SECURITIES & EXCHANGE COMMISSION EDGAR FILING

ALIMERA SCIENCES INC

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Table of Contents

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, 2020

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)**
6120 Windward Parkway, Suite 290 **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. □

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, 2020, 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 $29,531,837 based on the closing price of the registrant's Common Stock, on June 30, 2020, as reported by the Nasdaq Global Market. For the purposes of this disclosure, shares of Common Stock held by each executive officer, director and stockholder known by the registrant to be affiliated with such individuals 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 1, 2021, there were 5,753,434 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 2021 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, 2020, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Alimera Sciences, Inc.

Form 10-K

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

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

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND PROJECTIONS

Various statements in this report of Alimera Sciences, Inc. (we, our, Alimera or the Company) 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 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 and are based on information currently available to our management. Words such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "contemplates," "predict," "project," "target," "likely," "potential," "continue," "ongoing," "will," "would," "should," "could," or the negative of these terms and similar expressions or words, identify forward-looking statements. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements. Meaningful factors that could cause actual results to differ include those factors summarized in the immediately following section entitled "Summary of Principal Risk Factors," which we encourage you to read.

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 too heavily on the forward-looking statements we make or that are made on our behalf. 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. Please see, however, any further disclosures we make on related subjects in any annual, quarterly or current reports that we may file with the Securities and Exchange Commission (SEC).

We encourage you to read the discussion and analysis of our financial condition and our consolidated financial statements contained in this Annual Report on Form 10-K. We also encourage you to read Item 1A of Part 1 of this Annual Report on Form 10-K, entitled "Risk Factors," which contains a more detailed discussion of some of the risks and uncertainties associated with our business. In addition to the risks described above and in "Risk Factors," other unknown or unpredictable factors also could affect our results. 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 and estimates.

SUMMARY OF PRINCIPAL RISK FACTORS

Below is a summary of the principal risk factors we face. Please read it carefully and refer to the more detailed descriptions of the risk factors in Item 1A, "Risk Factors."

We face risks from:

Risks Related to the COVID-19 Pandemic

- the adverse effects of the COVID-19 pandemic, and its unpredictable duration and severity, in the regions where we have customers, employees and distributors;
- the possibility that manufacture or distribution of the ILUVIEN insert or applicator may be disrupted by government action related to COVID-19 or by the effect of the COVID-19 pandemic on our manufacturers' or distributors' workforces;
- the adverse effects of the COVID-19 pandemic on sales of ILUVIEN resulting from (a) limitations on in-person access to physicians for treatment imposed by governments or healthcare facilities, including those recently imposed in Europe and the U.K., and (b) the unwillingness of patients, many of whom suffer from diabetic macular edema and, in Europe and the U.K., non-infectious uveitis, to visit their physicians in person for fear of contracting the COVID-19 coronavirus;
- the financial uncertainty associated with the adverse effects of the COVID-19 pandemic and the duration and severity of those effects, which had an adverse effect on our revenue beginning late in the first quarter of 2020 and continuing to the date of this report, and if these adverse effects continue in the future, they may (a) adversely affect our revenue, financial condition and cash flows, and (b) affect certain estimates we use to prepare our quarterly financial results, including impairment of intangible assets, the income tax provision and recoverability of certain receivables;
- the possibility that the restrictions placed on regulatory and pricing bodies will delay or defer market access for ILUVIEN as we seek to secure reimbursement;
- the possibility that the economic impact of the COVID-19 pandemic will lead to changes in reimbursement policies and reduce market access for ILUVIEN in countries where we sell ILUVIEN;
- the possibility that we may fail to maintain or modify as necessary our internal controls over financial reporting in the current environment in which (a) some of our employees may be required to work remotely from time to time and (b) we or our distributors are required to modify our standard business processes to take into account the current environment in light of the COVID-19 pandemic;
- the possibility that staffing shortages resulting from the COVID-19 pandemic will recur at the third-party manufacturer where the ILUVIEN implant is made and the ILUVIEN applicator is assembled and packaged that may lead to product shortages;

- the possibility of reduced efficiency and potential distractions of our employees resulting from the prolonged impact of the COVID-19 pandemic, and the resulting loss of productivity;
- the possible delay in enrollment of patients in our NEW DAY Study;

Operational Risks

- our dependence on the commercial success of our only product, ILUVIEN;
- the competition we face, given that our competitors include larger, more established, fully integrated pharmaceutical companies and biotechnology companies that have substantially greater capital resources, existing competitive products, larger research and development staffs and facilities, greater marketing capabilities, and greater experience in drug development and in obtaining regulatory approvals than we do;
- uncertainty associated with our ability to retain our current employees and to recruit and retain the new employees we need in the future, in particular a productive sales force;
- the possibility that the NEW DAY Study may (a) fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early diabetic macular edema (DME) or to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, and (b) take longer or be more costly to complete than we currently anticipate;
- our possible inability to expand our portfolio of ophthalmic products;

