ILUVIEN or YUTIQ to physicians and accounts that are utilizing one of our products for the treatment of either DME or chronic NIU-PS, but not both.
- Complete our SYNCHRONICITY STUDY to provide additional data to physicians regarding the ability to treat chronic NIU-PS and the related intraocular inflammation to increase the utilization of both ILUVIEN and YUTIQ.
- Complete our NEW DAY Study to provide data to physicians comparing the utilization of ILUVIEN in comparison to current standard of care, anti-VEGF therapy in the treatment of naïve and near naïve patients suffering from DME to move the utilization of ILUVIEN earlier in the treatment of DME.
- 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 certain territories in 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 and YUTIQ

Both ILUVIEN and YUTIQ treat patients by delivering a continuous microdose of the corticosteroid fluocinolone acetonide ("FAc") in the eye, for up to 36 months. ILUVIEN was developed internally and initially 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 sold to treat DME only in the U.S. YUTIQ is sold to treat NIU-PS only in the U.S. In certain European and Middle Eastern countries, ILUVIEN is approved and commercialized to treat DME and to prevent relapse in recurrent NIU-PS, 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. We also have rights to commercialize ILUVIEN for NIU-PS in Africa.

ILUVIEN and YUTIQ are both intravitreal implants that are inserted into the back of the patient's eye in non-surgical procedures employing devices with 25-gauge needles, which allow for a self-sealing wounds. "Intravitreal" refers to the space inside the eye behind the lens that contains the jelly-like substance called vitreous. The implants, which are non-bioerodible, provide consistent delivery as a result of their constant surface area, permitting elution of FAc to the vitreous. We call this CONTINUOUS MICRODOSING™. This delivery mechanism 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. CONTINUOUS MICRODOSING delivery makes ILUVIEN and YUTIQ the only approved drug therapies for DME and NIU-PS that can deliver consistent daily therapeutic levels of corticosteroid and reduce the recurrence of DME and uveitis for up to three years. 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.

FAc is a non-proprietary corticosteroid and the active compound in ILUVIEN (0.19mg) and YUTIQ (0.18mg). We at Alimera believe that corticosteroids provide the best option in the treatment of DME and NIU-PS because they reduce the inflammatory aspects of both diseases. ILUVIEN and YUTIQ deliver continuous daily sub-microgram levels of FAc in in vivo release kinetic studies for up to 36 months. ILUVIEN and YUTIQ are the only single injection therapies available to treat retinal diseases consistently every day for up to three years, which may allow patients to see better, longer, with fewer injections.

Chronic inflammation results in a loss of integrity of retinal blood vessels, which begin to leak fluid into extracellular spaces. The buildup of fluid and other blood constituents leads to macular swelling (i.e. edema) and causes visual disturbances due to mechanical stress put upon retinal cells. To compensate for the damaged blood vessels, the body begins to upregulate production of VEGF, which promotes the generation of new blood vessels. However, these new blood vessels also lack structural integrity and add to the problem rather than solving it. This process, called neovascularization, has been well characterized in DME as well as other retinal diseases.

The primary way to combat the process of neovascularization is to inhibit the growth of new blood vessels by preventing downstream VEGF signaling via anti-VEGF agents. However, the inflammatory process is early and central to DME pathogenesis, often preceding the vascular changes that lead to symptoms perceived by the patient. Chronic hyperglycemia present in the diabetic state leads to upregulation of many inflammatory cytokines, including, but not limited to, VEGF. Early and complete control of this inflammatory cascade is essential to maintain vascular integrity and thus prevent macular edema. This is evident in the results from a Diabetic Retinopathy Clinical Research Network study showed that 32-65% of patients treated with anti-VEGF monotherapy on a monthly basis for six months had persistent macular edema, despite this aggressive treatment regimen.

Comprehensive control over the various inflammatory factors promoting macular edema is rarely achieved by focusing on only one vasogenic cytokine. This has been demonstrated throughout multiple studies, first establishing an understanding of the broad spectrum of inflammatory control steroids exert, and another demonstrating significant reductions in vitreous levels of multiple inflammatory cytokines after six months of ILUVIEN therapy. Further, a growing body of literature has identified particular biomarkers that predict better outcomes to early corticosteroid therapy, including intraretinal cysts, subretinal fluid, disorganization of inner retinal layers, and hyper-reflective foci on optical coherence tomography images. As the benefits of steroids become more widely understood and appreciated, more efforts are being put into identifying patients most likely to experience optimal therapeutic outcomes with this drug class.

Chronic NIU-PS is by definition an inflammatory disease and is almost always managed with some form of local or systemic steroid. In controlled studies, treatment with a local, low-dose, long-acting steroid (YUTIQ) extended time between recurrence of symptoms, led to visual increases, and fewer adjuvant therapies compared to sham-treated eyes. Though the etiologies differ between DME and NIU-PS, the resulting edema originating from excessive inflammatory factors is similar and responds well to corticosteroid therapy.

Corticosteroids, including FAc, have demonstrated a range of pharmacological actions, including inhibition of inflammation and neurodegeneration, as well as promoting cellular processes that protect the integrity of the blood-retinal barrier. These pharmacological actions have the potential to treat various ocular conditions, including DME and NIU-PS. FAc is highly lipophilic and therefore effectively penetrates retinal tissue and allows FAc to achieve a therapeutic effect at a low dose. Despite providing clinically significant anatomic and visual benefits, steroids are often relegated to second line therapy (particularly in DME) due to drug-class specific side effects of potential increases in intraocular pressure ("IOP") and accelerated cataract development. To mitigate these side effects, ILUVIEN and YUTIQ are designed to deliver significantly lower daily exposure than any other available corticosteroid dosage form while maintaining a therapeutic effect. Further, adherence to the US label requiring a steroid challenge prior to utilizing ILUVIEN has been shown to reduce the risk of uncontrolled IOP responses. Additionally, as demonstrated with real-world evidence, the side effects of ILUVIEN and YUTIQ 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.

An additional benefit of the consistent, durable therapy offered by long-duration corticosteroids is control over retinal thickness variability. Short-acting anti-VEGF or steroid therapies may work well while therapeutically active, but the disease recurs quickly once the drug wears off. This creates a "see-saw" effect where vital retinal cells experience repeated phases of stretch and relaxation, leading to cumulative damage over time. In the real-world, Phase IV, observational, open label PALADIN study, treatment with ILUVIEN demonstrated a significant reduction in measures of overall edema, maximal retinal stretch, and variability from the mean retinal thickness. Further, significant visual gains correlated with the most consistent control of edema. Taken together, these data suggest that consistent and continuous low-dose FAc treatment has the ability to decrease multiple inflammatory cytokines, improve anatomic and visual outcomes, and provide stability to retinal architecture while maintaining a predictable and manageable safety profile.

Agreements with EyePoint Parent and EyePoint

In February 2005, we entered into a license agreement with the predecessor entity to EyePoint Pharmaceuticals US, Inc. ("EyePoint") in which we received 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 in humans other than uveitis. In July 2017, we amended and restated our license agreement with EyePoint (the "New Collaboration Agreement"), to add a license from EyePoint for the use of steroids, including FAc, in EyePoint's proprietary insert technology for the treatment of uveitis in 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 of 6% for net revenues and other related consideration up to $75.0 million annually and 8% for net revenues and other related consideration in excess of $75.0 million on an annual basis. The New Collaboration Agreement included a right to offset $15.0 million of future royalty payments (the "Future Offset"), which reduces royalties that would otherwise be owed to EyePoint 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 until the future offset is recovered. As of December 31, 2023, the remaining value of the future offset is $6.5 million.

On May 17, 2023, we entered into a product rights agreement (the "Product Rights Agreement") with EyePoint Parent which grants Alimera an exclusive and sublicensable right and license to certain intellectual property to develop, manufacture, sell, commercialize and otherwise exploit certain products, including YUTIQ, for the treatment and prevention of uveitis in the entire world, except Europe, the Middle East and Africa, where we already have such rights pursuant to the New Collaboration Agreement, and except for China, Hong Kong, Macau, Taiwan, Brunei, Burma (Myanmar), Cambodia, Timor-Leste, Indonesia, Loas, Malaysia, the Philippines, Singapore, South Korea, Thailand and Vietnam, where Ocumension Therapeutics ("Ocumension") holds a license from EyePoint Parent. Pursuant to the agreement, we paid EyePoint Parent an upfront payment of $75.0 million and will also make four quarterly guaranteed payments to EyePoint Parent totaling $7.5 million during 2024. We will also pay royalties to EyePoint Parent from 2025 to 2028 at a percentage of mid-to-low double digits of annual U.S. net sales of YUTIQ and ILUVIEN, in excess of certain thresholds, beginning at $70.0 million in 2025, increasing annually thereafter. Upon completing the $7.5 million in payments, the licenses and rights granted to Alimera will automatically become perpetual and irrevocable.

We also entered into a commercial supply agreement (the "Supply Agreement") with EyePoint Parent pursuant to which, during the term of the Product Rights Agreement, EyePoint Parent will be responsible for manufacturing and exclusively supplying (subject to certain exceptions) to us agreed-upon quantities of YUTIQ necessary for us to commercialize YUTIQ in the U.S. at certain cost-plus amounts, subject to adjustments. EyePoint Parent's manufacture and supply to us of YUTIQ will be exclusive (subject to certain exceptions) until we have the right and ability to manufacture and supply YUTIQ for commercialization in the U.S. The term of the Supply Agreement is for a period of two years through May 2025 and thereafter automatically renews for successive one-year terms unless either party provides notice of non-renewal to the other party within a specified period of time prior to the beginning of the next automatic renewal term, provided that the Supply Agreement automatically terminates upon the successful completion of the transfer of manufacturing for YUTIQ to us or our designee. The Supply Agreement also automatically terminates upon termination of the Product Rights Agreement.

Disease Overview and Market Opportunity

Diabetes and Diabetic Retinopathy

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood glucose. Hyperglycaemia, also called raised blood glucose or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels. Diabetes mellitus is a disease of inadequate control of blood glucose levels. 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.

National Diabetes Statistics Report

The 2023 National Diabetes Statistics Report published by the U.S. Centers for Disease Control and Prevention ("CDC") reported that as of 2021, 38.4 million Americans of all ages, or 11.6% of the U.S. population, had diabetes and that there were 1.2 million new cases of diabetes diagnosed among people ages 18 and older. Approximately 1 in 5 U.S. adults living with diabetes, 8.7 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 97.6 million people have prediabetes, a condition that if not treated often leads to type 2 diabetes within five years. In this population, less than 20% 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. 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. There are an estimated 750,000 people with DME in the U.S., according to the National Eye Institute's 2019 update.

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 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
- non-infectious uveitis ("NIU"), where corticosteroids are used to reduce inflammation and prevent adhesions in the eye.

Chronic NIU-PS of the eye is an inflammatory disease that afflicts people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. This disease affects between 60,000 to 100,000 people each year in the U.S. and causes approximately 30,000 new cases of blindness every year. The standard of care treatment for this disease typically involves the use of short-acting corticosteroids to reduce uveitic flares followed by additional treatments of sustained release, lower dose steroids to minimize the risk of further flares.

Current Treatments for DME

Anti–vascular endothelial growth factor therapy "Anti- VEGF"

Anti-VEGF therapies are the current standard of care for the treatment of DME. Eylea® (aflibercept injection 4 mg.), Eylea® HD (aflibercept injection 8 mg.), Vabysmo® (faricimab), Lucentis® (ranibizumab), Beovu® (brolucizumab-dbll), and are approved in the U.S. Cimerli® and Byooviz® are ranibizumab biosimilars 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. Furthermore, 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.

Steroids

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.

Laser Photocoagulation

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 was fully enrolled with 300 treatment-naïve, or almost naïve, DME patients in approximately 42 sites around the U.S. We expect to share the study data in early 2025.

Patients who meet the entry criteria have been 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.

Our SYNCHRONICITY Study

The SYNCHRONICITY Study is a multicenter, open label study evaluating YUTIQ in chronic inflammation. The Synchronicity Study currently has enrolled 110 patient eyes in approximately 25 sites around the U.S. Patients who meet the entry criteria receive YUTIQ as an intravitreal injection in the designated study eye. The treatment period is 36 months, with data capture for this study being the first 24 months of YUTIQ drug treatment.

The primary outcome measure for the SYNCHRONICITY Study is the mean change from baseline in BCVA letter score in the study eye measured by EDTRS at Month 6 and the mean change from baseline central subfield thickness at Month 6. Key secondary endpoints include time to recurrence of non-infectious inflammation in the study eye, presence of vascular leakage at Months 1, 3, 6, 12, 18, and 24, proportion of subjects with resolution of macular edema at Months 1, 3, 6, 12, 18, and 24, mean change from baseline in BCVA letter score at Day 14 and at Months 1, 3, 12, 18, and 24, and mean change from baseline in CST at Months 1, 3, 12, 18, and 24.

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 and YUTIQ significantly extend 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	Territories Where ILUVIEN Has Received Marketing Authorization to Treat DME*	Territories Where ILUVIEN Is Reimbursed to Treat DME	Territories 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, Hong Kong, Bahrain, Kuwait, Lebanon and the United Arab Emirates	U.S., Kuwait, Lebanon and the United Arab Emirates	U.S., Bahrain, 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., 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

** In December 2023, Ocumension obtained the proper approvals to utilize ILUVIEN for the treatment of DME in Hong Kong.*

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

YUTIQ has received marketing authorization to treat NIU-PS for the indication and is reimbursed and marketed by us in the U.S. ILUVIEN has received marketing authorization 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	Territories Where ILUVIEN Has Received Marketing Authorization to Treat NIU-PS	Territories Where ILUVIEN Is Reimbursed to Treat NIU-PS	Territories 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, Italy, Austria, Belgium, Denmark, Norway, Finland, Sweden, Poland, the Czech Republic, the Netherlands, Luxembourg and the United Arab Emirates	The U.K., Germany, Ireland, Italy, France, Portugal, Spain, the Czech Republic, Luxembourg and the Netherlands	The U.K., Germany, France, Spain, Portugal, Ireland, Italy, Austria, Belgium, Denmark, Norway, Finland, Sweden, the Czech Republic, the Netherlands, Luxembourg, and the United Arab Emirates

Where We Sell ILUVIEN Direct

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

Where We Sell ILUVIEN 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, 2023, we have recognized net product revenue from our international distributors in the Middle East, China, Austria, Belgium, the Czech Republic, France, Italy, Luxembourg, Spain, the Netherlands and certain Nordic countries.

ILUVIEN for Other Diseases of the Eye

ILUVIEN is currently being studied in a DRCR Retina Network study entitled “A Randomized Clinical Trial Evaluating Intravitreal Faricimab (6.0 mg) Injections or Fluocinolone Acetonide (0.19 mg) Intravitreal Implants vs Observation for Prevention of Visual Acuity Loss due to Radiation Retinopathy (Protocol AL).” The study is planned to include 600 participants with primary choroidal melanoma receiving treatment with plaque brachytherapy. The study will assess development of macular edema and associated long-term visual acuity effects of consistent and continuous release of corticosteroid or repeated injections of anti-VEGF initiated near the time of radiation therapy compared to observation until macular edema develops in patients at risk for radiation retinopathy. When utilized as baseline therapy, we believe ILUVIEN’s CONTINUOUS MICRODOSING delivery may prevent, delay or reduce the occurrence of the complication of radiation retinopathy and consequent vision loss when used in patients treated with plaque brachytherapy.

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

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 our products. In our promotional efforts, we focus on three main areas to generate demand for our products. The first is to gain access for ILUVIEN or YUTIQ, as appropriate, on formularies and 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 and YUTIQ 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.

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, and Sweden for uveitis, and China and other countries of the Western Pacific and in the Middle East for DME only. 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 for China and certain Western Pacific territories, see Ocumension License Agreement contained herein.

Manufacturing

We do not have 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 and YUTIQ. 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 U.S. Food and Drug Administration’s (“FDA”) 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 and YUTIQ.

The manufacturing process for ILUVIEN and YUTIQ consist of filling a polyimide tube with a paste consisting of, for ILUVIEN, 190 micrograms, and for YUTIQ, 180 micrograms, of FAc in an aqueous slurry of polyvinyl alcohol, cutting the tube into smaller sections in the proper lengths for the 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 or YUTIQ implant, curing the implant at high temperature, loading the implant inside the ILUVIEN or YUTIQ applicator, packaging and sterilizing the product. This process has been validated at Alliance Medical Products Inc., a Siegfried Company (“Alliance”) for ILUVIEN and at EyePoint Parent for YUTIQ.

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. or “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 European Economic Area (“EEA”) (carried out in Ireland by Packaging Coordinators, Inc.);
- final product release to market in the U.K. (carried out in Ireland by Packaging Coordinators, Inc.); and

- the manufacture and exclusive supply of YUTIQ for the U.S. market (EyePoint Parent).

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

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. 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.

On May 17, 2023. we entered into the Supply Agreement with EyePoint Parent pursuant to which, during the term of the Product Rights Agreement, EyePoint Parent is responsible for manufacturing and exclusively supplying (subject to certain exceptions) agreed-upon quantities of YUTIQ necessary to commercialize YUTIQ in the U.S. We rely on EyePoint Parent through the Supply Agreement to provide 100% of our requirements for YUTIQ.

Business Segments

Our operations are managed as three operating segments: U.S., International and Operating Cost. We determined that each of these operating segments represented a reportable segment. 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 17 of the accompanying consolidated financial statements.

Customers

Our revenues for the fiscal years ended December 31, 2023 and 2022 were $56.7 million and $34.2 million, respectively, from the U.S. and $24.0 million and $19.9 million, respectively, internationally. In the U.S., two large pharmaceutical distributors accounted for 70% and 63% of our consolidated product revenues for the years ended December 31, 2023 and 2022, respectively. These distributors maintain inventories of ILUVIEN and YUTIQ, and sell to physician offices, pharmacies and hospitals. Internationally, in countries where we directly market our products, we maintain inventories of ILIUVIEN and sell directly to hospitals, clinics and pharmacies. We sometimes refer to physician offices, pharmacies, hospitals and clinics as end users. In foreign countries where we sell though partnering distributors, these distributors maintain inventory levels of our products 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 YUTIQ as well as 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 and YUTIQ have received or been recommended for marketing authorization or have been approved for use in the treatment of DME and/or NIU-PS, they compete or will compete against the use of anti-VEGF therapies, short duration corticosteroids, systemic steroids 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 NIU-PS and other indications. These competitive therapies may result in pricing pressure even if ILUVIEN or YUTIQ is otherwise viewed as a preferable therapy. We believe that the following drugs and treatments compete with our products:

DME Competitors

- Eylea© (aflibercept) 4 mg and Eylea® HD (aflibercept) 8 mg, marketed by Regeneron in the U.S. and by Bayer in the EEA, are VEGF antagonists that are approved for the treatment of DME, diabetic retinopathy in patients with DME, and neovascular wet AMD. Eylea 4 mg is also indicated for RVO in the U.S. In the EEA, Eylea 4 mg includes treatment for myopic choroidal neovascularization but does not include diabetic retinopathy and Eylea HD is only indicated for neovascular wet AMD and DME. In the EEA, a biosimilar exists but it is not indicated for DME.

- Vabysmo® (faricimab-svoa), marketed by Genentech, is a VEGF inhibitor and Ang-2 inhibitor indicated for the treatment of patients with neovascular wet AMD, DME, and macular edema following RVO in the U.S. In the EEA, it is indicated for the treatment of wet AMD and DME.

- 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.

- Lucentis© (ranibizumab injection), marketed by Genentech (Roche) in the U.S. and Novartis in the rest of the world, is an antibody that inhibits 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. Additionally, there are several ranibizumab biosimilars approved for DME. These include Cimerli® marketed by Sandoz, Inc., Byooviz® marketed by Samsung Bioepsis/Biogen.

- Ozurdex© (dexamethasone intravitreal implant), marketed by Allergan, an AbbVie company, 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 the treatment of NIU-PS 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.

- 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 (“EU”) member states as well as the U.K., Iceland, Norway and Liechtenstein. Beovu is approved by the European Commission and the FDA for the treatment of DME indication.

- 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.

NIU-PS Competitors

- Ozurdex© (dexamethasone intravitreal implant), marketed by Allergan, an AbbVie company, 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 the treatment of non-infectious uveitis affecting the posterior segment of the eye 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.

- Xipere® (triamcinolone acetonide injectable suspension 40 mg/ml) marketed by Bausch & Lomb is a suprachoroidal corticosteroid that inhibits pro-inflammatory mediators. It has been approved for use in the U.S. for the treatment of macular edema associated with uveitis.

- Retisert®, marketed by Bausch and Lomb, is a sterile intravitreal implant containing 0.59mg of FAc that is surgically implanted into the vitreous through the pars plana and is attached to the sclera by a suture. It is indicated for the treatment of chronic NIU-PS. While similar to YUTIQ, Retisert delivers a higher rate of FAc each day and has shown a much higher rate of cataract and intraocular pressure issues than YUTIQ.

- 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 chronic NIU-PS although it is not approved for NIU-PS.

In addition, a number of other companies are developing drug therapies or delivery platforms for the treatment of retinal diseases in Phase 1 and Phase 2 stages.

We believe we will be less likely to face a generic competitor for ILUVIEN and YUTIQ for the treatment of DME and NIU-PS, respectively, because of the bioequivalence requirements of a generic form of ILUVIEN or YUTIQ. A generic pharmaceutical competitor to ILUVIEN or YUTIQ would need to establish bioequivalence 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 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 and YUTIQ 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 and YUTIQ, see the section immediately below.

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, 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 the 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 4 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 and YUTIQ 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 $0.8 million for both ILUVIEN and YUTIQ, as of our last renewal in October 2023.

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 or YUTIQ.

As part of the ILUVIEN 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.

Additionally, as part of the approval process of ILUVIEN for NIU-PS in Europe, we are committed to conduct an open label trial in the pediatric population with NIU-PS.

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 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, U.S. 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, 2023, we owned or licensed three 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 and YUTIQ or the ILUVIEN and YUTIQ applicator, respectively. We licensed our one utility patent right relating to ILUVIEN and YUTIQ 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. Pursuant to the Product Rights Agreement, these rights have been expanded to include uveitis worldwide except for China and certain other countries in Asia. 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 and YUTIQ. 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 one of which expired in April 2021 and the other will expire in October 2024 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. An additional licensed patent relating to the YUTIQ injector will expire in January 2028.

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 $6.3 million and $5.4 million in research and development during 2023 and 2022, respectively.

Employees

As of February 29, 2024, we had 159 employees, 154 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 products, ILUVIEN and YUTIQ;
- 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 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 single-sourced third-party manufacturers to manufacture our products or any future products or product candidates in sufficient quantities and quality, in a timely manner and at an acceptable price;
- the possibility that we may fail to plan appropriately to meet the demand of our customers for our products , which could lead either to (a) our products 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 our products or to deliver our products into our current markets;
- uncertainty associated with manufacturing components and materials being superseded or becoming obsolete;
- the possibility that we may 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;
- the possibility we 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 EEA and other regions of the world where we sell ILUVIEN;
- uncertainty regarding our ability to achieve profitability and positive cash flow through the commercialization of YUTIQ in the U.S. to treat chronic NIU-PS;
- 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;
- 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 current or future studies;
- the possible delay in enrollment of patients in our pediatric study for 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 and YUTIQ or any future products or product candidates in additional markets where we do not currently sell ILUVIEN and YUTIQ;
- 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 and YUTIQ following regulatory approval in additional markets; and
- the possibility that we may be adversely affected by the expiration of patents that protect key aspects of our products in the near- to medium-term.

Risks Related to Our Business

Our business depends on our products, ILUVIEN and YUTIQ.

We are a pharmaceutical company with two products, ILUVIEN, currently 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, and our other product, YUTIQ, available for commercial sale in the U.S. 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 and YUTIQ.

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 and several countries in the Middle East. In addition, we have granted an exclusive license to Ocumension for the development and commercialization of our 0.19 mg fluocinolone acetonide intravitreal injection in China, East Asia and the Western Pacific. As of December 31, 2023 we have recognized sales of ILUVIEN to international distributors in the Middle East, China, Austria, Belgium, Czech Republic, France, Italy, Luxembourg, Spain, the Netherlands, and certain Nordic countries.

In the U.S., YUTIQ is indicated for the treatment and prevention of chronic NIU-PS. Pursuant to the Product Rights Agreement with EyePoint Parent, we have the commercialization rights to YUTIQ in the entire world, except Europe, the Middle East and Africa as we had previously licensed from EyePoint rights to certain products, which included YUTIQ (known as ILUVIEN in Europe, the Middle East and Africa) for the prevention of relapse in recurrent NIU-PS in those territories. The Product Rights Agreement also excludes any rights to YUTIQ for the treatment and prevention of chronic NIU-PS in China and certain other countries and regions in Asia, which rights are subject to a pre-existing exclusive license between EyePoint Parent and Ocumension.

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 and SYNCHRONICITY Studies; and
- to support our NIU-PS study in pediatric patients.

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

If we or our distributors do not successfully maintain our sales in countries where we are approved to sell our products or our distributors do not successfully commence and grow our sales of our products in other countries where we are seeking to begin selling our products or have recently done so, our business may be seriously harmed. In addition, we may experience delays and unforeseen difficulties in the commercialization of our products , 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 our products 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 our current products and to any future products or product candidates that we may develop or commercialize in the future.

Our commercial opportunities for our current products 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 our products.

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 our current products 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 our current products.

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 U.S. and outside the U.S. that we must overcome. Changes in U.S. social, political, regulatory, and economic conditions or in laws and policies governing foreign trade, manufacturing, development, and investment, and any negative sentiments towards the U.S. 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 ongoing conflicts between Russia and Ukraine and Israel and Hamas could lead to disruption, instability, and volatility in global markets and industries. It is not possible to predict the broader or longer-term consequences of these conflicts, which could include further sanctions, embargoes, regional instability, energy shortages, geopolitical shifts and adverse effects on macroeconomic conditions, security conditions, currency exchange rates and financial markets. Such geopolitical instability and uncertainty could adversely affect our business, both in the U.S. 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 our products 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 President of International Operations, Elliot Maltz, our Chief Financial Officer, Todd Wood, our President of U.S. Operations, Jason Werner, our Chief Operating 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 our products 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 our current products. 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 cybersecurity threats or 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 may be vulnerable to cybersecurity attacks, computer viruses (including worms, malware, ransomware and other destructive or disruptive software or denial of service attacks), service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners or other third parties, physical or electronic break-ins and similar disruptions. We or our third-party manufacturers, CROs and other contractors and consultants could also experience directed attacks intended to lead to interruptions and delays in our service and operations as well as loss, misuse, theft or release of proprietary, confidential, sensitive or otherwise valuable company or subscriber data or information. Such a cybersecurity attack, virus, break-in, disruption or attack could remain undetected for an extended period, could harm our business, financial condition or results of operations, be expensive to remedy, expose us to litigation and/or damage our reputation. Our insurance may not cover expenses related to such disruptions or unauthorized access fully or at all. 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. Subject to the Supply Agreement with EyePoint Parent, EyePoint Parent is responsible for manufacturing and exclusively supplying (subject to certain exceptions) to us agreed-upon quantities of YUTIQ necessary for us to commercialize YUTIQ in the U.S. during the term of the Product Rights Agreement. We may elect to manufacture YUTIQ after an initial 18-month term following the date of the Product Rights Agreement, upon the satisfaction of certain conditions.

A security breach that impairs these distribution or logistics operations could significantly impair our ability to deliver our products to healthcare providers. In addition, our products are manufactured and tested by third parties, and a security breach that impairs these third parties could significantly impair our ability to procure our products and deliver them 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 our current products, both in the U.S. and internationally. A commercial launch of our current products 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 our current products 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 our current products 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 our current products have received marketing authorizations. These delays may increase the cost of, and the resources required for successful commercialization of our current products. Further, a delay in the commercial launch of our current products in certain jurisdictions could result in the withdrawal of our marketing or regulatory authorization for our current products in those jurisdictions, including certain EEA member states where our current products have already received marketing authorizations.

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 our products 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.

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 fully enrolled as of May 2023 with 300 treatment-naïve, or almost naïve, DME patients in approximately 42 sites around the U.S. 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, or take longer or be more costly to complete than we currently anticipate, 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 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 our current products are 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 value-added tax) 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, which is currently working through regulatory filings. 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 U.S.;
- 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 U.S.-China diplomatic and trade friction and social unrest in China and the recent conflicts between Russia and Ukraine, Israel and Hamas, 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.

Adverse weather conditions, natural disasters and the effects of climate change could disrupt our manufacturers' supply chains and adversely impact our sales and financial performance.

Adverse weather conditions and natural disasters may affect our manufacturers' supply chains, which could negatively impact our ability to source materials and components to make our products and, in more severe cases, such as hurricanes, earthquakes, floods, droughts, tornadoes or blizzards, eliminate the availability, or significantly increase the cost, of the components to make our products, sometimes for prolonged periods of time. The response of federal, state and local governmental bodies and agencies to climate change through regulations, mandates, reporting and disclosure requirements, taxes or levies could materially increase our cost to operate or obtain product components at a reasonable price, resulting in a material adverse effect on our financial results. Any of these situations could materially and adversely harm our business and financial condition.

Manufacturing Risks and Dependence on Third Parties

We rely on third parties to manufacture and test our products , 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 our products' active pharmaceutical ingredients,
- the manufacture of our products' applicator,
- the manufacture of our products' implants, final assembly of the injectors with the implants and release testing in the U.S., and
- the quality release testing of ILUVIEN in the EEA and for the U.K.

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 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. Furthermore, 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 ingredients, our products' implants or our products' applicators in a timely manner from these third parties could delay commercial production of our current products. 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 our current products, 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 applicators, as described in "Business—Manufacturing." We also rely on distributors for a majority of our sales of our current products. We sell ILUVIEN to two large pharmaceutical distributors in the U.S., which accounted for 70% and 63% of our consolidated product revenues in 2023 and 2022, respectively. These same two customers accounted for approximately 70% and 71% of our consolidated accounts receivable at December 31, 2023 and 2022, respectively. Internationally, our distributors produced approximately 43% and 39% of our international product revenues in 2023 and 2022, respectively. 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 our products to their customers. In turn, distributors could reduce their sales efforts for our products or choose to terminate their representation of us. They may also fail to perform their obligations under the agreements with us. Additionally, in certain Nordic countries 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 our current products 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 our products. 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 our products 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 our products that we expect. Moreover, although we have agreements with our suppliers for the supply of the active pharmaceutical ingredients in our products , the commercial production of the implants and the commercial production of our products' applicators, 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 our products and thus the supply of our products for sale would be delayed, which could significantly reduce the sales of our products and have an adverse impact on our business. We may incur higher costs in acquiring component parts for our products' inserters and inserts 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 conflicts between Russia and Ukraine and Israel and Hamas, 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, 2023, we had approximately $12.1 million in cash and cash equivalents. We raised gross proceeds of $78.6 million in 2023 through the sale of shares of our Series B Convertible Preferred Stock and warrants to purchase common stock to certain institutional investors and received $22.5 million loan proceeds through amendments to an existing loan agreement. $75.0 million was utilized for the upfront payment in acquiring YUTIQ. Whether current levels of liquidity will be sufficient to meet contractual obligations, 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. These factors include:

- the level of continued success of the commercialization of our products in the U.S., and in our international markets,
- expenses relating to the commercialization of our products;
- our research, development and general and administrative expenses;
- the timing of approvals, if any, of our products 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 our products 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 Global Market ("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.

In the past 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 that we did not meet the Revenue Covenant in the past, the lenders provided a consent that permitted us not to maintain the Revenue Covenant 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 2024. 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 through 2023.

We have incurred recurring losses and negative cash flow from operations, and we have accumulated a deficit of $418.5 million from our inception through December 31, 2023. Our ability to achieve profitability and positive cash flow depends on our ability to increase 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 our products in the geographic areas where we or our distributors offer our products. We cannot

assure that we will be profitable even if we successfully commercialize our current products 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 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 our products (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 approvals of our products in additional jurisdictions or for additional indications;
- regulatory developments affecting our current products, our future product candidates or our competitors' products;
- the emergence of products or treatments that compete with our products;
- 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 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 U.S. 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 COVID-19 pandemic and the ongoing conflicts between Russia and Ukraine and Israel and Hamas. 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 U.S. 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 30% of our product revenues in 2023 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, which went effective for tax years beginning in 2023. 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, 2023, we had U.S. federal and state net operating loss (“NOL”) carry-forwards of approximately $146.8 million and $106.8 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 2023 and 2043. 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 late 2015 and in 2023. As a result of these changes in ownerships, we estimated that substantially all of our federal and state NOL carry-forwards and tax credits generated prior to the 2023 change in ownership will be subject to Section 382 limitations and may not be fully utilized in the future. We are currently in the process of evaluating the Section 382 impact to determine if a write-off is necessary.

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 11 times since March 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 and YUTIQ 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 and YUTIQ, which must be conducted in accordance with the FDA's 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 our current products 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 our current products 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 our current products, resulting in delays and additional costs that could significantly and adversely affect our business. Any significant delays in the manufacture of our current products 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 our products 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 our products for only a limited indication, the size of our potential market for our products 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 than 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., our current products 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 our current products 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 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, U.S. 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 our current products 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 and for YUTIQ is based upon the burden of DME and NIU-PS, respectively, the current pricing of approved therapies for DME and NIU-PS, our perception of the overall cost-to-benefit ratio of ILUVIEN and NIU-PS, 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 and YUTIQ, which would reduce our anticipated revenue in the U.S.

In the U.S., the Medicare and Medicaid programs currently provide reimbursement for our products, but the reimbursement amount for our products could be modified in the future, and the types of patients for whom our products are reimbursed could be reduced to a smaller subset of patients. In addition, in some states, Medicare reimburses physicians for less than the cost of our products. 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 our current products 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 our products 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 or fiscal intermediaries were to make such a determination and deny or limit the reimbursement of our products. If the local contractors that administer the Medicare program are slow to reimburse retinal specialists for our products, 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 our products, but the reimbursement amount could be modified in the future, and the types of patients for whom our products are reimbursed could be reduced to a smaller subset of patients. We expect that private insurers will consider the efficacy, cost effectiveness and safety of our products in determining whether to maintain approval for reimbursement for our products 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 our products 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 our products 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 ("EEA") 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 our products in any additional countries is uncertain, and our regulatory approval in certain countries is contingent on our ability to sell our products 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 our products would prevent us from marketing and commercializing our products 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, Spain and certain Nordic countries (Sweden, Norway, Finland and Denmark) in 2024. 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.