Manufacturing Risks

- uncertainty associated with our transition from the previous third-party manufacturer of certain component parts of the ILUVIEN applicator to the successor manufacturer;
- our dependence on third-party manufacturers to manufacture ILUVIEN or any future products or product candidates in sufficient quantities and quality, in a timely manner (particularly during the COVID-19 pandemic), and at an acceptable price;
- the possibility that we may fail to plan appropriately to meet the demand of our customers for ILUVIEN, which could lead either to (a) ILUVIEN being out of stock or (b) our investment of a greater amount of cash in inventory than we need;

Financial Risks

- the possibility that we may fail to comply with the financial covenants in our $45.0 million Loan and Security Agreement with Solar Capital Ltd. as Collateral Agent (Agent), and certain other lenders, including Solar Capital in its capacity as a lender, dated December 31, 2019 (the 2019 Solar Loan Agreement);
- our possible need to raise additional financing, the terms of which may restrict our operations and, if the capital we raise is equity or a debt security that is convertible into equity, could dilute our stockholders' investment;
- uncertainty regarding our ability to achieve profitability and positive cash flow through the commercialization of ILUVIEN in the U.S., the European Economic Area (EEA) and other regions of the world where we sell ILUVIEN;
- a slowdown or reduction in our sales due to, among other things, a reduction in end user demand, unexpected competition, regulatory issues or other unexpected circumstances;
- the possibility that we may not be entitled to forgiveness of our PPP Loan;

Regulatory Risks

- the possibility that we may not timely obtain the necessary regulatory approvals to perform manufacturing at Cadence, Inc. of the components used in the ILUVIEN applicator;
- uncertainty associated with our pursuit of reimbursement from local health authorities in certain countries for the recently obtained additional indication for ILUVIEN for prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye (NIU-PS);
- delay in or failure to obtain regulatory and reimbursement of ILUVIEN or any future products or product candidates in additional markets where we do not currently sell ILUVIEN;
- uncertainty associated with our ability to meet any post-market requirements for NIU-PS in the EEA;
- uncertainty associated with our ability to successfully commercialize ILUVIEN following regulatory approval in additional markets; and

Intellectual Property Risks

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

ITEM 1. *BUSINESS*

Overview

Alimera Sciences, Inc., and its subsidiaries (we or Alimera), is a pharmaceutical company that specializes in the commercialization and development of prescription ophthalmic pharmaceuticals. We presently focus on diseases affecting the back of the eye, or retina, because we believe these diseases are not well treated with current therapies and affect millions of people globally.

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

The crisis caused by the COVID-19 pandemic and the measures being taken by governments, health authorities, businesses, and the public at large to limit the COVID-19 pandemic's spread have had, and we expect will continue to have, certain negative effects on, and present certain risks to, our business. We expect these factors to continue to adversely impact our revenue, but the extent and duration of that impact is uncertain at this time. As more and more people in our markets are vaccinated and as governmental restrictions are gradually lifted, however, we look forward to the prospect of a return to more normal conditions later this year and continuing the growth trends we saw prior to the COVID-19 pandemic. (Please refer to "Special Note Regarding Forward-Looking Statements and Projections" above.)

In response to the COVID-19 pandemic, we have implemented measures to mitigate the impact of the pandemic on our financial position and operations. These measures include the following:

- We are continuing to manage our cost structure, minimizing all non-payroll spending where possible to mitigate our anticipated loss of revenue and conserve our cash until the COVID-19 pandemic begins to resolve.
- We have decreased our external spending on commercial and medical affairs activities related to the promotion of ILUVIEN.
- Because we believe that our employees are critical to both (a) serving our customers and patients through alternative forms of engagement as the pandemic-related restrictions continue, and (b) realizing the long-term value of ILUVIEN, we have maintained our staffing levels and do not currently have any plans to reduce them.

For more information about the effect of the COVID-19 pandemic on our business and the related risks we face, please see Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Effects of the COVID-19 Pandemic," and Item 1A, "Risk Factors – Risks Related to the Public Health Pandemic."

ILUVIEN

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

ILUVIEN is inserted into the back of the patient's eye in a non-surgical procedure employing a device with a 25-gauge needle, which allows for a self-sealing wound. We believe that corticosteroids provide the best option in the treatment of DME and NIU-PS because they reduce the inflammatory aspects of the disease. Further, we believe that ILUVIEN's CONTINUOUS MICRODOSING™ delivery makes it the only approved drug therapy for DME that can deliver consistent daily therapeutic levels of corticosteroid. The delivery mechanism of ILUVIEN provides lower daily and aggregate exposure to corticosteroids than any other intraocular dosage forms currently available, which we believe mitigates the typical risks associated with corticosteroid therapy. Further, ILUVIEN, which is non-bioerodible, provides consistent delivery as a result of its constant surface area, permitting elution of FAc to the vitreous. This provides a sustained therapeutic effect on DME and NIU-PS. Other therapies that physicians currently use to treat DME, such as anti-vascular endothelial growth factor (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 or reestablish the therapeutic effect.