In the U.S., YUTIQ is indicated for the treatment and prevention of chronic NIU-PS. Pursuant to the Product Rights Agreement with EyePoint Parent, we have the commercialization rights to YUTIQ in the entire world, except Europe, the Middle East and Africa as we had previously licensed from EyePoint rights to commercialize ILUVIEN in Europe, the Middle East and Africa for the prevention of relapse in recurrent NIU-PS in those territories. The Product Rights Agreement also excludes any rights to YUTIQ for the treatment and prevention of chronic NIU-PS in China and certain other countries and regions in Asia, which rights are subject to a pre-existing exclusive license between EyePoint Parent and Ocumension. We intend to continue to pursue market authorizations for our products 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 the necessary approvals to commercialize our products in any additional market.

The process of obtaining regulatory approvals and clearances in jurisdictions where our products are 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 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, and similar laws are under consideration in other states. 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 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 U.K. 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 U.K. 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 U.K. adopted versions of their own SCCs. Updating agreements to incorporate these new SCCs for the EEA and U.K. 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 U.S. 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 our products in the near- to medium-term.

The patent rights relating to ILUVIEN and YUTIQ licensed to us from EyePoint include one U.S. patent that will expire in August 2027, and in the EU in October 2024, although extensions have been obtained or applied for through May 2027 in various EU countries. Otherwise, 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 or YUTIQ.

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 U.S. and most major markets outside of the U.S. 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. Pursuant to the Product Rights Agreement with EyePoint Parent, we also have the commercialization rights to YUTIQ in the entire world, except Europe, the Middle East and Africa as we had previously licensed from EyePoint rights to certain products, which included YUTIQ (known as ILUVIEN in Europe, the Middle East and Africa) for the prevention of relapse in recurrent NIU-PS in those territories. The Product Rights Agreement also excludes any rights to YUTIQ for the treatment and prevention of chronic NIU-PS in China and certain other countries and regions in Asia, which rights are subject to a pre-existing exclusive license between EyePoint Parent and Ocumension.

Our ability to pursue the development and commercialization of our products depends upon the continuation of our agreements with EyePoint and EyePoint Parent. 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.

On December 17, 2020, EyePoint entered into a royalty purchase agreement (the "SWK Agreement") with SWK Funding, LLC ("SWK"). 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 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 our current products or the development or regulatory approval of other product candidates.

Our current products 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 our products. 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 our current products' 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 our current products, then the owners of such patents would be able to block our ability to commercialize our current products 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 products 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 a 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 and the rights we have licensed from EyePoint Parent relating to YUTIQ, 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 generic versions of our products 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 our products or the patents we pursue related to our products or any future product candidate is threatened, it could dissuade companies from collaborating with us to commercialize our products 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 our current products 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 our current products.

Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to our current products, 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 our current products 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 our current products, 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 our current products 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 our current products 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 our current products 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 our current products 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 being issued.

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 our current products 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 our current products grows, and we expand distribution into new markets, our current products 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 our current products into unanticipated markets. Sales of our 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 our current products, especially in the U.S. If the use of our current products 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 our current products are inserted into the eye, and it is possible that we may be held liable for eye injuries of patients who receive our products. 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 our current products 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 our current products, which could have a material adverse effect on our business, results or operations and financial condition. We have not had any material claims against us through the date of this report.

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. These insurance policies provide 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

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock and make it 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 Nasdaq 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 were 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”). Although we regained compliance within the Compliance Period on June 7, 2023 by qualifying under the equity standard under Nasdaq Listing Rule 5450(b)(1)(C) as a result of our Series B preferred stock financing, there can be no assurance that we will be able to maintain compliance with the Market Value of Publicly Held Shares requirement or other Nasdaq listing requirements in the future.

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 a 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. 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 our products 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 our current products 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. 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, 2023, options to purchase 3,046,195 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. 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.

Pursuant to the 2023 Omnibus Incentive Plan, our board of directors is authorized to grant various types of equity-based awards, including stock options, restricted stock units ("RSUs") and performance stock units ("PSUs"), to our employees, directors and consultants. As of December 31, 2023, a total of 142,511 shares of our common stock were available for issuance under new awards granted under our 2019 Omnibus Incentive Plan.

Subsequent to year end, we adopted the 2024 Equity Inducement Plan on February 8, 2024 under which our board of directors is authorized to grant inducement awards, including stock options, RSUs and PSUs, to our employees and directors of up to 800,000 common shares.

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. Furthermore, the rights and preferences of 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 cover 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 1C. *CYBERSECURITY*

Risk Management and Strategy:

The Company has processes for assessing, identifying, and managing material risks from cybersecurity threats. The Company has designed and implemented a Security Incident Response Plan for cybersecurity incidents and related processes which are overseen by management and cybersecurity professionals. Cybersecurity threats are identified and escalated to a Security Incident Response Team or member thereof pursuant to criteria set forth in these processes. These processes also include overseeing and identifying risks from cybersecurity threats associated with the use of third-party service providers, if any.

Our cybersecurity policies, standards, processes, and practices are integrated into the Company's overall risk management and compliance program and are overseen by the Audit Committee. The Compliance Committee, led by our Chief Compliance Officer ("CCO") and the IT Committee, led by our Chief Financial Officer ("CFO") are responsible for establishing and monitoring the integrity and effectiveness of controls and other procedures. In general, we seek to address cybersecurity risks through a cross-functional approach focused on preserving the security and availability of information that we collect and store by identifying, preventing, and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

The Company also engages consultants, auditors, and other third parties in connection with these processes to assist in the design of cybersecurity measures and employee training and to test the effectiveness of the Company's processes and measures.

Governance:

- **Board of Directors**

The Board's oversight of cybersecurity risk management is led by the Audit Committee which interacts with our CFO, who has oversight for information technology and our CCO, as well as other members of management. The Audit Committee receives presentations and reports on cybersecurity risks, which address a wide range of topics including recent developments, evolving standards, vulnerability assessments, the threat environment, technological trends and information security considerations arising with respect to our peers and third parties. The board of directors and the Audit Committee also receive prompt and timely information regarding any cybersecurity incident, as well as ongoing updates regarding any such incident until it has been addressed. On a periodic basis, the board of directors, through the Audit Committee, discuss our approach to cybersecurity risk management with the CFO and CCO.

The Audit Committee is informed of material risks, if any, from cybersecurity threats pursuant to Company policies, and at least once per quarter the Company's CCO reports to the Audit Committee generally on cybersecurity matters and material risks, if any, from cybersecurity threats.

- **Management**

The Company's management, including members of its IT and Compliance Committees, also assess and manage material risks, if any, from cybersecurity threats with the assistance of our third-party IT and cybersecurity vendors.

Collaborative Approach: We have implemented a comprehensive, cross-functional approach to identifying, preventing, and mitigating cybersecurity threats and incidents, while also implementing controls and procedures that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by management in a timely manner.

Technical Safeguards: We deploy technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality, and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence.

Incident Response and Recovery Planning: We are committed to establishing and maintaining comprehensive incident response and recovery plans to address our response to a cybersecurity incident.

Third-Party Risk Management: We maintain a risk-based approach to identifying and overseeing cybersecurity risks presented by third parties, including vendors, service providers and other external users of our systems, as well as the systems of third parties that could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems.

Education and Awareness: We provide periodic mandatory training for personnel regarding cybersecurity threats as a means to equip our employees with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices. We also perform periodic email phishing tests to keep cybersecurity awareness top of mind.

We engage in the periodic assessment of our policies, standards, processes and practices that are designed to address cybersecurity threats and incidents. These efforts include a wide range of activities, including audits, assessments, vulnerability testing and other exercises focused on evaluating the effectiveness of our cybersecurity measures and planning. The results of such assessments, audits and reviews are reported to the Audit Committee, and we adjust our cybersecurity policies, standards, processes and practices as necessary based on the information provided by these assessments, audits and reviews. See "*—Risk Management and Strategy*" above.

As of the date of this Annual Report on Form 10-K, the Company is not aware of any cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected the Company, including its business strategy, results of operations or financial condition. As cybersecurity threats become more sophisticated and coordinated, it is reasonably likely that we will be required to expend greater resources to continue to modify and enhance our protective measures as we pursue our business strategies. For additional information concerning risks related to cybersecurity, see Item 1.A. *Risk Factors — Our internal information technology systems, or those of our third-party contract research organizations ("CROs") or other contractors or consultants, may fail or suffer cybersecurity threats or 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*.

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. 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 currently are not a party to any threatened or pending material litigation and do not have contingency reserves established for any litigation liabilities. 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 under the symbol ALIM.

Stockholder Data

As of March 6, 2024, there were 26 holders of record of our common stock, and there were 52,354,450 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 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 2023, 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 global pharmaceutical company developing and commercializing ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg, in the U.S. and abroad for the treatment of DME, a leading cause of severe vision loss and blindness, and outside the U.S. for 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, and Middle East. Additionally, on May 17, 2023, we acquired from EyePoint Parent the exclusive commercialization rights to YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg, for the treatment and prevention of NIU-PS worldwide, except for Europe, the Middle East, Africa and China.

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 reimbursement in ten countries for the prevention of relapse in recurrent 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 and several countries in the Middle East. In addition, we have

granted an exclusive license to Ocumension for the development and commercialization of ILUVIEN in China, East Asia and the Western Pacific, however in these regions, the name may change. As of December 31, 2023, we have recognized sales of ILUVIEN to international distributors in the Middle East, China, Austria, Belgium, Czech Republic, France, Italy, Luxembourg, Spain, the Netherlands, and certain Nordic countries.

In the U.S., YUTIQ is indicated for the treatment and prevention of chronic NIU-PS. Pursuant to the product rights agreement dated May 17, 2023 (the "Product Rights Agreement") with EyePoint Parent, we have the commercialization rights to YUTIQ in the entire world, except Europe, the Middle East and Africa as we had previously licensed from EyePoint rights to certain products, which included YUTIQ (known as ILUVIEN in Europe, the Middle East and Africa) for the prevention of relapse in recurrent NIU-PS in those territories. The Product Rights Agreement also excludes any rights to YUTIQ for the treatment and prevention of chronic NIU-PS in China and certain other countries and regions in Asia, which rights are subject to a pre-existing exclusive license between EyePoint Parent and Ocumension.

Recent Developments

Fifth Amendment to Loan and Security Agreement and Exit Fee Agreement

On March 24, 2023, the Company entered into a Fifth Amendment to the 2019 Loan Agreement (the "Fifth Amendment") and a related Fifth Amendment Exit Fee Agreement (the "New Exit Fee Agreement"). Pursuant to the Fifth Amendment, the Lenders agreed to, among other things, (i) an additional tranche of $2.5 million to increase the Company's existing term loan facility to $47.5 million, subject to certain closing conditions, (ii) extend a $15.0 million additional term loan available to be funded at the Lender's sole discretion, and (iii) amended the Revenue Covenants to be effective for calendar quarters ending on or after March 31, 2023.

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. 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% or (ii) one-month SOFR, which will reset monthly. As of December 31, 2023 and 2022, the interest rate on the 2019 Loan Agreement was approximately 10.50% and 11.82%, respectively. 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.

Sixth Amendment to Loan and Security Agreement and Exit Fee Agreements

On May 17, 2023, we entered into a Sixth Amendment to the 2019 Loan Agreement (the "Sixth Amendment"). Pursuant to the Sixth Amendment, the Lenders agreed to, among other things, (i) an increase of the limit in the additional term loan facility from $15.0 million to $20.0 million, and (ii) amended the Revenue Covenants to be effective for calendar quarters ending on or after June 30, 2023. The Company received aggregate gross proceeds of $5.0 million upon execution of the Sixth Amendment. The Company has met such financial targets during the year ended December 31, 2023, and provided there are no events of default as defined by the Loan Agreement on or prior to April 20, 2025, the Company anticipates being able to extend the interest only period for an additional 12 months.

On May 17, 2023, we amended the revenue criteria for the 2018 Exit Fee Agreement, 2019 Exit Fee Agreement and the New Exit Fee Agreement to include the sales of YUTIQ in the ordinary course of business to third-party customers. The fees payable pursuant to our existing exit fee agreements and the New Exit Fee Agreement will not exceed $3.7 million in total.

During the year ended December 31, 2023, the Company met one revenue milestone under the 2018 Exit Fee Agreement and one revenue milestone under the 2019 Exit Fee Agreement. Accordingly, the Company recognized $1.3 million of interest expense during the year ended December 31, 2023, in the accompanying consolidated statement of operations. The Company anticipates meeting the remaining revenue milestones over the next 12 months, which will trigger $2.4 million exit fee payments.

As of December 31, 2023, the Company had approximately $12.1 million in cash and cash equivalents. Based on the Company's evaluation of its ability to continue as a going concern, the Company has concluded that the factors which previously raised substantial doubt about its ability to continue as a going concern no longer exist as of the issuance date of the accompanying consolidated financial statements. The Company believes its commercial operations, including its rights under the Product Rights Agreement to commercialize YUTIQ, will generate sufficient cash flow, combined with its current financial assets, to fund all conditional and unconditional financial obligations for at least the next 12 months.

Sources of Revenues

Our revenues for the twelve months ended December 31, 2023, and 2022 were generated from product sales primarily in the U.S., and certain territories in Europe. In the U.S., two large pharmaceutical distributors accounted for 70% and 63% of our consolidated product revenues for the twelve months ended December 31, 2023, and 2022, respectively. These U.S.-based distributors purchase ILUVIEN and YUTIQ in 2023 from us, maintain inventories of ILUVIEN and YUTIQ 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. Internationally, in countries where we sell to distributors, these distributors purchase ILUVIEN from us and maintain inventories of ILUVIEN that they sell to their customers.

Agreements with EyePoint Parent and EyePoint

In July 2017, we amended and restated our license agreement with 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, 2023, the balance of the Future Offset was approximately $6.5 million, which is fully reserved. 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.

On May 17, 2023 we entered into a product rights agreement (the "Product Rights Agreement") with EyePoint Parent whereby we were granted an exclusive and sublicensable right and license under EyePoint Parent's and its affiliates' interest in certain of EyePoint Parent's and its affiliates' intellectual property to develop, manufacture, sell, commercialize and otherwise exploit certain products, including YUTIQ, for the treatment and prevention of uveitis in the entire world, except Europe, the Middle East and Africa. Pursuant to the agreement, we paid EyePoint Parent an upfront payment of $75.0 million and will also make four quarterly guaranteed payments to EyePoint Parent totaling $7.5 million during 2024. We will also pay royalties to EyePoint Parent from 2025 to 2028 at a percentage of mid-to-low double digits of annual U.S. net sales of ILUVIEN and YUTIQ in excess of certain thresholds, beginning at $70.0 million in 2025, increasing annually thereafter. Upon making payments totaling $7.5 million, the licenses and rights granted to Alimera will automatically become perpetual and irrevocable.

We also entered into a commercial supply agreement (the "Supply Agreement") with EyePoint Parent pursuant to which, EyePoint Parent will be responsible for manufacturing and exclusively supplying (subject to certain exceptions) to us agreed-upon quantities of YUTIQ necessary for us to commercialize YUTIQ in the U.S. at certain cost-plus amounts, subject to adjustments. EyePoint Parent will have exclusive rights (subject to certain exceptions) to manufacture and supply YUTIQ until we have the right and ability to manufacture and supply YUTIQ for commercialization in the U.S. The term of the Supply Agreement is for a period of two years and thereafter automatically renews for successive one-year terms unless either party provides notice of non-renewal to the other party within a specified period of time prior to the beginning of the next automatic renewal term, provided that the Supply Agreement automatically terminates upon the successful completion of the transfer of manufacturing for YUTIQ to us or our designee. The Supply Agreement also automatically terminates upon termination of the Product Rights Agreement.

For more information about our agreements with EyePoint Parent and EyePoint, including how we calculate the royalty percentages we are required to pay, see Note 4 in the consolidated financial statements.

Results of Operations - Year ended December 31, 2023 compared to year ended December 31, 2022

	Years Ended December 31,	
	2023	2022
	(In thousands, except share and per share data)	
Net revenue	$ 80,754	$ 54,129
Cost of goods sold, excluding depreciation and amortization	(10,837)	(7,977)
Gross profit	69,917	46,152
Operating expenses:		
Research, development and medical affairs expenses	16,626	16,228
General and administrative expenses	18,530	12,871
Sales and marketing expenses	27,946	25,987
Depreciation and amortization	8,747	2,706
Total operating expenses	71,849	57,792
Loss from operations	(1,932)	(11,640)
Interest expense and other, net	(10,185)	(5,881)
Unrealized foreign currency gain, net	116	92
Loss on extinguishment of debt	(1,079)	—
Change in fair value of common stock warrant	(6,836)	—
Change in fair value of warrant asset	(131)	(650)
Net loss before taxes	(20,047)	(18,079)

Provision for taxes	(85)	(28)
Net loss	(20,132)	(18,107)
Preferred stock dividends	(1,259)	—
Net loss applicable to common stockholders	(21,391)	(18,107)
Net loss per share — basic and diluted	$ (0.84)	$ (2.59)
Weighted average shares outstanding — basic and diluted	25,561,885	6,996,850

Revenue

We generate revenue primarily from sales of ILUVIEN and YUTIQ, our two products. In addition to generating revenue from product sales, we 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. 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.