ILUVIEN delivers continuous daily sub-microgram levels of FAc in both in vitro and in vivo release kinetic studies for up to 36 months, making it the only single injection therapy available to treat the retina consistently every day for up to three years, to control the recurrence of edema, allowing patients to see better, longer with fewer injections. The delivery mechanism of ILUVIEN provides lower daily and aggregate exposure to corticosteroids than any other intraocular dosage forms currently available for DME in the U.S. and in the other countries in which we have approval. We believe that the lower daily and aggregate exposure to corticosteroids mitigates the typical risks associated with corticosteroid therapy. 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.

The active compound in ILUVIEN is FAc, a non-proprietary corticosteroid that is a member of the class of steroids known as corticosteroids. Corticosteroids have demonstrated a range of pharmacological actions, including inhibition of inflammation, inhibition of leukostasis, up regulation of occludin, inhibition of the release of certain inflammatory cytokines and suppression of VEGF secretion. Leukostasis refers to the accumulation of white blood cells at a particular site, which leads to further tissue damage. Occludin is an important protein in maintaining and reinforcing the tight junctions between cells. These pharmacological actions have the potential to treat various ocular conditions, including DME, NIU-PS, Non-Proliferative Diabetic Retinopathy (NPDR), retinal vein occlusion (RVO), dry age-related macular degeneration (AMD) and wet AMD. However, FAc shares many of the same "class effect" side effects seen with other corticosteroids that are currently available for intraocular use. The two main side effects of using corticosteroids to treat ocular conditions are (a) increased intraocular pressure, which may increase the risk of glaucoma, and (b) the acceleration of cataract formation. FAc is uniquely lipophilic, making it very effective at penetrating retina tissue, and allowing it to achieve a therapeutic effect at a very low dose, typically lower than other corticosteroids.

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 in the countries shown in the following table:

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

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

In December 2017, we filed in the 17 EEA countries in Europe where ILUVIEN is currently approved for the treatment of DME an application for a new indication for ILUVIEN for the prevention of relapse in recurrent NIU-PS. In March 2019, we announced that the U.K.'s National Institute for Health and Care Excellence (NICE), in its Final Appraisal Determination for national reimbursement, had recommended funding for ILUVIEN 190 micrograms intravitreal implant in applicator for the prevention of relapse in recurrent NIU-PS. In addition, ILUVIEN has received marketing authorization in 16 European countries and reimbursement in three countries, Germany, the Netherlands and the U.K., for the prevention of relapse in recurrent NIU-PS.

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

We launched ILUVIEN for the NIU-PS indication in Germany and the U.K. during the third quarter of 2019 and the Netherlands during the fourth quarter of 2020.

Where We Sell Direct

We commercially market ILUVIEN directly in the U.S., Germany, the U.K., Portugal, and Ireland. We are planning to launch directly in the Nordic Region (Denmark, Finland, Norway and Sweden) with the support of an exclusive wholesaler to support tendering processes in hospitals and regions.

Where We Sell Through Distributors

We have entered into various agreements under which distributors are providing or will provide regulatory, reimbursement or sales and marketing support for ILUVIEN in Austria, Belgium, the Czech Republic, France, Italy, Luxembourg, the Netherlands, Spain, Australia, New Zealand, Canada and several countries in the Middle East. We have an extended distribution relationship with our French distributor Horus Pharma to distribute ILUVIEN in Belgium, the Netherlands and Luxembourg. Our Canadian distributor is currently pursuing reimbursement. As of December 31, 2020, we have recognized revenue from sales of ILUVIEN to our international distributors in the Middle East, Austria, France, Italy, Spain and the Netherlands.

Business Strategy

We presently focus on diseases affecting the back of the eye, or retina, because we believe these diseases are not well treated with current therapies and represent a significant market opportunity. Our strategy is to establish ILUVIEN as a leading therapy for DME and NIU-PS patients for which ILUVIEN is proven safe and effective because of its ability to help patients see better, longer with fewer injections for up to three years. We intend to capitalize on our management's experience, the breadth of our commercial resources in both the U.S. and Europe, and to maintain focus on the retinal space to commercialize ILUVIEN. We intend to use those same strengths to acquire, obtain regulatory approval for and commercialize other potential eye care products. To implement our strategy, and taking into account the effects and potential future effects of the COVID-19 pandemic, we intend to:

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

Pursue commercialization of ILUVIEN for treatment of DME in additional countries outside the U.S. and Europe where we have obtained regulatory approval. We have established distribution relationships in Australia, New Zealand, Canada and the Middle East. Our distributor in the Middle East began selling ILUVIEN in 2016 and launched commercial sales in 2019. Our distributor in Canada received regulatory approval in 2018 and is currently pursuing reimbursement in certain provinces of Canada. Our distributor in Australia secured regulatory approval during 2019 but has been unable to achieve reimbursement. Our distributor has chosen to abandon pursuing reimbursement further.

Pursue commercialization of ILUVIEN for NIU-PS in Europe where we have obtained regulatory approval. We are seeking to increase our direct sales in Germany, the Netherlands and the U.K. where we have obtained regulatory approval and are currently marketing ILUVIEN for NIU-PS. We are pursuing opportunities to sell ILUVIEN for NIU-PS in 13 additional European countries, where we have obtained regulatory approval but are not currently marketing ILUVIEN.

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 have the license to use ILUVIEN.

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.

Disease Overview and Market Opportunity

Diabetes and Diabetic Retinopathy

Diabetes mellitus, with its systemic and ophthalmic complications, represents a global public health threat. The International Diabetes Federation (IDF) estimated prevalence of diabetes worldwide in 2017 increased to 425 million people and is expected to increase to 629 million people by 2045.

The 2020 National Diabetes Statistics Reports published by the U.S. Centers for Disease Control and Prevention (CDC) reported that as of 2018, 34.2 million Americans, or 10.3% of the U.S. population, had diabetes and that there were 1.5 million new cases of diabetes diagnosed among people ages 18 and older. Approximately 1 in 5 adults living with diabetes, 7.3 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 88.0 million people have prediabetes, a condition that if not treated often leads to type 2 diabetes within five years. In this population, only 15.3% of adults know they had prediabetes. In the International Diabetes Federation 9th Edition IDF Diabetes Atlas, it is estimated that there are approximately 59.3 million people in Europe in 2019 with diabetes and that 24.2 million remain undiagnosed. In the Middle East, it is estimated there are approximately 23.0 million people with diabetes and 10.0 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 74. 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

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

Studies have shown that DME is a multifactorial disease that is 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 these 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 (DME) 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 (the 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.

Current Treatments for DME

Anti-vascular endothelial growth factor (anti-VEGF) therapies are the current standard of care for the treatment of DME. Lucentis (ranibizumab) and Eylea (aflibercept) are the only approved anti-VEGF therapies marketed for the treatment of vision

loss associated with DME in Europe and for the treatment of DME in the U.S. Off-label injections of the anti-VEGF therapy Avastin (bevacizumab) are also used to treat DME. However, anti-VEGF therapies are acute therapies and are limited by a need for multiple and frequent injections to achieve the same therapeutic effect reported in randomized controlled trials. Further, DME is a multi-factorial disease, and anti-VEGF therapy does not address all of these factors. As a result, many patients either do not achieve a sufficient response or are unable 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. This risk of endophthalmitis is associated with any intravitreal injection. There is evidence that intravitreal anti-VEGF therapy affects systemic VEGF levels, which may have cardiovascular complications.

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 is another short-acting steroid 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, fluocinolone acetonide, or 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 is 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. Visual acuity gains are less frequently seen 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.

Current Treatments for NIU-PS

Historically, the treatment of uveitis varies according to the type and location of uveitis. The inflammation in non-infectious uveitis (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 non-infectious uveitis and for the treatment of non-infectious uveitis.

In contrast, ILUVIEN has specifically been studied to evaluate the prevention of relapse in recurrent NIU-PS. Clinical trials have demonstrated that ILUVIEN significantly extends the time to relapse in patients with recurrent NIU-PS, while at the same time reducing the need for adjunctive treatments, including systemic drug treatment.

Our NEW DAY Study

On July 9, 2020, we announced the initiation of our NEW DAY clinical trial, a multicenter, single masked, randomized and controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its advantages over using the current standard of care of repeat anti-VEGF injections. The NEW DAY Study is planned to enroll 320 treatment-naïve, or almost naïve, DME patients in approximately 42 sites around the U.S. As of February 28, 2021, we have enrolled 19 DME patients. We expect the pace of the enrollment to increase as the COVID-19 pandemic begins to resolve.

We believe that ILUVIEN continues to be underutilized in the treatment of 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 this 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.

Patients who meet the entry criteria will be randomized to receive either an ILUVIEN intravitreal implant or five injections of intravitreal aflibercept 2 mg at four-week intervals for the first 16 weeks as a loading dose. After the initial 16-week period, both 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 NEW DAY 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 study 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.

ILUVIEN for Other Diseases of the Eye

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

ILUVIEN Commercialization Status

Diabetic Macular Edema

ILUVIEN has received marketing authorization for two indications in various countries as noted above in "Overview - Where We Market ILUVIEN to Treat Diabetic Macular Edema (DME)." We plan to pursue regulatory approval for ILUVIEN for the treatment of DME, directly or with a partner, in additional countries.