Net revenue increased by approximately $26.7 million, or 49%, to approximately $80.8 million for 2023, compared to approximately $54.1 million for 2022. The increase was primarily due to sales of YUTIQ beginning in May 2023 in the U.S., as well as increased unit sales volume of ILUVIEN in both the U.S. and International segments of our business. U.S. net revenue increased 66%, or approximately $22.5 million, to $56.7 million compared to $34.2 million in 2022. The increase was primarily attributable to the acquisition of YUTIQ. International net revenue increased 21% to approximately $24.0 million for 2023, compared to approximately $19.9 million in 2022. The increase in product revenue was primarily due to increasing growth in the international markets where we sell ILUVIEN directly and improving demand from our international distributor partners.

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 $2.8 million, or 35%, to approximately $10.8 million for 2023, compared to approximately $8.0 million for 2022. The increase was primarily attributable to our increased net revenue in 2023 as compared to 2022, including sales of YUTIQ.

Gross profit increased by approximately $23.7 million, or 51%, to approximately $69.9 million for 2023, compared to approximately $46.2 million for 2022. Gross margin was 87% and 85% for 2023 and 2022, respectively.

Research, Development and Medical Affairs Expenses

Currently, our research, development and medical affairs expenses are primarily focused on activities that support ILUVIEN and YUTIQ. These expenses include salaries and related expenses for research and development and medical affairs personnel, expenses related to clinical trials including our NEW DAY Study, SYNCHRONICITY Study, which is a prospective, open-label clinical study evaluating the safety and efficacy of YUTIQ for the treatment and prevention of chronic NIU-PS and related intraocular inflammation and expenses tied to physician engagement by our medical science 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. We expense both internal and external research and development costs as they are incurred.

Research, development and medical affairs expenses increased by approximately $0.4 million, or 2%, to approximately $16.6 million for 2023, compared to approximately $16.2 million for 2022. The increase was primarily attributable to increases of approximately $0.8 million of clinical study costs including costs related to our NEW DAY Study, and $0.3 million in registration costs including those registration costs for YUTIQ since May 2024 offset by decreases of approximately $0.4 million in inserter component design costs and $0.2 million in consultant costs.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and administrative functions, including finance, accounting, legal, 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 and managing license agreements. 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 $5.7 million, or 44%, to approximately $18.6 million for 2023, compared to approximately $12.9 million for 2022. The increase was primarily attributable to increases of approximately $2.5 million of bad debt expense, $1.6 million in personnel costs including severance and stock-based compensation expenses,

$0.9 million in professional fees primarily driven by the acquisition of YUTIQ and the financing transactions in 2023, and $0.2 million in office-related costs.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation for employees for commercial promotion of ILUVIEN and YUTIQ, 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 plans for ILUVIEN and YUTIQ or any future products or product candidates and maintaining public relations.

Sales and marketing expenses increased by approximately $1.9 million, or 7%, to approximately $27.9 million for 2023, compared to approximately $26.0 million for 2022. The increase was primarily attributable to increased personnel costs for 2023, including costs for additional personnel to market and sell YUTIQ.

Depreciation and amortization

Depreciation and amortization increased $6.2 million, or 230%, to approximately $8.9 million for 2023, compared to approximately $2.7 million for 2022. The increase was primarily attributable to amortization of the YUTIQ intangible asset which was acquired in May 2023.

Operating Expenses

Primarily as a result of the changes in expenses described above, total operating expenses increased by approximately $14.2 million, or 25%, to approximately $72.0 million for 2023, compared to approximately $57.8 million for 2022.

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 $2.5 million or 42%, to approximately $8.4 million for 2023, compared to $5.9 million for 2022. This increase is related to the change in the fair value of our outstanding common stock warrants held as liabilities until the mandatory conversion of our Series B Convertible Preferred Stock in full into our common stock in August 2023 (the Mandatory Conversion), as well as additional borrowing under our credit facility.

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”). For the year ended December 31, 2022, our then outstanding preferred stockholders would have participated in dividends equally with common stockholders (if we were to have declared and paid 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 18.6 million shares to approximately 25.6 million for 2023 compared to approximately 7.0 million for 2022. The increase was primarily attributable to an increase in our common shares outstanding, including the mandatory conversion of our Series B Convertible Preferred Stock in full into our common stock in August 2023.

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 17 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,	
	2023	2022
	(In thousands)	
Net Revenue	$ 56,711	$ 34,202
Cost of goods sold, excluding depreciation and amortization	(6,152)	(4,165)
Gross profit	50,559	30,037
Operating expenses:		
Research, development and medical affairs expenses	4,276	5,036
General and administrative expenses	2,309	1,238
Sales and marketing expenses	21,000	17,898
Total operating expenses	27,585	24,172
Segment income from operations	$ 22,974	$ 5,865

U.S. Segment - Year ended December 31, 2023 compared to year ended December 31, 2022

Product Revenue, net. Product revenue, net increased by approximately $22.5 million, or 66%, to approximately $56.7 million for 2023, compared to approximately $34.2 million for 2022. The increase was primarily attributable to the acquisition of YUTIQ in May of 2023.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately $2.0 million, or 48%, to approximately $6.2 million for 2023 compared to approximately $4.2 million for 2022. The increase was primarily attributable to our increased product sales, including sales of YUTIQ.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately $0.8 million, or 16%, to approximately $4.2 million for 2023, compared to approximately $5.0 million for 2022. The decrease was primarily attributable to decreases of approximately $0.9 million in personnel costs, and $0.1 million in consultant costs, partially offset by an increase of $0.3 million in registration costs primarily related to YUTIQ under the Prescription Drug User Fee Act.

General and administrative expenses. General and administrative expenses increased by approximately $1.1 million, or 92%, to approximately $2.3 million for 2023, compared to approximately $1.2 million for 2022. The increase was primarily attributable to an increase of approximately $1.3 million in bad debt expense.

Sales and marketing expenses. Sales and marketing expenses increased by approximately $2.9 million, or 16%, to approximately $20.8 million for 2023, compared to approximately $17.9 million for 2022. The increase was primarily attributable to an increase of approximately $3.7 million in personnel and travel costs as we expanded our sales team following the acquisition of YUTIQ. This increase was offset by a decrease of approximately $1.0 million in marketing costs, including costs incurred in 2022 related to our direct-to-patient marketing campaign.

International Segment

	Years Ended December 31,	
	2023	2022
	(In thousands)	
Net Revenue	$ 24,043	$ 19,927
Cost of goods sold, excluding depreciation and amortization	(4,685)	(3,812)
Gross profit	19,358	16,115
Operating expenses:		
Research, development and medical affairs expenses	2,720	3,470

General and administrative expenses	3,318	1,740
Sales and marketing expenses	6,222	7,356
Total operating expenses	12,260	12,566
Segment income from operations	$ 7,098	$ 3,549

International Segment - Year ended December 31, 2023 compared to year ended December 31, 2022

Net Revenue. Net revenue increased by approximately $4.1 million, or 21%, to approximately $24.0 million for 2023, compared to approximately $19.9 million for 2022. The increase in product revenue was primarily due to increasing growth in the international markets where we sell ILUVIEN directly and improving demand from our international distributor partners.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately $0.9 million, or 24%, to approximately $4.7 million for 2023, compared to approximately $3.8 million for 2022. The increase was primarily attributable to our increased product sales.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately $0.9 million, or 26%, to approximately $2.6 million for 2023, compared to approximately $3.5 million for 2022. The decrease was primarily attributable to a decrease of $0.7 million in consultant costs.

General and administrative expenses. General and administrative expenses increased by approximately $1.6 million, or 31%, to approximately $3.3 million for 2023, compared to approximately $1.7 million for 2022. The increase was primarily attributable to an increase of approximately $1.2 million in bad debt expenses related to certain distributors and $250,000 of logistics fees.

Sales and marketing expenses. Sales and marketing expenses decreased by approximately $1.1 million, or 15%, to approximately $6.3 million for 2023, compared to approximately $7.4 million for 2022. The decrease was primarily attributable to a decrease of approximately $0.8 million in marketing costs, including costs to attend conventions and costs associated with customer engagement and $0.5 million of personnel costs.

Operating Cost Segment

	Years Ended December 31,	
	2023	2022
	(In thousands)	
Research, development and medical affairs expenses	$ 9,522	$ 7,657
General and administrative expenses	11,798	9,258
Sales and marketing expenses	502	523
Total operating expenses	21,822	17,438
Segment loss from operations	$ (21,822)	$ (17,438)

Operating Cost Segment - Year ended December 31, 2023 compared to year ended December 31, 2022

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately $1.8 million, or 23%, to approximately $9.5 million for 2023, compared to approximately $7.7 million for 2022. The increase was primarily attributable to increases of approximately $1.0 million in personnel costs, $0.7 million in consultant costs, and $0.7 million of clinical study costs, partially offset by a decrease of $0.4 million in safety and quality related costs.

General and administrative expenses. General and administrative expenses increased by approximately $2.6 million or 28%, to approximately $11.9 million for 2023, compared to approximately $9.3 million for 2022. The increase was primarily attributable to increases of approximately $0.8 million in professional fees, $0.6 million in severance expenses, $0.4 million in personnel costs, and $0.3 million in office related costs.

Sales and marketing expenses. Sales and marketing expenses decreased by approximately $0.1 million, or 19%, to approximately $0.6 million for 2023, compared to approximately $0.5 million for 2022. These costs are tied to executive management of our global sales and marketing.

Other

	Years Ended December 31,	
	2023	2022
	(In thousands)	
Research, development and medical affairs expenses	$ 108	$ 65
General and administrative expenses	1,105	635
Sales and marketing expenses	222	210
Depreciation and amortization	8,747	2,706
Total operating expenses	10,182	3,616
Segment loss from operations	$ (10,182)	$ (3,616)

Other - Year ended December 31, 2023 compared to year ended December 31, 2022

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 increased by approximately $6.8 million or 189%, to approximately $10.4 million for 2023, compared to approximately $3.6 million for 2022. The increase was primarily attributable to an increase of $6.2 million in depreciation and amortization expenses, as described below.

Depreciation and amortization. Depreciation and amortization increased by approximately $6.2 million or 230%, to approximately $8.9 million for 2023, compared to approximately $2.7 million for 2022. The increase was primarily attributable to amortization of the YUTIQ intangible asset which was acquired in May 2023.

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 $416.9 million as of December 31, 2023. As of December 31, 2023, we had approximately $12.1 million in cash and cash equivalents. In March 2023 we received $12.0 million in gross proceeds from the Tranche 1 closing of our Series B Convertible Preferred Stock financing and an additional $2.5 million in cash in connection with the Fifth Amendment to the 2019 Loan Agreement. We have used these funds to commercialize ILUVIEN, to fund our NEW DAY Study and for general corporate purposes. In May 2023 we received $67.0 million in gross proceeds from the Tranche 2 closing of our Series B Convertible Preferred Stock financing and an additional $20.0 million in cash in connection with the Sixth Amendment to the 2019 Loan Agreement. We used these funds to fund a portion of the upfront payment to acquire the commercial rights for YUTIQ.

Indebtedness

Loans from SLR Investment Corp. ("SLR"). 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"). 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 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 June 30, 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 we must submit to the Collateral Agent by January 15 of such year, such plan to be thereafter approved by our board of directors (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 June 30, 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 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 (the Fifth Amendment), which among other things:

(a) added an additional tranche of $2.5 million to increase the existing term loan facility to $47.5 million, subject to certain closing conditions (the New Term Loan);

(b) extended a $15.0 million additional term loan available to be funded at the Lender's sole discretion;

(c) specified an 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) extended 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 and no event of default shall have occurred and be continuing by April 20, 2025; and

(e) specified the minimum revenue amount, calculated on a trailing six-month basis beginning with the six-month period ended September 30, 2023, and tested at the end of each calendar quarter, that the Company must achieve for each such period.

On May 17, 2023 we entered into a Sixth Amendment to the 2019 Loan Agreement (the Sixth Amendment and the 2019 Loan Agreement as so amended, the "Amended Loan Agreement"), which among other things:

(a) increased the term loan available to $20.0 million and fully funded the term loan;

(b) specified the minimum revenue amount calculated on a trailing six-month basis and tested at the end of each calendar quarter in 2023 and 2024, that we must achieve for each such period.

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.

The Federal Reserve raised interest rates seven times in 2022 and four times to date in 2023 and it may continue to do so to combat the effects of inflation. 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 Amended Loan Agreement, and any increase in the interest we pay would reduce our cash available for working capital, acquisitions, and other uses.

We have maintained compliance with our revenue covenant throughout 2022 and 2023, including at December 31, 2023. We expect to comply with the revenue covenant for the remaining measurement dates in 2024. If we fail to comply with the revenue covenant and the lenders do not provide 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.

Series B Preferred Stock Financings

In March 2023, we issued and sold an aggregate of 12,000 shares of Series B Convertible Preferred Stock at a per-share purchase price of $1,000 and warrants to purchase common stock for aggregate gross proceeds of $12.0 million. In May 2023, we issued and sold an aggregate of 67,000 shares of Series B Convertible Preferred Stock at a per-share purchase price of $1,000 and warrants to purchase common stock for aggregate gross proceeds of $67.0 million. On August 1, 2023, we amended the Certificate of Designation of Series B Convertible Preferred Stock to allow for the issuance of Pre-Funded Warrants. Stockholder approval was received at our 2023 annual meeting of stockholders held on August 1, 2023, and we designated August 15, 2023, as the date for Mandatory Conversion of the Series B Convertible Preferred Stock into our common stock and Pre-Funded Warrants to purchase common stock. In connection with the Mandatory Conversion, we issued 43,617,114 shares of common stock and Pre-Funded Warrants exercisable for 2,000,000 shares of common stock to the holders of the Series B Convertible Preferred Stock. Following the Mandatory Conversion, no shares of the Series B Convertible Preferred Stock remain outstanding.

Year-end Cash Position

As of December 31, 2023, we had approximately $12.1 million in cash and cash equivalents, an increase of $6.8 million from the $5.3 million in cash and cash equivalents as of December 31, 2022.

We believe our commercial operations will generate sufficient cash flow, combined with our current financial assets, to fund all conditional and unconditional financial obligations for at least the next 12 months. Therefore, we have concluded the factors which previously raised substantial doubt about our ability to continue as a going concern no longer exist. However, we may need to raise alternative or additional financing to fund our operations and support growth. The source, timing, and availability of any future financing will depend upon market conditions and other factors that may be outside of our control. Funding may not be available when needed, at all, or on terms acceptable to us. 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 permission or participation of SLR, which we might not be able to obtain.

Sources and Uses of Cash in 2023 and 2022

For 2023, net cash used in our operations was approximately $14.3 million. The cash used in our operations was primarily due to our net loss of $20.1 million, an increase of $17.2 million in accounts receivable, a $0.7 million increase in prepaid and other current assets, $0.3 million in inventory, and $0.1 million of unrealized foreign currency gains. These cash decreases were partially offset by $8.7 million of non-cash depreciation and amortization, $6.8 million for the change in the estimated fair value of warrant liabilities, $2.5 million in provision for credit losses, a net increase of $2.2 million in accounts payable, accrued expenses and other current liabilities, $1.4 million of non-cash stock-based compensation expense, a $1.1 million loss on extinguishment of debt, $1.0 million of non-cash interest expense associated with the amortization of our debt discount, an increase of $0.1 million in long-term liabilities and a $0.1 million change in fair value of warrant asset.

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 $0.9 million in accounts receivable, a decrease of $0.4 million in long-term liabilities and $0.1 million 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, $1.0 million decrease in prepaid and other current assets, $0.9 million of non-cash stock-based compensation expense and a $0.7 million change in fair value of warrant asset.

For 2023, net cash used in our investing activities was approximately $75.5 million, which was primarily due to the acquisition of the YUTIQ intangible asset in May 2023.

For 2022, net cash used in our investing activities was approximately $0.3 million, 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 2023, net cash provided by our financing activities was approximately $96.5 million, which was primarily due to the $78.6 million gross proceeds from the closings of our Series B Convertible Preferred Stock financings, the $22.5 million received in connection with the Fifth and Sixth Amendments to the 2019 Loan Agreement, and $2.4 million received in connection with common stock issuances. The cash provided was partially offset by $4.1 million of debt issuance costs, $1.2 million in preferred stock issuance costs, the $0.9 million repurchase of Series A Preferred Stock, and the $0.3 million repurchase of common stock.

For 2022, net cash used in our financing activities was approximately $0.3 million, which was primarily due to $0.1 million in payments of debt costs and payments of $0.3 million in finance lease obligation, partially offset by $0.1 million in proceeds from the issuance of common stock and $20,000 in proceeds from stock options exercised.

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 both of 2023 and 2022, we incurred approximately $4.3 million, of expense associated with the NEW DAY Study. In connection with the NEW DAY Study, we expect to incur approximately an additional $2.1 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, 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 $0.7 million in 2024.

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 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, 2023, we had federal NOL carry-forwards of approximately $146.8 million and state NOL carry-forwards of approximately $106.8 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 2023 and 2043. 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. 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 Section 382 changes in ownership occurred in late 2015 and in 2023. As a result of these changes in ownerships, the Company estimated that substantially all of its federal and state NOL carry-forwards and tax credits generated prior to the 2023 change in ownership will be subject to Section 382 limitations and may not be fully utilized in the future. The Company is currently in the process of evaluating the Section 382 impact to determine if a write-off is necessary. 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.

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, 2023, and December 31, 2022, are approximately $0.2 million and $0.1 million, 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 the statute of limitations. Tax years from 2020 to 2022 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 increased our net product revenue for the year ended December 31, 2023 by approximately $620,000.

Non-GAAP Financial Measure

We provide all information required in accordance with U.S. GAAP, but we believe that evaluating our ongoing operating results may be difficult if limited to reviewing only U.S. GAAP financial measures. In an effort to provide investors with additional information regarding our results, we also provide non-GAAP information that management believes is useful to investors. We discuss net income (loss) performance measures that are, for comparison purposes, adjusted to eliminate items or results stemming from discrete events. We do this because management uses these measures in evaluating our underlying performance on a consistent basis across periods. We also believe non-GAAP measures are frequently used by securities analysts, investors and other interested parties in the evaluation of our ongoing performance.

See the table below entitled “Reconciliation of GAAP Net Loss to Non-GAAP Adjusted EBITDA.” GAAP net loss is the most directly comparable GAAP financial measure to adjusted EBITDA.

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 LOSS TO NON-GAAP ADJUSTED EBITDA

	Years Ended December 31,	
	2023	2022
	(unaudited)	
GAAP net loss	$ (20,132)	$ (18,107)
Adjustments to net loss:		
Interest expense and other, net	10,185	5,881
Provision for taxes	85	28
Depreciation and amortization	8,747	2,706
Stock-based compensation	1,435	910
Foreign currency exchange gains	(116)	(92)
Extinguishment of debt	1,079	—
Change in fair value of common stock warrants	6,836	—
Change in fair value of warrant asset	131	650
Severance expenses	461	147
Non-GAAP adjusted EBITDA	$ 8,711	$ (7,877)

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 61 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, 2023.

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, 2023.

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 2023 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 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023 (the “2024 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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 Proxy Statement and is incorporated herein by reference.

Equity Compensation Plan Information

The following table provides information, as of December 31, 2023, 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"), (b) existing and future awards under our 2019 Omnibus Incentive Plan ("2019 Plan"), (c) existing and future awards under our 2023 Omnibus Incentive Plan ("2023 Plan"); and (d) existing and future awards under our 2024 Equity Inducement Plan ("2024 Plan"). The following table also provides information, as of December 31, 2023, 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	4,473,024 (1)	$ 26.72	149,506 (2)
Equity compensation plans not approved by security holders	—	—	—
Total	4,473,024	$ 26.72	149,506

(1) Of these shares, the number of shares subject to stock options then outstanding was 396,117, 657,544, 2,015,913 and 125,000 under the 2010 Plan, 2019 Plan, 2023 Plan and 2024 Plan, respectively. The number of unvested shares of restricted stock units and performance-based stock units outstanding was 592,076 and 1,250,000 under the 2019 Plan and 2023 Plan, respectively.

(2) Of these shares, the number of shares available for issuance was 142,511 and 6,995 under our 2023 Plan and ESPP, respectively. 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, 2024, an additional 25,966 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 2024 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 2024 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 2024 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 2024 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, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

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 8, 2024

ALIMERA SCIENCES, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2023	2022
	(In thousands, except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,058	$ 5,274
Restricted cash	32	30
Accounts receivable, net	34,545	19,612
Prepaid expenses and other current assets	3,909	2,892
Inventory	1,879	1,605
Total current assets	52,423	29,413
Property and equipment, net	2,466	2,525
Right of use assets, net	1,124	1,395
Intangible asset, net	97,355	8,957
Deferred tax asset	104	129
Warrant asset	52	183
Total assets	$ 153,524	$ 42,602
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 8,252	$ 10,088
Accrued expenses	6,192	3,998
Accrued licensor payments	7,275	—
Notes payable	—	25,313
Finance lease obligations	194	333
Total current liabilities	21,913	39,732
Notes payable	64,489	18,683
Accrued licensor payments	15,136	—
Other non-current liabilities	5,816	4,995
Total liabilities	107,354	63,410
Commitments and contingencies (Note 15)		
Stockholders' equity (deficit):		
Preferred stock, $.01 par value — 10,000,000 shares authorized at December 31, 2023 and 2022:		
Series A Convertible Preferred Stock, 0 and 1,300,000 authorized at December 31, 2023 and 2022, 0 and 600,000 issued and outstanding at December 31, 2023 and 2022; liquidation preference of $0 and $24,000 at December 31, 2023 and 2022	—	19,227
Common stock, $.01 par value — 150,000,000 shares authorized, 52,354,450 shares issued and outstanding at December 31, 2023 and 6,995,513 issued and outstanding at December 31, 2022	524	70
Common stock warrants	4,396	—
Additional paid-in capital	462,446	378,238
Accumulated deficit	(418,490)	(415,388)
Accumulated other comprehensive loss — foreign currency translation adjustments	(2,706)	(2,955)
Total Stockholders' equity (deficit)	46,170	(20,808)
Total liabilities and stockholders' equity (deficit)	$ 153,524	$ 42,602

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2023	2022
	(In thousands, except share and per share data)	
Net revenue	$ 80,754	$ 54,129
Cost of goods sold, excluding depreciation and amortization	(10,837)	(7,977)
Gross profit	69,917	46,152
Operating expenses:		
Research, development and medical affairs expenses	16,626	16,228
General and administrative expenses	18,530	12,871
Sales and marketing expenses	27,946	25,987
Depreciation and amortization	8,747	2,706
Total operating expenses	71,849	57,792
Loss from operations	(1,932)	(11,640)
Interest expense and other, net	(10,185)	(5,881)
Unrealized foreign currency gain, net	116	92
Loss on extinguishment of debt	(1,079)	—
Change in fair value of common stock warrant	(6,836)	—
Change in fair value of warrant asset	(131)	(650)
Net loss before income taxes	(20,047)	(18,079)
Income tax provision	(85)	(28)
Net loss	$ (20,132)	$ (18,107)
Preferred stock dividends	(1,259)	—
Net loss applicable to common stockholders	$ (21,391)	$ (18,107)
Net loss per share — basic and diluted	$ (0.84)	$ (2.59)
Weighted average shares outstanding — basic and diluted	25,561,885	6,996,850

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years Ended December 31,	
	2023	2022
	(In thousands)	
Net loss	$ (20,132)	$ (18,107)
Other comprehensive income (loss):		
Foreign currency translation adjustments	249	(1,106)
Total other comprehensive income (loss)	249	(1,106)
Comprehensive loss:	$ (19,883)	$ (19,213)

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Additional Paid-In	Common Stock		Accumulated Other	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Warrants	Accumulated Deficit	Comprehensive Loss	Total
	(In thousands, except share data)										
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)
Issuance of common stock, net issuance costs	2,024,867	20	—	—	—	—	2,384	—	—	—	2,404
Repurchase of common stock	(200,919)	(2)	—	—	—	—	(312)	—	—	—	(314)
Repurchase of Preferred Stock - Series A	—	—	(600,000)	(19,227)	—	—	—	—	18,289	—	(938)
Issuance of Preferred Stock-Series B, net of issuance costs	—	—	—	—	78,617	74,041	3,399	—	—	—	77,440
Conversion of Preferred Stock - Series B into common stock and common stock warrants	43,617,114	436	—	—	(78,617)	(75,300)	71,075	4,396	—	—	607
Preferred stock dividends	—	—	—	—	—	1,259	—	—	(1,259)	—	—
Forfeiture of common stock warrants	—	—	—	—	—	—	6,227	—	—	—	6,227
Forfeitures of restricted stock	(82,125)	—	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,435	—	—	—	1,435
Net loss	—	—	—	—	—	—	—	—	(20,132)	—	(20,132)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	249	249
Balance — December 31, 2023	52,354,450	$ 524	—	$ —	—	$ —	$ 462,446	$ 4,396	$ (418,490)	$ (2,706)	$ 46,170

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2023	2022
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (20,132)	$ (18,107)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8,747	2,706
Loss on extinguishment of debt	1,079	—
Provision for credit losses	2,508	—
Unrealized foreign currency transaction gain	(116)	(92)
Amortization of debt discount and deferred financing costs	1,023	1,153
Deferred tax expense	29	116
Stock-based compensation expense	1,435	910
Change in fair value of warrant asset	131	650
Change in fair value of warrant liabilities	6,836	—
Changes in assets and liabilities:		
Accounts receivable	(17,159)	(863)
Prepaid expenses and other current assets	(720)	973
Inventory	(260)	1,010
Accounts payable	(1,875)	1,468
Accrued expenses and other current liabilities	4,104	483
Other long-term liabilities	109	(382)
Net cash used in operating activities	(14,261)	(9,975)
Cash flows from investing activities:		
Purchases of property and equipment	(260)	(255)
Purchase of intangible assets	(75,272)	—
Net cash used in investing activities	(75,532)	(255)
Cash flows from financing activities:		
Proceeds from issuance of Series B Convertible Preferred Stock	78,617	—
Series B Convertible Preferred Stock issuance costs	(1,177)	—
Proceeds from issuance of common stock	2,404	85
Repurchase of Series A Preferred Stock	(938)	—
Repurchase of common stock	(314)	—
Proceeds from exercise of stock options	—	15
Issuance of debt	22,500	—
Debt issuance costs	(4,108)	(113)
Payments on finance lease obligations	(485)	(289)
Net cash provided by (used in) financing activities	96,499	(302)
Effect of exchange rates on cash and cash equivalents and restricted cash	80	(708)
Net change in cash and cash equivalents and restricted cash	6,786	(11,240)
Cash and cash equivalents and restricted cash at beginning of year	5,304	16,544
Cash and cash equivalents and restricted cash at end of year	$ 12,090	$ 5,304
Supplemental cash flow information:		
Cash paid for interest	$ 6,283	$ 4,489
Cash paid for income taxes	$ 22	$ 232
Supplemental noncash investing and financing activities:		
Property and equipment acquired under finance leases	$ 474	$ 259
Property and equipment acquired under operating leases	$ —	$ 7
Note payable end of term payment accrued but unpaid	$ 3,375	$ 2,250
Accretion of preferred stock dividends	$ 1,259	$ —
Accrued licensor payments in connection with purchase of intangible asset	$ 22,411	$ —

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 global pharmaceutical company that specializes in the commercialization and development of ophthalmic retinal 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 commercialized products are ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg, which has received marketing authorization and reimbursement in the U.S. and 24 countries for the treatment of diabetic macular edema ("DME") and YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg, available in the United States ("U.S.") for the treatment and prevention of non-infectious uveitis affecting the posterior segment of the eye ("NIU-PS").

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 reimbursement in ten countries for the prevention of relapse in recurrent 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 ("Ocumension") for the development and commercialization of the Company's 0.19 mg fluocinolone acetonide intravitreal injection in China, East Asia and the Western Pacific. As of December 31, 2023, the Company has recognized sales of ILUVIEN to its international distributors in the Middle East, China, Austria, Belgium, Czech Republic, France, Italy, Luxembourg, Spain, the Netherlands, and certain Nordic countries.

In the U.S., YUTIQ is indicated for the treatment and prevention of chronic NIU-PS of the eye. The Company has the rights to commercialize YUTIQ under a product rights agreement dated May 17, 2023 (the "Product Rights Agreement") with EyePoint Pharmaceuticals, Inc. ("EyePoint Parent") in the entire world, except Europe, the Middle East and Africa as the Company had previously licensed from EyePoint Pharmaceuticals US, Inc. ("EyePoint") rights in those territories to certain products, which included YUTIQ (known as ILUVIEN in Europe, the Middle East and Africa) for the prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment (see Note 4). The Product Rights Agreement also excludes any rights to YUTIQ for the treatment and prevention of chronic NIU-PS in China and certain other countries and regions in Asia, which rights are subject to a pre-existing exclusive license between EyePoint Parent and Ocumension.

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 U.S. ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") issued by the Financial Accounting Standards Board ("FASB").

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.

As of December 31, 2023, the Company had approximately $12.1 million in cash and cash equivalents. Based on the Company's evaluation of its ability to continue as a going concern, the Company has concluded that the factors which previously raised substantial doubt about its ability to continue as a going concern no longer exist as of the issuance date of the accompanying consolidated financial statements. The Company believes its commercial operations, including its rights under the Product Rights Agreement to commercialize YUTIQ, will generate sufficient cash flow, combined with its current financial assets, to fund all conditional and unconditional financial obligations for at least the next 12 months.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Management considers many factors in selecting appropriate financial accounting policies and in developing

the estimates and assumptions that are used in the preparation of the consolidated financial statements. Management must apply significant judgment in this process and assess the use of estimates on an ongoing basis. However, actual results could materially differ from those estimates and changes in estimates are reflected in the results of operations in the period in which they become known.

Subsequent Event(s)

The Company considers events or transactions that occur after the balance sheet date but before the consolidated financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The Company evaluated all events and transactions through the date these consolidated financial statements were filed with the Securities and Exchange Commission ("SEC") or were available to be issued (see Note 18).

Fair Value Measurements

The Company applies FASB ASC 820, *Fair Value Measurements ("ASC 820")*, in determining the fair value of certain assets and liabilities. ASC 820 defines fair value and establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1 – Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

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

Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

Pursuant to the Company's warrant agreement with Ocumension, the Company has the right to exercise the warrants at its option, which are considered to be derivative instruments and classified as non-current warrant assets. 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 the fair value during each reporting period are reported in the consolidated statement of operations (see Note 3).

There have been no changes to the valuation methods during the years ended December 31, 2023 and 2022.

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.

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 $12.1 million and $5.3 million as of December 31, 2023 and 2022, respectively, of which approximately 62% and 72% of these balances, respectively, is held in U.S.-based financial institutions.

Revenue Recognition

The Company recognizes revenue when a customer obtains control of the related good or service pursuant to FASB ASC 606, *Revenue from Contracts with Customers ("ASC 606")*. The amount recognized reflects the consideration that the entity expects to receive in exchange for those goods or services. 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.

Product Revenue

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 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.

Collaboration and 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.

Accounts Receivable, net

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 expected credit losses that reflects management's best estimate of the amounts that will not be collected. Management considers many factors in assessing the need for an allowance for expected credit losses, including the length of time trade accounts receivable are past due, the customer's ability to pay its obligation, customer types, credit worthiness and the condition of the general economy and the industry as a whole. From time to time, management may adjust its assumptions for anticipated changes in any of those or other factors expected to affect collectability.

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, 2023 and 2022, the Company had $1.2 million and $0 reserved for expected credit losses, respectively. During the twelve months ended December 31, 2023 and 2022, the Company wrote off $1.3 million and $0 for expected credit losses, respectively.

Allowance for doubtful accounts consisted of the following as of December 31, 2023 and 2022, respectively:

	December 31,	
	2023	2022
	(In thousands)	
Beginning balance	$ —	$ —
Provision for credit losses	2,508	—
Write-off of bad debt	(1,286)	—
Ending Balance	$ 1,222	$ —

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 in the period in which the impairment is identified.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Additions and improvements with expected economic benefit period over one year 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.

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 assets ranged between ten and thirteen years (see Note 7).

Impairment of Long-lived Assets

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, 2023, and 2022.

Leases

The Company evaluates all of its contracts to determine whether it is or contains a lease component under FASB ASC 842 – *Leases ("ASC 842")*. 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 determination and classification for existing 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 that it is not reasonably certain it will exercise any applicable renewal options. Accordingly, 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.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include payroll and personnel expense, stock-based compensation expense, consulting costs, external contract research and development expenses, as well as utilities. Prepaid research and development costs are deferred and amortized over the service period, as the services are provided.

General and Administrative Costs

General and administrative expenses are primarily comprised of compensation and benefits associated with finance, human resources, legal, information technology and other administrative personnel, business development and other general and administrative costs.

Sales and Marketing Costs

Sales and Marketing expenses are primarily comprised of compensation and benefits associated with sales and marketing, managed markets, and advertising costs. 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 $0.7 million and $1.8 million for 2023, and 2022, respectively.

Stock-Based Compensation

Stock-based compensation awards are accounted for in accordance with FASB ASC 718, *Compensation — Stock Compensation ("ASC 718")*. The Company expenses the fair value of stock awards granted to employees, members of the board of directors and consultants over the requisite service period, which is typically the vesting period. Compensation cost for stock-based awards issued is measured using the estimated fair value at the grant date, net of estimated forfeitures. Fair value of option awards are estimated as of the date of grant using the Black-Scholes option-pricing model that requires management to apply judgment and make estimates, including:

- expected volatility, which is calculated using the historical volatility of the Company's publicly traded stock for awards granted. The Company computes the historical volatility data using the daily closing prices during the equivalent period of the calculated expected term of its stock-based awards;

- risk-free interest rate, which is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption;

- expected term, which is calculated using the simplified method, as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, as the Company has insufficient historical information regarding its stock options to provide a basis for an estimate. Under this approach, the weighted-average expected life is presumed to be the average of the contractual term of ten years and the weighted-average vesting term of the stock options, taking into consideration multiple vesting tranches; and

- dividend yield, which is zero based on the fact that the Company never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

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 FASB ASC 718-50, *Employee Share Purchase Plans*.

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.

Earnings Per Share ("EPS")

The Company follows FASB 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.

Foreign Currency Translation

The financial statements of each of the Company's subsidiaries with a functional currency other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders' equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income (loss) in stockholders' equity. Foreign currency transaction gains and losses are included in other (expense) income, net in the results of operations.

Concentrations of Credit Risk and Off -Balance-Sheet Risk

The Company has no significant off-balance-sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash and cash equivalents, accounts receivable and certain exclusive or single-source supply arrangements.

The Company's cash and cash equivalents and accounts receivables are subject to significant concentrations of credit risk. Periodically, the Company maintains deposits in government insured financial institutions in excess of government insured limits. The Company deposits its cash and cash equivalents in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk. The Company has a limited number of commercial customers. The Company monitors the creditworthiness of its customers to whom it grants credit terms and has not experienced any credit losses.