Uveitis

ILUVIEN has received marketing authorization for treatment of NIU-PS in 15 countries of the EEA, and we plan to pursue our right to seek approval in the Middle East and Africa. Because we do not have the contractual right to pursue approval to treat NIU-PS in the U.S., we do not have marketing authorization in the U.S. We have obtained marketing authorization for ILUVIEN to treat NIU-PS in various countries as noted above in "Overview - Where We Market ILUVIEN to Treat Recurrent Non-Infectious Uveitis Affecting the Posterior Segment of the Eye (NIU-PS)." We will evaluate seeking approval for the treatment of NIU-PS in other countries in Europe, the Middle East and Africa where we have the license to use ILUVIEN.

Sales and Marketing

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

The COVID-19 pandemic has negatively affected our sales and marketing efforts in a number of ways, which has in turn had an adverse impact on our revenues. Governments and private parties have imposed limitations on in-person access to physicians, which have made it difficult or impossible for our sales representatives (including those employed by our distributors) to meet with retina specialists and their staff to educate them about the benefits of ILUVIEN and to provide support for insurance pre-certifications. These limitations have also affected patient access to treatment, given that ILUVIEN is administered only by

an injection into the eye, which means telemedicine is not a viable substitute. Our business is also negatively affected by patient behavior in the current environment. Most of our ILUVIEN sales are driven by the use of ILUVIEN to treat diabetic macular edema, or DME. Given that governmental authorities have cited diabetes as a factor that places a person at higher risk for severe illness from the COVID-19 pandemic, many of those patients are or may be unwilling to visit their physicians in person (even if otherwise permitted) for fear of contracting the COVID-19 coronavirus.

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, the Czech Republic, Italy, Spain, France, Belgium, the Netherlands, Luxembourg, Canada, Australia and New Zealand and in several countries in the Middle East. Pursuant to these agreements, our distributors assisted or will assist us in obtaining and maintaining approval and reimbursement approval, or they will seek approval or reimbursement approval with our oversight in those countries, if such approval or reimbursement approval has not already been obtained.

Manufacturing

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

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

Third party manufacturers are responsible for the commercial-scale production of ILUVIEN. We have agreements with a single third-party manufacturer for each of:

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

Although we may seek alternative providers in the future, we do not currently have alternate providers for any of these tasks. We recently replaced FlexMedical, an affiliate of Flextronics International, Ltd. (Flextronics), with Cadence as described below.

Under our agreement with Alliance, which we entered into in 2010 and amended and restated in 2016, 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 U.S., Canada and Europe 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. Currently, we order 100% of our global requirements for ILUVIEN units from Alliance because we do not have an alternate supplier. Unless terminated earlier in accordance with its provisions, the amended and restated agreement has a remaining term through February 2022 and will automatically renew 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 filing, we have not received a notice of non-renewal that would take effect in February 2022.

Under the Flextronics Agreement dated March 2, 2012, Flextronics agreed to manufacture the component parts of the ILUVIEN applicator (the components) for us. As we reported in a Current Report on Form 8-K dated March 28, 2019, we received notice from Flextronics on that date that it intended to terminate the Flextronics Agreement on September 30, 2020. The Flextronics Agreement terminated in accordance with the notice on September 30, 2020. Before the Flextronics Agreement

expired, Flextronics manufactured a supply of components that has served and is serving as a safety stock until the components can be supplied by Cadence, the replacement manufacturer.

On October 30, 2020, we entered into a Manufacturing Services Agreement with Cadence, Inc., to manufacture the components used in the ILUVIEN applicator. Cadence is in the final stages of process qualification and is expected to begin manufacturing production components during the second quarter of 2021. We have filed with European Regulatory Agencies for the necessary approvals needed for Cadence to manufacture components to be used in ILUVIEN sold in Europe, and we anticipate receiving European approval in April 2021. We will be filing a Prior Approval Supplement (PAS) with the FDA in the next one-to-two months. We believe we have sufficient safety stock produced by Flextronics to meet the anticipated demand of our distributors and end users until FDA approval is obtained and throughout 2021. Until the transition to Cadence is complete, however, there can be no assurances that Cadence will manufacture the components in a timely and otherwise acceptable manner. Significant disruption in this transition, or unanticipated costs related to the transition, could materially and adversely affect our business, financial condition and cash flows, and results of operations.

Business Segments

Our business has a U.S. segment and an International segment, and we report Other to reconcile to consolidated totals. You can find financial information about our business segments below in (a) Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Segment Review” and (b) Note 19 of the accompanying consolidated financial statements.

Customers

Our revenues for the fiscal years ended December 31, 2020 and 2019 were generated from product sales primarily in the U.S., Germany, France and the U.K. In the U.S., two large pharmaceutical distributors accounted for 49% and 60% of our consolidated revenues for the years ended December 31, 2020 and 2019, respectively. These distributors maintain inventories of ILUVIEN and sell to physician offices, pharmacies and hospitals. Internationally, in countries where we sell direct, our customers are hospitals, clinics and pharmacies. We sometimes refer to physician offices, pharmacies, hospitals and clinics as end users. In international countries where we sell to distributors, these distributors maintain inventory levels of ILUVIEN and sell to their customers.