Reporting Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer. The Company operates in the U.S. and internationally with its headquarters located in the US and all material long-lived assets of the Company reside in the U.S. The Company and the chief operating decision maker view the Company's operations and manage its business as three operating segments: U.S., International and Operating Cost (see Note 17).

Adoption of New Accounting Standards

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 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 became effective for the Company on January 1, 2023. The adoption of this guidance did not have a material impact on the Company's 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 ASC 606. The amendments in this ASU are effective for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company adopted this ASU on January 1, 2023. The adoption of this ASU had no impact on the Company's financial statements.

Accounting Standards Issued but Not Yet Effective

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848) - Facilitation of the Effects of Reference Rate Reform on Financial Reporting ("ASU 2020-04")*. 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 ASU 2020-04 covers the period of time during which a significant number of modifications may take place and the ASU defers the sunset date of ASU 2020-04 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 June 2022, the FASB issued ASU No. 2022-03, *Fair Value Measurement (Topic 820) – Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions.* This standard clarifies that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. This standard will be effective for the Company on January 1, 2024. The Company does not anticipate the adoption of this ASU will have a material impact on its financial statements.

In October 2023, the FASB issued ASU No. 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative ("ASU 2023-06")*. This standard modifies the disclosure or presentation requirements of a variety of topics and aligns requirements with the SEC's existing disclosure requirements. ASU 2023-06 is effective on the date each amendment is removed from Regulation S-X or Regulation S-K with early adoption prohibited. The amendments in ASU 2023-06 will be applied prospectively in the consolidated financial statements. The Company is currently evaluating the timing of its adoption of this standard and the impact on its financial statements.

In November 2023 the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures*. This standard requires disclosure of significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items to reconcile to segment profit or loss and the title and position of the entity's CODM. The amendments in this update also expand the interim segment disclosure requirements. All disclosure requirements under this standard are also required for public entities with a single reportable segment. This standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted and the amendments in this update are required to be applied on a retrospective basis. This standard will be effective for the Company on January 1, 2024. The Company is currently evaluating the potential impact that this new standard will have on its financial statements and related disclosures.

In December 2023, ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09")* requires public business entities to disclose on an annual basis additional information in specified categories with respect to the reconciliation of the effective tax rate to the statutory rate for federal, state, and foreign income taxes. It also requires greater detail about individual reconciling items in the rate reconciliation to the extent the impact of those items exceeds a specified threshold. In addition, ASU 2023-09 requires disclosure pertaining to taxes paid, net of refunds received, to be disaggregated for federal, state, and foreign taxes and further disaggregated for specific jurisdictions to the extent the related amounts exceed a quantitative threshold. ASU 2023-09 is effective for the Company for the annual period beginning on January 1, 2025. Early adoption is permitted. ASU 2023-09 should be applied on a prospective basis. However, companies have the option to apply the standard retrospectively. The Company is currently evaluating the potential impact that this new standard will have on its financial statements and related disclosures.

3. FAIR VALUE

The following fair value table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2023 and December 31, 2022, respectively:

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Warrant asset (1)	$ —	$ 52	$ —	$ 52
Assets measured at fair value	$ —	$ 52	$ —	$ 52

	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

(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.

4. REVENUE

Product Revenue, net

For the years ended December 31, 2023 and 2022, there were three customers within the U.S. segment. Two of these customers, which are large pharmaceutical distributors, accounted for approximately 70% and 63%, respectively, of the Company's total consolidated product revenues. These two customers accounted for approximately 70% and 71% of the Company's consolidated accounts receivable as of December 31, 2023 and 2022, respectively.

EyePoint Agreements

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 several 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.

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. 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 million in any year.

On December 17, 2020, EyePoint entered into a royalty purchase agreement (the "SWK Agreement") with SWK Funding, LLC ("SWK"). 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 $16.5 million 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.

During 2023 and 2022, the Company recognized approximately $3.1 million and $2.8 million of royalty expense, respectively, which is included in cost of goods sold in the accompanying consolidated financial statements. As of December 31, 2023 and December 31, 2022, approximately $0.9 million and $0.7 million of this royalty expense was included in the Company's accounts payable, respectively.

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 $15.0 million of the Future Offset. In March 2019, pursuant to the New Collaboration Agreement, the Company forgave $5.0 million of the Future Offset in connection with the approval of ILUVIEN for NIU-PS in the U.K. As of December 31, 2023 and 2022, the balance of the Future Offset was approximately $6.5 million and $7.0 million, respectively, which was fully reserved. The Company would 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 on an annual basis.

On May 17, 2023, the Company entered into a product rights agreement with EyePoint Parent which grants the Company an exclusive and sublicensable right and license under EyePoint Parent's and its affiliates' interest in certain of EyePoint Parent's and its affiliates' intellectual property to develop, manufacture, sell, commercialize and otherwise exploit certain products, including YUTIQ, for the treatment and prevention of uveitis in the entire world, except Europe, the Middle East and Africa, where the Company already has such rights pursuant to the New Collaboration Agreement, and except for China, Hong Kong, Macau, Taiwan, Brunei, Burma (Myanmar), Cambodia, Timor-Leste, Indonesia, Loas, Malaysia, the Philippines, Singapore, South Korea, Thailand and Vietnam, where Ocumension holds a license from EyePoint Parent. Pursuant to the agreement, the Company paid EyePoint Parent an upfront payment of $75.0 million and will also make four quarterly guaranteed payments to EyePoint Parent totaling $7.5 million during 2024. The Company will also pay royalties to EyePoint Parent from 2025 to 2028 at a percentage of mid-to-low double digits of annual U.S. net sales of certain products (including YUTIQ and ILUVIEN) in excess of certain thresholds, beginning at $70.0 million in 2025, increasing annually thereafter. Upon making the quarterly payments in the aggregate amount of $7.5 million in 2024, the licenses and rights granted to the Company will automatically become perpetual and irrevocable. The present value of the 2024 quarterly payments and the present value of estimated royalties payable

to EyePoint Parent for years 2025 to 2028 is included in the cost of the intangible the Company recorded. The estimated royalties will continue to be revalued at each reporting date until they are settled.

Concurrently in May 2023, the Company also entered into a commercial supply agreement (the "Supply Agreement") with EyePoint Parent pursuant to which, during the term of the Product Rights Agreement, EyePoint Parent will be responsible for manufacturing and exclusively supplying (subject to certain exceptions) to agreed-upon quantities of YUTIQ necessary for the Company to commercialize YUTIQ in the U.S. at certain cost-plus amounts, subject to adjustments. EyePoint Parent's manufacture and supply of YUTIQ will be exclusive (subject to certain exceptions) until the Company has the ability to manufacture and supply YUTIQ for commercialization in the U.S. The term of the Supply Agreement is for a period of two years through May 2025 and thereafter automatically renews for successive one-year terms unless either party provides notice of non-renewal to the other party within a specified period of time prior to the beginning of the next automatic renewal term, provided that the Supply Agreement automatically terminates upon the successful completion of the transfer of manufacturing for YUTIQ to the Company or its designee. The Supply Agreement also automatically terminates upon termination of the Product Rights Agreement.

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.

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, 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 $10.0 million from Ocumension HK and may in the future receive additional sales-based milestone payments totaling up to $89.0 million upon the achievements by Ocumension HK of certain specified sales milestones during the term of the License Agreement of the Product. 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 $11.0 million in license revenue from the Ocumension transaction (including the value of a warrant subscription agreement, which the Company received as consideration, to purchase 1,000,000 shares of Ocumension during a period of four years). As of December 31, 2023 and 2022, the Company has approximately $0.4 million and $0.3 million, respectively, of deferred revenue under the Ocumension license agreement that will be recognized over the remaining term of the agreement once Ocumension begins to sell the covered products under the license agreement.

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.

Ocumension Share Purchase Agreement

When the Company entered into the license agreement in April 2021, it also entered into a share purchase agreement ("Share Purchase Agreement") with Ocumension, pursuant to which the Company offered and sold to Ocumension 1,144,945 shares of common stock at a purchase price of $8.734044 per share and aggregate gross proceeds of $10.0 million from the sale of the shares.

Ocumesion Warrant Subscription Agreement

On April 14, 2021, the Company entered into the warrant agreement with Ocumension 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. These warrants are revalued at each of the Company's reporting dates with fluctuations being booked to the Company's statement of operations.

5. INVENTORY

Inventory consisted of the following as of December 31, 2023 and 2022, respectively:

	December 31,	
	2023	2022
	(In thousands)	
Component parts (1)	$ 688	$ 152
Work-in-process (2)	134	560
Finished goods	1,057	893
Total inventory	$ 1,879	$ 1,605

(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.

6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following as of December 31, 2023 and 2022, respectively:

	December 31,	
	2023	2022
	(In thousands)	
Furniture and fixtures	$ 428	$ 427
Office equipment	510	509
Finance leases	1,213	1,127
Software	1,238	1,228
Leasehold improvements	1,467	1,364
Manufacturing equipment	2,011	1,931
Total property and equipment	6,867	6,586
Less accumulated depreciation and amortization	(4,401)	(4,061)
Property and equipment — net	$ 2,466	$ 2,525

Depreciation and amortization expense associated with property and equipment totaled $0.8 million and $0.8 million for the years ended December 31, 2023 and 2022, respectively.

7. 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 $25.0 million (the "EyePoint Milestone Payment") to EyePoint.

The gross carrying amount of the ILUVIEN intangible asset is $25.0 million, which is being amortized over approximately 13 years from the acquisition date. The net book value of the ILUVIEN intangible asset was $7.0 million and $9.0 million as of

December 31, 2023 and 2022, respectively, and amortization expense was $1.9 million for each of the years ended December 31, 2023 and 2022, respectively.

The estimated remaining amortization as of December 31, 2023 is as follows (in thousands):

Years Ending December 31	
2024	$ 1,946
2025	1,940
2026	1,940
2027	1,191
Total	$ 7,017

Pursuant to the Product Rights Agreement with EyePoint Parent executed in May 2023, which expands the Company's commercial rights to certain products, including YUTIQ, the Company paid EyePoint Parent an upfront payment of $75.0 million and will also make four quarterly guaranteed payments to EyePoint Parent totaling $7.5 million during 2024. The acquisition of YUTIQ commercial rights also utilized certain Future Offset.

As of December 31, 2023, the gross carrying amount of the YUTIQ intangible asset is $96.4 million to be amortized over 10 years. The net book value of the YUTIQ intangible asset was $90.3 million as of December 31, 2023, and amortization expense was $6.0 million for the year ended December 31, 2023.

The estimated remaining amortization as of December 31, 2023 is as follows (in thousands):

Years Ending December 31	
2024	$ 9,654
2025	9,627
2026	9,627
2027	9,627
2028	9,654
Thereafter	42,149
Total	$ 90,338

8. ACCRUED EXPENSES

Accrued expenses consisted of the following as of December 31, 2023 and 2022, respectively:

	December 31,	
	2023	2022
	(In thousands)	
Accrued compensation expenses	3,458	2,294
Accrued rebate and other revenue reserves	1,416	709
Accrued lease liabilities (Note 13)	634	768
Other accrued expenses	684	227
Total accrued expenses	$ 6,192	$ 3,998

9. LOAN AGREEMENTS

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

On January 5, 2018, the Company entered into a $40.0 million loan and security agreement with SLR Investment Corp. ("SLR," also formerly known as 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") and a related exit fee agreement (the "2018 Exit Fee Agreement"). On December 31, 2019, the Company refinanced the 2018 Loan Agreement by entering into a $45.0 million loan and security agreement (the "2019 Loan Agreement") and a related exit fee agreement (the "2019 Exit Fee 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"). The Company has amended the 2019 Loan Agreement on multiple occasions, which are summarized as follows:

On February 22, 2022, the Company entered into a Third Amendment to the 2019 Loan Agreement (the "Third Amendment"), which, among other things, amended the provisions relating to the minimum revenue amount that the Company must achieve at the end of each calendar quarter, as calculated on a trailing six-month basis (the "Revenue Covenant").

On December 7, 2022, the Company entered into a Fourth Amendment to the 2019 Loan Agreement (the "Fourth Amendment"), which, among other things, extended the amortization date from January 1, 2023 to April 1, 2023, and provided that such date might 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. The Fourth Amendment also amended the provisions relating to the Revenue Covenant effective with the first calendar quarter in 2023.

On March 24, 2023, the Company entered into a Fifth Amendment to the 2019 Loan Agreement (the "Fifth Amendment") and a related Fifth Amendment Exit Fee Agreement (the "New Exit Fee Agreement"). Pursuant to the Fifth Amendment, the Lenders agreed to, among other things, (i) an additional tranche of $2.5 million to increase the Company's existing term loan facility to $47.5 million, subject to certain closing conditions, (ii) extend a $15.0 million additional term loan available to be funded at the Lender's sole discretion, and (iii) amended the Revenue Covenants to be effective for calendar quarters ending on or after March 31, 2023.

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. 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% or (ii) one-month SOFR, which will reset monthly. As of December 31, 2023 and 2022, the interest rate on the 2019 Loan Agreement was approximately 10.50% and 11.82%, respectively. 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 April 20, 2025, followed by monthly payments of principal and interest through the loan maturity date of April 30, 2028. The Company has met such financial targets during the year ended December 31, 2023, and provided there are no events of default as defined by the Loan Agreement on or prior to April 20, 2025, the Company anticipates being able to extend the interest only period for an additional 12 months.

On May 17, 2023, the Company entered into a Sixth Amendment to the 2019 Loan Agreement, as so amended, will collectively be referred to as the "Amended Loan Agreement." Pursuant to the Amended Loan Agreement, the Lenders agreed to, among other things, (i) an increase of the limit in the additional term loan facility from $15 million to $20 million, and (ii) amended the Revenue Covenants to be effective for calendar quarters ending on or after June 30, 2023. The Company received aggregate gross proceeds of $5.0 million upon execution of the Amended Loan Agreement. The Company has complied with the Revenue Covenant as of December 31, 2023, and expects to comply with the Revenue Covenant at the next reportable date and for the foreseeable future.

On March 6, 2024, the Company entered into a Seventh Amendment to the 2019 Loan Agreement. See Note 18 for further details on this transaction.

Exit Fee Agreements

Pursuant to the existing 2018 Exit Fee Agreement, the Company is obligated to pay up to a $2.0 million exit fee upon the occurrence of an exit event, which generally means a change in control, and will survive the termination of the Amended Loan Agreement and has a term of 10 years. To the extent that the Company has not already paid the $2.0 million exit fee, the Company is obligated to pay a fee of $1.0 million on achieving each of the following milestones:

(a) First, if the Company achieves revenues of $80.0 million 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

(b) Second, if the Company achieves revenues of $100.0 million or more from the sale of its ILUVIEN product in the ordinary course of business to third-party customers, measured in the same manner.

Pursuant to the existing 2019 Exit Fee Agreement, the Company is obligated to pay up to a $0.7 million exit fee upon the occurrence of an exit event, which generally means a change in control, and will survive the termination of the Amended Loan Agreement and has a term of 10 years. To the extent that the Company has not already paid the $0.7 million exit fee, the Company is obligated to pay a fee of $0.3 million on achieving each of the following milestones:

(a) First, if the Company achieves revenues of $75.0 million 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

(b) Second, if the Company achieves revenues of $95.0 million or more from the sale of its ILUVIEN product in the ordinary course of business to third-party customers, measured in the same manner.

Pursuant to the existing New Exit Fee Agreement, the Company is obligated to pay 1.5% of the aggregate principal amount funded under the Amended Loan Agreement as an exit fee upon the occurrence of an exit event, which generally means a change in control, and will survive the termination of the Amended Loan Agreement and has a term of 10 years. To the extent that the Company has not already paid the 1.5% of the aggregate principal amount funded under the Amended Loan Agreement, the Company is obligated to pay a fee of 1.5% of the aggregate principal amount funded under the Amended Loan Agreement upon achieving the following milestone:

(a) If the Company achieves revenues of $82.5 million 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.

On May 17, 2023, the Company amended the revenue criteria for all three Exit Fee Agreements to include the sales of YUTIQ in the ordinary course of business to third-party customers. The fees payable pursuant to the Company's existing exit fee agreements and the New Exit Fee Agreement will not exceed $3.7 million in total.

During the year ended December 31, 2023, the Company met one revenue milestone under the 2018 Exit Fee Agreement and one revenue milestone under the 2019 Exit Fee Agreement. Accordingly, the Company recognized $1.3 million of interest expense during the year ended December 31, 2023 in the accompanying consolidated statement of operations. The Company anticipates meeting the remaining revenue milestones over the next 12 months, which will trigger $2.4 million exit fee payments. No exit fees were triggered or paid for the year ended December 31, 2022.

Modification of Debt

In accordance with the guidance in FASB 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 $0.1 million 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. The Company capitalized approximately $2.6 million of deferred financing costs in connection with the Fifth and Sixth Amendments during 2023.

Extinguishment of Debt

In accordance with the guidance in FASB ASC 470-50, *Debt*, the Company entered into and accounted for the Sixth Amendment as an extinguishment of debt. The Company recognized a loss on extinguishment of $1.1 million in connection with the Sixth Amendment.