Competition

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

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

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

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

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

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

Humira© (adlimumab), 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 non-infectious uveitis. 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.

Beovu®(brolucizumab-dbll), marketed by Novartis, is a VEGF inhibitor indicated for the treatment of neovascular wet AMD. Beovu is the first FDA approved anti-VEGF to offer both greater fluid resolution versus aflibercept and the ability to maintain eligible wet AMD patients on a three-month dosing interval immediately after a three-month loading phase with uncompromised efficacy. Beovu is also approved by the European commission for the treatment of wet AMD in all 27 European Union member states as well as the U.K., Iceland, Norway and Liechtenstein. Novartis has completed trials for the treatment of DME and is in the process of preparing a submission to the FDA in 2021.

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

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

In addition, a number of other companies, including Ampio Pharmaceuticals, Aerie Pharmaceuticals, Allegro Opthalmics, and Clearside Biomedical are developing drug therapies or sustained delivery platforms for the treatment of retinal diseases.

We believe we will be less likely to face a generic competitor for ILUVIEN for the treatment of DME because of the bioequivalency requirements of a generic form of ILUVIEN. A generic pharmaceutical competitor to ILUVIEN would need to establish bioequivalency through the demonstration of an equivalent pharmacodynamic endpoint in a clinical trial. We believe conducting such a clinical trial would be cost-prohibitive and time-consuming, although we cannot provide any assurances in that regard.

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

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

Licenses and Agreements

EyePoint Pharmaceuticals US, Inc.

In 2005, we entered into an agreement with EyePoint Pharmaceuticals US, Inc. (EyePoint), formerly known as pSivida US, Inc., for the use of FAc in EyePoint's proprietary insert technology. In July 2017, we amended and restated the EyePoint agreement in the Second Amended and Restated Collaboration Agreement (New Collaboration Agreement). The New Collaboration Agreement provides us with a license to utilize certain underlying technology used in the development and commercialization of ILUVIEN. Before entering into the New Collaboration Agreement, we held 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. The New Collaboration Agreement expands the license to include uveitis, including NIU-PS, in Europe, the Middle East and Africa.

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

of the eye, (b) to deliver any compound outside the back of the eye unless it is to treat DME through an incision required for a 25-gauge or larger needle, or (c) to deliver non-corticosteroids to the back of the eye, unless it is to treat DME through an incision required for a 25-gauge or larger needle.

Before we entered into the New Collaboration Agreement, we were required to share 20% of our net profits on a country-by-country basis. We were permitted to offset up to 20% of this amount with our commercialization costs incurred during unprofitable calendar quarters in each country. The New Collaboration Agreement converts this profit share obligation to a royalty payable on global net revenues of ILUVIEN. We began paying a 2% royalty on net revenues and other related consideration to EyePoint effective July 1, 2017. This royalty amount increased to 6% effective December 12, 2018. We will pay an additional 2% royalty on global net revenues and other related consideration in excess of $75.0 million in any year. During 2020, we recognized approximately $2.1 million of royalty expense. During 2019, we recognized approximately $2.2 million of royalty expense.

Following the signing of the New Collaboration Agreement, we retained a right to offset $15.0 million of future royalty payments (the Future Offset). In accordance with the terms of the New Collaboration Agreement, this offset was reduced by $5.0 million when we obtained regulatory approval in the U.K. in March 2019 for the use of ILUVIEN to treat NIU-PS. As of December 31, 2020, the balance of the Future Offset was approximately $7.9 million.

Our license rights to EyePoint's proprietary insert technology could revert to EyePoint if we were to:

(a) fail twice to cure our breach of an obligation to make certain payments to EyePoint following receipt of written notice of the breach;

(b) fail to cure other breaches of material terms of our agreement with EyePoint 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;

(c) 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 our property, file a petition under any bankruptcy or insolvency act or have any such petition filed against us and such proceeding remains undismissed or unstayed for a period of more than 60 days; or

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

On December 17, 2020, EyePoint and its parent, EyePoint Pharmaceuticals, Inc., entered into a royalty purchase agreement (the "SWK Agreement") with SWK Funding, LLC ("SWK"). In its Current Report on Form 8-K filed on December 18, 2020, EyePoint Pharmaceuticals, Inc. stated that pursuant to the SWK Agreement, EyePoint Pharmaceuticals, Inc. sold its interest in royalties that we are obligated to pay EyePoint under the New Collaboration Agreement. EyePoint Pharmaceuticals, Inc. 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 we are obligated to pay to EyePoint under the New Collaboration Agreement. We are not a party to the SWK Agreement.