Under the 2019 Loan Agreements, as amended, the Company was obligated to make the following future minimum principal payments as of December 31, 2023:

Years Ending December 31	(In thousands)
2024	$ —
2025	14,594
2026	21,892
2027	21,892
2028	9,122
Total	67,500
Less unamortized debt discount and deferred financing costs	(3,011)
Less current portion	—
Non-current portion	$ 64,489

At each of December 31, 2023 and 2022, the Company had $0.6 million and $0.5 million, respectively, of accrued and unpaid interest payable under the 2019 Loan Agreement, as amended.

10. STOCKHOLDERS' EQUITY (DEFICIT)

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 $40.0 million prior to the payment of approximately $0.6 million of related issuance costs. The Company subsequently 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. The authorized shares of Series A Preferred Stock were returned to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series.

Series B Convertible Preferred Stock

In March 2023, the Company issued and sold an aggregate of 12,000 shares of Series B Convertible Preferred Stock at a purchase price of $1,000 per share and warrants to purchase common stock for aggregate gross proceeds of $12.0 million. In May 2023, the Company issued and sold an additional aggregate of 67,000 shares of Series B Convertible Preferred Stock at a purchase price of $1,000 per share and warrants to purchase common stock for aggregate gross proceeds of $67.0 million. On August 1, 2023, the Company amended the Certificate of Designation of Series B Convertible Preferred Stock to allow for the issuance of pre-funded warrants ("Pre-Funded Warrants") to certain holders of Series B Preferred Stock. Prior to such amendment, the Certificate of Designation provided that the Series B Preferred Stock (including any accrued but unpaid dividends) would automatically convert at the then-applicable conversion price (the "Mandatory Conversion") in full into the Company's common stock following stockholder approval. Stockholder approval was received at the Company's 2023 annual meeting of stockholders held on August 1, 2023, and the Company designated August 15, 2023, as the date for the Mandatory Conversion of the Series B Convertible Preferred Stock into its common stock and Pre-Funded Warrants to purchase common stock. In connection with the Mandatory Conversion, the Company issued 43,617,114 shares of common stock and Pre-Funded Warrants exercisable for 2,000,000 shares of common stock at an exercise price of $0.01 per share to the holders of the Series B Convertible Preferred Stock. Following the Mandatory Conversion, no shares of the Series B Convertible Preferred Stock remain outstanding. The authorized shares of Series B Preferred Stock were returned to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series.

Common and Preferred Stock

The Company's authorized capital stock consists of (a) 150,000,000 shares of common stock, par value $0.01 per share; and (b) 10,000,000 shares of preferred stock, par value $0.01 per share. At December 31, 2023 and 2022, there were 52,354,450 and 6,995,513 shares of common stock issued and outstanding.

11. STOCK-BASED COMPENSATION

Equity Incentive Plan(s)

On August 1, 2023, the Company's stockholders approved the 2023 Equity Incentive Plan (the "2023 Plan"), which replaced the 2019 Omnibus Incentive Plan (the "2019 Plan"). The 2023 Plan has a share reserve equal to the sum of (a) 3,231,755 shares of common stock, (b) shares that are subject to awards granted under the 2019 Plan that are outstanding on or after August 1, 2023 (the "Effective Date") and that are subsequently forfeited, cancelled, expire or lapse unexercised or unsettled or are reacquired by the Company, (c) the number of shares reserved under the 2019 Plan that are not issued or subject to outstanding awards under the 2019 Plan on the Effective Date, and (d) the increase in shares described in the next sentence. On the first anniversary of the Effective Date, the number of shares of common stock that may be issued under the 2023 Plan will increase by a number of shares equal to 6% of the number of outstanding shares of common stock. Under the 2023 Plan, the Compensation Committee of the Company's board of directors is authorized to grant equity-based incentive awards that include stock options, restricted stock units ("RSU"), shares of restricted stock ("RSS") and performance-based restricted stock units ("PSU") to officers, directors, employees and contractors. Equity-based awards are also outstanding under the Company's 2019 and 2010 equity incentive plans, although no new awards can be granted under either plan. The Company's equity incentive plans permit the issuance of various types of awards including but not limited to stock options, restricted stock, RSU and PSU.

An aggregate 142,511 and 754,033 shares of the Company's common stock were available for issuance of new awards granted under the Company's equity incentive plans as of December 31, 2023 and 2022, respectively.

Stock-based Compensation Expense

The Company recognized stock-based compensation expense in the aggregate amount of $1.4 million and $0.9 million for the years ended December 31, 2023 and 2022, respectively. Stock-based compensation expense by award type included within the consolidated statements of operations is as follows:

	Years Ended December 31,	
	2023	2022
	(In thousands)	
Stock options	$ 975	$ 820
Restricted stock units and restricted stock	429	56
Employee stock purchase plan	31	34
Total employee stock-based compensation expense	$ 1,435	$ 910

Stock-based compensation expense recognized in accordance with ASC 718 by classification during the years ended December 31, 2023 and 2022, respectively, was as follows:

	Years Ended December 31,	
	2023	2022
	(In thousands)	
Sales and marketing	$ 204	$ 193
Research, development and medical affairs	126	103
General and administrative	1,105	614
Total employee stock-based compensation expense	$ 1,435	$ 910

Stock Options

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

	Years Ended December 31,			
	2023		2022	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of period	1,175,339	$ 19.03	1,075,795	$ 23.35
Grants	2,312,636	3.21	287,800	4.96
Forfeitures	(293,401)	20.76	(185,694)	22.26
Exercises	—	—	(2,562)	5.85
Options outstanding at year end	3,194,574	7.42	1,175,339	19.03
Options exercisable at year end	993,037	16.34	878,115	23.62
Weighted average per share fair value of options granted during the year	$ 2.31		$ 3.33	

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, 2023:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
				(In thousands)
Outstanding	3,194,574	$ 7.42	8.35 years	$ 2,460
Exercisable	993,037	16.34	5.40 years	258
Outstanding, vested and expected to vest	2,887,226	7.84	8.20 years	2,164

The weighted-average assumptions used at the date of grant in the respective Black-Scholes for option grants were as follows:

	Years Ended December 31,	
	2023	2022
Risk-free interest rate	4.5%	1.5%
Volatility factor	81.0%	77.0%
Grant date fair value of common stock options	$ 2.31	$ 3.33
Weighted-average expected life	6.03 years	6.02 years
Assumed forfeiture rate	25.0%	10.0%

As of December 31, 2023 and 2022, there was approximately $3.9 million and $1.0 million of total unrecognized compensation cost related to outstanding stock option awards that will be recognized over a weighted average period of 3.27 and 2.50 years, respectively. The total fair value of shares vested during 2023 and 2022 was approximately $0.8 million and $0.8 million, respectively.

The total estimated fair value of options granted during the years ended December 31, 2023 and 2022 was $5.4 million and $1.0 million, respectively. The total estimated intrinsic value of options exercised was $0 and less than $0.1 million for the years ended December 31, 2023, and 2022, respectively.

Restricted Stock

A summary of restricted stock transactions under the plans for the years ended December 31, 2023 and 2022 is as follows:

	Years Ended December 31,			
	2023		2022	
	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
RSSs & RSUs outstanding at beginning of period	73,594	$ 4.98	46,250	$ 5.65
Granted	1,257,050	2.19	57,500	4.96
Vested	(24,843)	4.60	(9,687)	5.01
Forfeited	(88,725)	1.57	(20,469)	6.42
RSSs & RSUs outstanding at year end	1,217,076	2.35	73,594	4.98

As of December 31, 2023 and 2022, there was approximately $2.2 million and $0.3 million of total unrecognized compensation cost related to outstanding restricted stock, respectively, that will be recognized over a weighted average period of 3.48 and 2.69 years, respectively.

Performance-based restricted stock units

During the fourth quarter of 2023, the Company began granting performance-based PSUs that will settle in stock. PSUs awarded to employees have a three-year performance period and vest equally upon the achievement of annual performance measures established at the date of grant. Participants may ultimately earn between zero and 100% of the number of PSUs granted based on the degree of achievement of the performance metrics. If zero PSUs vest in a given year because the annual performance metric was not achieved, such PSUs will not be eligible to vest in a later year for the participant.

The following table summarizes the PSU activity for year ended December 31, 2023:

	Years Ended December 31, 2023	
	Shares	Weighted Average Grant Date Fair Value
PSU outstanding at beginning of period	—	$ —
Granted	625,000	2.99
Vested	—	—
Forfeited	—	—
PSU outstanding at year end	625,000	2.99

The Company recognized $0 in compensation costs related to the PSUs during the year ended December 31, 2023, as it was not deemed probable that any performance conditions would be achieved. As of December 31, 2023, there was approximately $1.9 million of total unrecognized compensation cost related to outstanding PSUs that will be recognized over a weighted average period of 3.25 years.

Employee Stock Purchase Plan

In 2010, the Company established an 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 the applicable annual limit allowed by the applicable IRS rules and regulations. The Company recognized ESPP compensation expense totaling $31,000 and $34,000 for each of the years ended December 31, 2023, and 2022, respectively.

12. EARNINGS (LOSS) PER SHARE

Basic net loss per share is calculated by dividing net loss by the weighted average shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. For purposes of the diluted net loss per share calculation, stock options, unvested restricted stock units and ESPP shares are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive; therefore, basic and diluted net loss per share were the same for all periods presented as a result of the Company's net loss.

The following common stock equivalents were excluded from the computation of diluted net loss per share for the years ended December 31, 2023 and 2022, respectively, because their inclusion would have had anti-dilutive effect:

	Years Ended December 31,	
	2023	2022
Series A convertible preferred stock	—	601,504
Common stock warrants	1,600,000	—
Stock options	3,194,574	1,175,339
Total	4,794,574	1,776,843

13. 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, 2023 and December 31, 2022, respectively, for the Company's operating leases is as follows:

	December 31,	
	2023	2022
	(In thousands)	
Non-current assets:		
Right of use assets, net	$ 1,124	$ 1,395
Total lease assets	$ 1,124	$ 1,395
Current liabilities:		
Accrued expenses	$ 634	$ 768
Non-current liabilities:		

Other non-current liabilities	1,826	2,267
Total lease liabilities	$ 2,460	$ 3,035

The Company's operating lease costs for the years ended December 31, 2023 and 2022, were $0.5 million and $0.5 million, respectively, and were included in general and administrative expenses in its consolidated statements of operations.

As of December 31, 2023, a schedule of maturity of lease liabilities under all of the Company's operating leases is as follows:

Years Ending December 31	(In thousands)
2024	$ 662
2025	474
2026	488
2027	503
2028	518
Thereafter	534
Total	3,179
Less amount representing interest	(719)
Present value of minimum lease payments	2,460
Less current portion	(634)
Non-current portion	$ 1,826

Cash paid for operating leases was $0.7 million and $0.3 million during the years ended December 31, 2023 and 2022, respectively. No right-of-use assets were obtained in connection with operating leases for the years ended December 31, 2023 and 2022.

As of December 31, 2023 and 2022, the weighted average remaining lease terms of the Company's operating leases was 5.7 and 6.9 years, respectively, and the weighted average discount rate used to determine the lease liabilities was 9.5% for both years. 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, 2023 and December 31, 2022 for the Company's finance leases is as follows:

	December 31,	
	2023	2022
	(In thousands)	
Non-current assets:		
Property and equipment, net	$ 554	$ 366
Total lease assets	$ 554	$ 366
Current liabilities:		
Finance lease obligations	$ 194	$ 333
Non-current liabilities:		
Finance lease obligations — less current portion	256	131
Total lease liabilities	$ 450	$ 464

Depreciation expense associated with property and equipment under finance leases was approximately $0.2 million and $0.3 million for the years ended December 31, 2023 and 2022, respectively. Interest expense associated with finance leases was insignificant for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, 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)
2024	$ 304
2025	220
2026	68
Total	592
Less amount representing interest	(142)
Present value of minimum lease payments	450
Less current portion	(194)
Non-current portion	$ 256

Cash paid for financing leases was $0.5 million and $0.3 million during the years ended December 31, 2023, and 2022, respectively. Property and equipment in the aggregate amount of $0.5 million and $0 was obtained and classified as financing leases during the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023 and 2022, the weighted average remaining lease terms of the Company's financing leases was 1.2 and 0.7 years, respectively. As of December 31, 2023 and 2022, the weighted average discount rate used to determine the financing lease liabilities was 10.1% and 9.7%, respectively. 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.

14. INCOME TAXES

The Company's components of net loss before taxes are as follows:

	Years Ended December 31,	
	2023	2022
	(In thousands)	
United States	$ (16,139)	$ (11,000)
Foreign	(3,908)	(7,079)
Loss before provision for income taxes	$ (20,047)	$ (18,079)

In accordance with ASC 740, *Income Taxes,* 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.

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The provision for income taxes consists of the following components:

	Years Ended December 31,	
	2023	2022
	(In thousands)	
Current expense:		
Federal	$ —	$ —
State	—	—
Foreign	56	144
Current income tax expense	56	144
Deferred expense (benefit):		
Federal	—	—
State	—	—
Foreign	29	(116)
	29	(116)
Valuation allowance	—	—
Deferred income tax expense (benefit)	29	(116)
Total income tax expense	$ 85	$ 28

Activities related to the Company's valuation allowance are summarized as follows:

	Years Ended December 31,	
	2023	2022
	(In thousands)	
Valuation allowance at beginning of period	$ (53,165)	$ (48,855)
Increase in valuation allowance	(4,157)	(4,310)
Valuation allowance at end of period	$ (57,322)	$ (53,165)

Worldwide net deferred tax assets and liabilities, including net operating loss ("NOL") carry-forwards, are summarized as follows:

	December 31,	
	2023	2022
	(In thousands)	
Deferred tax assets:		
Depreciation and amortization	$ 77	$ 94
Intangible assets	6,113	6,841
IRC Section 174 costs	2,007	969
Other deferred tax assets	1,334	(878)
NOL carry-forwards	44,283	41,800
Equity compensation	2,021	2,749
Collaboration agreement receivable reserves	1,591	1,719
Valuation allowance	(57,322)	(53,165)
Total deferred tax assets	$ 104	$ 129

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

	Years Ended December 31,			
	2023		2022	
	Amount	Percent	Amount	Percent
	(in thousands, except percentages)			
Federal tax benefit at statutory rate	$ (4,474)	21.0%	$ (3,797)	21.0%
State tax benefit — net of federal benefit	(256)	1.2	(379)	2.1
Permanent items	791	(3.7)	718	(4.0)
Change in fair market of common stock warrants	1,727	(8.1)	—	—
Foreign rate differential	(2,349)	11.0	(1,680)	9.3
Tax credits and true-ups	489	(2.3)	856	(4.8)
Increase in valuation allowance	4,157	(19.5)	4,310	(23.8)
Total tax expense	$ 85	(0.4)%	$ 28	(0.2)%

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

	Years Ended December 31,	
	2023	2022
	(In thousands)	
Balance of uncertain tax positions at beginning of period	$ 112	$ 88
Gross increases - tax positions in current period	25	24
Gross decreases - tax positions in prior period	15	—
Balance of uncertain tax positions at end of period	$ 152	$ 112

Included in the balance of unrecognized tax benefits as of December 31, 2023 and 2022 are approximately $0.2 million and $0.1 million, 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 2020 to 2022 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, 2023 and 2022, the Company had federal NOL carry-forwards of approximately $146.8 million and $147.2 million, and state NOL carry-forwards of approximately $106.8 million and $107.7 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 2023 and 2043.

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 Section 382 changes in ownership occurred in late 2015 and in 2023. As a result of these changes in ownerships, the Company estimated that substantially all of its federal and state NOL carry-forwards and tax credits generated prior to the 2023 change in ownership will be subject to Section 382 limitations and may not be fully utilized in the future. The Company is currently in the process of evaluating the Section 382 impact to determine if a write-off is necessary. 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, 2023 and 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 utilized $1.1 million of this carryforward as of December 31, 2023. The Company expects the remaining 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.

15. COMMITMENTS AND OFF-BALANCE SHEET RISKS

Significant Agreements

ILUVIEN

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 $1.0 million at Alliance as of December 31, 2023.

In October 2020, the Company entered into a Manufacturing Services Agreement with Cadence, Inc. (the "Cadence Agreement"), under which Cadence, Inc. has replaced the prior manufacturer. In 2021, Cadence, Inc. 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, Inc. 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 $0.8 million at Cadence Inc. as of December 31, 2023.

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.

YUTIQ

In connection with the Product Rights Agreement, the Company entered into a commercial supply agreement (the Supply Agreement) with EyePoint Parent pursuant to which, during the term of the Product Rights Agreement, EyePoint Parent will be responsible for manufacturing and exclusively supplying (subject to certain exceptions) to the Company agreed-upon quantities of

YUTIQ necessary for Alimera to commercialize YUTIQ in the U.S. at certain cost plus amounts, subject to adjustments set forth in the Supply Agreement.

EyePoint Parent's manufacture and supply to Alimera of YUTIQ under the Supply Agreement will be exclusive (subject to certain exceptions set forth in the Supply Agreement) until Alimera has the right and ability to manufacture and supply YUTIQ for commercialization in the U.S.

The Company may elect to manufacture YUTIQ after an initial 18-month term following the closing date upon the satisfaction of certain conditions. (see Note 4)

16. 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 expenses associated with the Company's matching plan totaled $0.5 million and $0.4 million for the years ended December 31, 2023 and 2022, respectively. The Company may also make an annual discretionary profit-sharing contribution. No such discretionary contributions were made during the years ended December 31, 2023 and 2022, respectively.

17. SEGMENT INFORMATION

The Company's operations are managed as three operating segments: U.S., International and Operating Cost. The Company determined that each of these operating segments represented a reportable segment. 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 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.

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, 2023 and 2022:

	Year Ended December 31, 2023				
	U.S.	International	Operating Cost	Other	Consolidated
	(In thousands)				
Net revenue	$ 56,711	$ 24,043	$ —	$ —	$ 80,754
Cost of goods sold, excluding depreciation and amortization	(6,152)	(4,685)	—	—	(10,837)
Gross profit	50,559	19,358	—	—	69,917
Operating expenses:					
Research, development and medical affairs expenses	4,276	2,720	9,522	108	16,626
General and administrative expenses	2,309	3,318	11,798	1,105	18,530

Sales and marketing expenses	21,000	6,222	502	222	27,946
Depreciation and amortization	—	—	—	8,747	8,747
Total operating expenses	27,585	12,260	21,822	10,182	71,849
Segment income (loss) from operations	22,974	7,098	(21,822)	(10,182)	(1,932)
Other income and expenses, net				(18,115)	(18,115)
Net loss before taxes					$ (20,047)

	Year Ended December 31, 2022				
	U.S.	International	Operating Cost	Other	Consolidated
			(In thousands)		
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
Operating expenses:					
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
Total 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)

18. SUBSEQUENT EVENTS

Seventh Amendment to Loan and Security Agreement

On March 6, 2024, Alimera entered into the Seventh Amendment (the “Seventh Amendment”) to its Loan and Security Agreement dated December 31, 2019, (the “Loan Agreement”), with SLR as collateral agent, and the lenders party thereto, including SLR in its capacity as a lender (each a “Lender” and collectively, the “Lenders”). Pursuant to the Seventh Amendment, the Lenders agreed to, among other things, increase the amount available under the facility from $67.5 million to $72.5 million and funded an additional term loan of $5.0 million on March 6, 2024. The maturity date of the Loan Agreement remains April 30, 2028, and the interest-only period remains in effect through April 30, 2025. As previously disclosed, the interest-only period may be extended an additional 12 months if Alimera meets certain financial targets by April 20, 2025.

Chief Financial Officer Changes

On December 28, 2023, the Company determined that Russell Skibsted’s last day of employment as the Chief Financial Officer of the Company was December 31, 2023. On January 3, 2024, the Company entered into a separation and release agreement with Mr. Skibsted that provides for severance benefits in exchange for a release of claims in favor of the Company, consistent with the terms of a termination without cause under Mr. Skibsted’s employment agreement dated January 9, 2023. Mr. Skibsted’s termination was not due to any disagreement with the Company’s management team or the Company’s Board of Directors on any matter relating to the operations, policies or practices of the Company or any issues regarding the Company’s accounting policies or practices.

On January 2, 2024, the Company entered into an employment agreement with Elliot Maltz pursuant to which Mr. Maltz currently serves as the Company’s Chief Financial Officer.

Equity Inducement Plan

The Company formally adopted a 2024 Equity Inducement Plan (the “2024 Plan”) on February 8, 2024, under which its board of directors is authorized to grant inducement awards, including stock options and RSUs, to employees and directors up to 800,000 common shares.

EXHIBIT INDEX

Exhibit Number	Exhibit Title
2.1**	Product Rights Agreement, dated May 17, 2023, by and among Alimera Sciences, Inc. and EyePoint Pharmaceuticals, Inc. (filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K, as filed on May 18, 2023, and incorporated herein by reference)
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)
3.6	Certificate of Amendment to Certificate of Designation of Series B Convertible Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, as filed on May 18, 2023, and incorporated herein by reference)
3.7	Certificate of Amendment to Certificate of Designation of Series B Convertible Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, as filed on August 2, 2023, and incorporated herein by reference)
3.8	Certificate of Elimination of Series B Convertible Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, as filed on August 15, 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)
4.2	Form of Pre-Funded Warrant (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, as filed on August 2, 2023, 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)
10.2.F†	Alimera Sciences, Inc. 2023 Equity Incentive Plan and forms of award agreements thereunder (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on August 2, 2023, 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†	Alimera Sciences, Inc. 2023 Equity Incentive Plan and forms of award agreements thereunder (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on August 2, 2023, and incorporated herein by reference)
10.7†	Alimera Sciences, Inc. 2024 Equity Inducement Plan as Adopted on February 8, 2024 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed February 9, 2024, and incorporated herein by reference)
10.8.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)
10.8.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)
10.8.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)
10.8.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)
10.8.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)
10.8F†	Chairman Emeritus Agreement, dated as of August 1, 2023 by and between Alimera Sciences, Inc. and C. Daniel Myers (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, as filed on August 2, 2023, and incorporated herein by reference)
10.8G†	Employment Agreement dated as of October 2, 2023 between Alimera Sciences, Inc. and Jason Werner (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on October 3, 2023, and incorporated herein by reference)
10.8H†	Amended and Restated Employment Agreement, dated as of December 11, 2023, by and between Alimera Sciences, Inc. and Richard S. Eiswirth, Jr. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on December 12, 2023, and incorporated herein by reference)
10.8I†	Employment Agreement, dated as of December 11, 2023, by and between Alimera Sciences, Inc. and Todd Wood (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, as filed on December 12, 2023, and incorporated herein by reference)

10.8J†	Inducement Stock Option Agreement, dated as of December 11, 2023, by and between Alimera Sciences, Inc. and Todd Wood (Non-Plan Inducement Award) (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K, as filed on December 12, 2023, and incorporated herein by reference)
10.8K†	Employment Agreement, dated as of (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, as filed on January 4, 2024, and incorporated herein by reference)
10.8L†	Inducement Stock Option Agreement, (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K, as filed on January 4, 2024, and incorporated herein by reference)
10.9‡	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)
10.10**	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)
10.11‡	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)
10.12.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)
10.12.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)
10.12.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)
10.12.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)
10.12.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)
10.12.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)
10.12.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)
10.12H**	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 (filed as Exhibit 10.12 to the Registrant's Annual Report on Form 10-K, as filed on March 31, 2023)
10.12.I**	Fifth Amendment to Loan and Security Agreement dated as of March 24, 2023, 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 10.3 to the Registrant's Quarterly Report on Form 10-Q, as filed on May 15, 2023, and incorporated herein by reference)
10.12.J**	Sixth Amendment to Loan and Security Agreement dated as of May 17, 2023, 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 10.3 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2023, and incorporated herein by reference)

10.12.K	Omnibus Exit Fee Agreement dated as of May 17, 2023, 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 10.4 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2023, and incorporated herein by reference)
10.13.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)
10.13.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)
10.13.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)
10.13.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)
10.14.A	Registration Rights Agreement, dated March 24, 2023, by and among Alimera Sciences, Inc. and the purchasers party thereto (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, as filed on March 27, 2023, and incorporated herein by reference)
10.14.B	Joinder and Amendment to Registration Rights Agreement dated as of May 17, 2023, by and among Alimera Sciences, Inc. and the purchasers party thereto (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2023, and incorporated herein by reference)
10.15A	Securities Purchase Agreement, dated March 24, 2023, by and among Alimera Sciences, Inc. and the purchasers party thereto (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on March 27, 2023, and incorporated herein by reference)
10.15B	Joinder and Amendment to Securities Purchase Agreement, dated May 17, 2023, by and among Alimera Sciences, Inc. and the purchasers party thereto (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, as filed on May 18, 2023, and incorporated herein by reference)
10.16**	Commercial Supply Agreement, dated May 17, 2023, by and among Alimera Sciences, Inc. and EyePoint Pharmaceuticals, Inc. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on May 18, 2023, and incorporated herein by reference)
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
97.1*	Alimera Sciences, Inc. Clawback Policy
101	The following financial information from The Registrant's Annual Report on Form 10-K for the year ended December 31, 2023, formatted in iXBRL (Inline Extensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2023 and 2022, (ii) Consolidated Statements of Operations for the years ended December 31, 2023 and 2022, (iii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2023 and 2022, (iv) Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the years ended December 31, 2023 and 2022, and (v) Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022
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 8, 2024.

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 Elliott Maltz, 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 8, 2024
/s/ Elliot Maltz Elliot Maltz	Chief Financial Officer (Principal Financial and Accounting Officer)	March 8, 2024
/s/ Adam Morgan Adam Morgan	Chairman of the Board of Directors	March 8, 2024
/s/ Ross DeMont Ross DeMont	Director	March 8, 2024
/s/ Michael Kaseta Michael Kaseta	Director	March 8, 2024
/s/ Erin Parsons Erin Parsons	Director	March 8, 2024
/s/ Margaret A. Pax Margaret A. Pax	Director	March 8, 2024
/s/ Peter J. Pizzo, III Peter J. Pizzo, III	Director	March 8, 2024
/s/ John Snisarenko John Snisarenko	Director	March 8, 2024

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 8, 2024, 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, 2023. We consent to the incorporation by reference of said report in the Registration Statements of Alimera Sciences, Inc. on Forms S-3 (File No. 333-249804 and File No. 333-273090) and 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, File No. 333-263784, File No. 333-271519, File No. 333-273951, File No. 333-276991, and File No. 333-276996).

/s/ GRANT THORNTON LLP

Atlanta, Georgia

March 8, 2024

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 8, 2024

/s/ Richard S. Eiswirth, Jr.
Richard S. Eiswirth, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Elliot Maltz, 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 8, 2024

/s/ Elliot Maltz
Elliot Maltz
Chief Financial Officer
(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, 2023 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 8, 2024

/s/ Richard S. Eiswirth, Jr.
Richard S. Eiswirth, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 8, 2024

/s/ Elliot Maltz
Elliot Maltz
Chief Financial Officer
(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.

Exhibit 97.1

ALIMERA SCIENCES, INC.
POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED INCENTIVE COMPENSATION

(Adopted: November 21, 2023)

1. INTRODUCTION

Alimera Sciences, Inc. (the "***Company***") is adopting this policy (this "***Policy***") to provide for the Company's recovery of certain Incentive Compensation (as defined below) erroneously awarded to Affected Officers (as defined below) under certain circumstances. This Policy is effective as of October 2, 2023 (the "***Effective Date***").

This Policy is administered by the Compensation Committee (the "***Committee***") of the Company's Board of Directors (the "***Board***"). The Committee shall have full and final authority to make any and all determinations required or permitted under this Policy. Any determination by the Committee with respect to this Policy shall be final, conclusive and binding on all parties. The Board may amend or terminate this Policy at any time.

This Policy is intended to comply with Section 10D of the Securities and Exchange Act of 1934, as amended (the "***Exchange Act***"), Rule 10D-1 thereunder and the applicable rules of any national securities exchange on which the Company's securities are then listed (the "***Exchange***") and will be interpreted and administered consistent with that intent.

Each Affected Officer subject to this Policy must execute the Acknowledgment and Agreement attached hereto as Exhibit A before such Affected Officer will be entitled to receive any cash- or equity-based incentive compensation that is approved, granted or awarded on or after the Effective Date.

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation received by an Affected Officer on or after the Effective Date, to the extent permitted or required by applicable law or the rules of the Exchange.

3. DEFINITIONS

For purposes of this Policy, the following terms shall have the meanings set forth below:

"***Affected Officer***" means any current or former "officer" as defined in Exchange Act Rule 16a-1, and any other senior executives as determined by the Committee.

"***Erroneously Awarded Compensation***" means the amount of Incentive Compensation received that exceeds the amount of Incentive Compensation that otherwise would have been received had it been
determined based on the Restatement, computed without regard to any taxes paid. In the case of Incentive Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the Restatement, the amount shall reflect a reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Incentive Compensation was received, as determined by the Committee in its sole discretion. The Committee may determine the form and amount of Erroneously Awarded Compensation in its sole discretion.

"***Financial Reporting Measure***" means any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures, whether or not such
measure is presented
within the financial statements or included in a filing with the Securities and Exchange Commission. Stock price and total shareholder return are also Financial Reporting Measures.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based in whole or in part on the attainment of a
Financial Reporting Measure. For purposes of clarity, base salaries, bonuses or equity awards paid solely upon satisfying one or more subjective standards, strategic or operational measures, or continued employment are not considered Incentive Compensation, unless such awards were granted, earned or vested based in part on a Financial Reporting Measure.

"***Restatement***" means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements (i.e., a "Big R" restatement), or that would result in a material misstatement if the error was corrected in the current period or left uncorrected in the current period (i.e., a "little r" restatement).

4. RECOVERY

If the Company is required to prepare a Restatement, the Company shall seek to recover and claw back from any Affected Officer reasonably promptly the Erroneously Awarded Compensation that is received by the Affected Officer:

(i) on or after the Effective Date;

(ii) after the person begins service as an Affected Officer;

(iii) who served as an Affected Officer at any time during the performance period for that Incentive Compensation;

(iv) while the Company has a class of securities listed on the Exchange; and

(v) during the three completed fiscal years immediately preceding the date on which the Company was required to prepare the Restatement (including any transition period within or immediately following those years that results from a change in the Company's fiscal year, provided that a transition period of nine to 12 months will be deemed to be a completed fiscal year).

For purposes of this Policy:

· Erroneously Awarded Compensation is deemed to be received in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive Compensation is attained, even if the payment or grant of the Incentive Compensation occurs after the end of that period; and

· the date the Company is required to prepare a Restatement is the earlier of (x) the date the Board, the Committee or any officer of the Company authorized to take such action concludes, or reasonably should have concluded, that the Company is required to prepare the Restatement, or (y) the date a court, regulator, or other legally authorized body directs the Company to prepare the Restatement.

To the extent required by applicable law or the rules of the Exchange, any profits realized from the sale of securities of the Company are subject to recoupment under this Policy.

For purposes of clarity, in no event shall the Company be required to award any Affected Officers an additional payment or other compensation if the Restatement would have resulted in the grant, payment or vesting of Incentive Compensation that is greater than the Incentive Compensation actually received by the Affected Officer. The recovery of Erroneously Awarded Compensation is not dependent on if or when the Restatement is filed.

5. SOURCES OF RECOUPMENT

To the extent permitted by applicable law, the Committee may, in its discretion, seek recoupment from the Affected Officer(s) through any means it determines, which may include any of the following sources: (i) prior Incentive Compensation payments; (ii) future payments of Incentive Compensation; (iii) cancellation of outstanding Incentive Compensation; (iv) direct repayment; and (v) non-Incentive Compensation or securities held by the Affected Officer. To the extent permitted by applicable law, the Company may offset such amount against any compensation or other amounts owed by the Company to the Affected Officer.

6. LIMITED EXCEPTIONS TO RECOVERY

Notwithstanding the foregoing, the Committee, in its discretion, may choose to forgo recovery of Erroneously Awarded Compensation under the following circumstances, provided that the Committee (or a majority of the independent members of the Board) has made a determination that recovery would be impracticable because:

(i) The direct expense paid to a third party to assist in enforcing this Policy would exceed the recoverable amounts; provided that the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation, has documented such attempt and has (to the extent required) provided that documentation to the Exchange;

(ii) Recovery would violate home country law where the law was adopted prior to November 28, 2022, and the Company provides an opinion of home country counsel to that effect to the Exchange that is acceptable to the Exchange; or

(iii) Recovery would likely cause an otherwise tax-qualified retirement plan to fail to meet the requirements of the Internal Revenue Code of 1986, as amended.

7. NO INDEMNIFICATION OR INSURANCE

The Company will not indemnify, insure or otherwise reimburse any Affected Officer against the recovery of Erroneously Awarded Compensation.

8. NO IMPAIRMENT OF OTHER REMEDIES

This Policy does not preclude the Company from taking any other action to enforce an Affected Officer's obligations to the Company, including termination of employment, institution of civil proceedings, or reporting of any misconduct to appropriate government authorities. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to the Company's Chief Executive Officer and Chief Financial Officer.

EXHIBIT A

ALIMERA SCIENCES, INC.
POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED INCENTIVE COMPENSATION
ACKNOWLEDGMENT AND AGREEMENT

This Acknowledgment and Agreement (the "***Acknowledgment***") is delivered by the individual named below as of the date set forth below. The undersigned is an Affected Officer (as defined in the Policy for Recovery of Erroneously Awarded Incentive Compensation (the "***Policy***")) to which the form of this Acknowledgement is attached as Exhibit A) of Alimera Sciences, Inc. (the "***Company***") and an employee of the Company or one of its subsidiaries.

The Board of Directors of the Company adopted the Policy to establish the conditions under which the Company may seek to recoup certain compensation from Affected Officers in the event that the Company is required to prepare a Restatement (as defined in the Policy).

The undersigned has received or may receive compensation, including cash-based incentive compensation and equity-based incentive compensation from the Company to which the Policy applies.

In consideration of the continued benefits to be received from the Company (or a subsidiary of the Company) and the right to participate in, and receive future awards under, the Company's cash- and equity-based incentive programs, the undersigned hereby acknowledges and agrees that:

1. S/he has read and understands the Policy;

2. S/he agrees that, to the extent provided in the Policy, the Policy shall also apply to Incentive Compensation (as defined in the Policy) established before or after the date of this Acknowledgment and the programs and agreements under which such compensation may have been or will be issued in the future shall be deemed to incorporate the terms of the Policy even if the Policy is not explicitly referenced therein. Nothing in this Acknowledgment shall be construed to expand the scope or terms of the Policy, and the undersigned is not waiving any defenses s/he may have in the event of an action for recoupment of compensation under the Policy, other than (i) waiving any defense regarding the retroactive application of the Policy to existing awards and (ii) waiving any claim that the integration clause of any agreement excludes the application of the Policy.

Date:

Signature:

Print Name.