As noted above, we have from time to time amended our license agreement with EyePoint, and we may again seek to do so in the future if the need arises. We believe that given the terms of the SWK Agreement, however, it could be more difficult for us to agree with EyePoint on an amendment to the New Collaboration Agreement, because SWK must consent to any amendment that could reasonably be expected to adversely affect the amount of the royalty payments that EyePoint 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.

We are not in breach of the New Collaboration Agreement with EyePoint as of the date of this filing.

Government Regulation

General Overview

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

U.S.

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 $325,000 as of our last renewal in October 2020.

Post-Marketing Requirements

We are required to meet post-marketing safety surveillance requirements to continue marketing an approved product. We must report any adverse events with the product to the FDA, and the FDA could impose market restrictions through labeling changes or in product removal. The FDA may withdraw product approvals if we fail to maintain compliance with regulatory requirements or if problems concerning safety and/or efficacy of the product occur following approval. The FDA may, at its discretion, also require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. The FDA did not require any post-marketing testing as part of its approval of ILUVIEN.

As part of the approval process in Europe, we committed to conduct a five-year, post-authorization, open label registry study in 800 patients treated with ILUVIEN. Due to our post market safety surveillance not showing any unexpected safety signals, we requested and received approval to modify our protocol to cap enrollment in the study. Enrollment was completed with 562 patients. The study was completed in 2020 and the results were submitted to regulatory authorities, fulfilling our post-marketing commitment. The results of the study confirmed existing safety information on ILUVIEN, and no new risks were identified.

Also, as part of the approval process in Europe, we are committed to conduct an open label trial in the pediatric population with NIU-PS. We have initiated this trial and enrollment will start shortly provided that the COVID-19 pandemic does not interfere with our ability to execute the study.

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, a requirement that future advertising and promotional materials must be pre-cleared by the FDA, and (d) federal civil and criminal investigations and prosecutions (as well as state prosecutions).

The manufacturing facility that produces our product, as well as our corporate headquarters facility, must maintain compliance with the FDA’s current Good Manufacturing Practices (cGMP) and is 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). The decentralized procedure provides for applications to be submitted for marketing authorization in a select number of EU 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 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, we may need to submit our application to a country within the EU if we seek to obtain an additional indication or an expanded indication for ILUVIEN in the EU.

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. We cannot predict the changes that the new Biden Administration may make to current federal reimbursement policies under this law and whether those changes will affect 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.

In many foreign markets, including the countries in the EEA, pricing of pharmaceutical products is subject to governmental control. In the U.S., there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing 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.

For a summary of the countries where we have received reimbursement, see Item 1, “Business – Overview – Where We Market ILUVIEN to Treat Diabetic Macular Edema (DME)” and “ – Where We Market ILUVIEN to Treat Recurrent Non-Infectious Uveitis Affecting the Posterior Segment of the Eye (NIU-PS).”

Patents and Proprietary Rights

Our success depends in part on our 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, 2020, we owned or licensed two U.S. utility patents and one U.S. design patent as well as numerous foreign counterparts to many of these patents and patent applications relating to ILUVIEN or the ILUVIEN applicator. We licensed our one utility patent right relating to ILUVIEN from EyePoint. Pursuant to our agreement with EyePoint, our ILUVIEN-related patent rights are only for diseases of the human eye in Europe, the Middle East and Africa, and for diseases of the human eye excluding uveitis in the rest of the world. In addition to the U.S. patents licensed from EyePoint, we also license two European patents from EyePoint. We have a U.S. utility patent directed to our applicator system for ILUVIEN. Our licensed patent portfolio includes U.S. patents (with no currently pending or issued corresponding European applications or patents) with claims directed to methods for administering a corticosteroid with an implantable sustained delivery device to deliver the corticosteroid to the vitreous of the eye wherein aqueous corticosteroid concentration is less than vitreous corticosteroid concentration during release.

U.S. utility patents generally have a term of 20 years from the date of filing. The utility patent rights relating to ILUVIEN that EyePoint licensed to us include five U.S. patents that expired between April 2020 and June 2020, one U.S. patent that will expire August 2027, two European patents that are directed to our low-dose device that expire in April 2021 and 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.

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 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 $1.3 million and $368,000 in research and development during 2020 and 2019, respectively.

Employees

As of February 1, 2021, we had 140 employees, 130 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 6120 Windward Parkway, Suite 290, 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.

Available Information

We file annual, quarterly and current reports, proxy statements, and other documents with the Securities and Exchange Commission (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.

Risks Related to the COVID-19 Pandemic

The COVID-19 pandemic has had, and we expect will continue to have, adverse effects on our business, results of operations, financial condition and cash flows.

The public health crisis caused by the COVID-19 pandemic and the measures being taken by governments, health authorities, businesses, and the public at large to limit the COVID-19 pandemic's spread have had, and we expect will continue to have, certain negative effects on, and present certain risks to, our business that include the following:

- Governments and private parties have imposed limitations on in-person access to physicians, which have:
  - affected patient access to treatment, given that ILUVIEN is administered only by an injection into the eye, which means telemedicine is not a viable substitute; and
  - made it difficult or impossible for our sales representatives (including those employed by our distributors) to meet with retina specialists and their staff to educate them about the benefits of ILUVIEN and to provide support for insurance pre-certifications.
- Our business is also negatively affected by patient behavior in the current environment. Most of our ILUVIEN sales are driven by the use of ILUVIEN to treat diabetic macular edema, or DME. Given that governmental authorities have cited diabetes as a factor that places a person at higher risk for severe illness from the COVID-19 pandemic, many of those patients are or may be unwilling to visit their physicians in person (even if otherwise permitted) for fear of contracting the COVID-19 coronavirus.

These limitations had an adverse impact on our revenues beginning late in the first quarter and continuing through the date of this report. We expect these factors to continue to adversely impact our revenue, and the extent and duration of that impact is uncertain at this time, particularly in light of the emergence of COVID-19 variants that may increase the transmissibility of the coronavirus or be more deadly, or both. If the COVID-19 pandemic intensifies (as is currently the case in most of the U.S. and Europe and the U.K.), its duration is longer than we expect, or the coronavirus becomes transmissible at a greater rate or becomes more deadly, its negative effect on our sales and thus our liquidity and financial condition could be more prolonged and may be severe. Financial uncertainty associated with the adverse effects of the COVID-19 pandemic, and the duration and severity of those effects, could affect certain estimates we use to prepare our quarterly financial results, including impairment of intangible assets, the income tax provision and recoverability of certain receivables.

Other effects or possible effects of the COVID-19 pandemic on us include:

- Limitations on travel within and between the countries in which we market and sell ILUVIEN, as well as various types of "shelter in place" orders, have curtailed our in-person marketing activities, which have in turn contributed to lower sales of ILUVIEN.
- Cancellation of in-person trade shows, medical congresses and similar events which have affected our ability to market the product as we had in the past.
- As a result of the COVID-19 pandemic, including related governmental guidance or directives, we required almost all office-based employees, including almost all employees based at our headquarters in Georgia, to work remotely for some or all of the second quarter of 2020. While most of our personnel in our headquarters have returned to work in the office, we may in the future experience reductions in productivity and disruptions to our business routines if remote work requirements are reinstated in Georgia or we voluntarily decide to direct our employees to work remotely. Governmental directives continue to affect the ability of non-U.S. office-based personnel to return to full-time work in the office.
- We may fail to maintain or modify as necessary our internal controls over financial reporting in an environment in which (a) many of our employees are working remotely and (b) we or our distributors have been and may be required to modify our standard business processes to take into account the current environment in light of the pandemic. If we fail to maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

- We may fail to plan appropriately to meet the demand of our customers for ILUVIEN, which could lead either to (a) ILUVIEN being out of stock or (b) our investment of a greater amount of cash in inventory than we need. Either event could have an adverse effect on our results of operations, financial condition and cash flows.
- As a result of lower sales of ILUVIEN due to the COVID-19 pandemic, we may fail to comply with financial covenants in the 2019 Solar Loan Agreement. If an event of default under the 2019 Solar Loan Agreement occurs, Solar Capital may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to raise additional financing, renegotiate the 2019 Solar Loan Agreement on terms less favorable to us or immediately cease operations. Any declaration by Solar Capital of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline significantly after we publicly disclose that event in an SEC filing. Further, if we were liquidated, Solar Capital's right to repayment would be senior to the rights of our stockholders.
- We have four third-party manufacturers in our supply chain, each of which performs an essential task in the manufacture and testing of ILUVIEN. We do not currently have alternate providers for any of these tasks. If workers at one or more of these facilities become ill or are quarantined and in either or both events are therefore unable to work, our manufacturing operations have been and could again be subject to disruption. Further, if our manufacturers become unable to obtain necessary raw materials or components, we may incur higher supply costs or our manufacturers may be required to reduce production levels, either of which could negatively affect our financial condition or results of operations.

Risks Related to Our Business, Including Our Dependence on ILUVIEN

Our business depends on our only product, ILUVIEN.

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

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

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

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

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

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

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

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

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

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

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

We depend on the principal members of our management team, including Richard S. Eiswirth, Jr., our President and Chief Executive Officer, Philip Ashman, Ph.D., our Chief Operating Officer and Senior Vice President Commercial Operations Europe, J. Philip Jones, our Chief Financial Officer, and David Holland, our Chief Marketing Officer and Senior Vice President Corporate Communications and Managed Markets. These executives have significant ophthalmic, regulatory industry, sales and marketing, operational and/or corporate finance experience. The loss of any such executives or any other principal member of our management team may impair our ability to identify, develop and market ILUVIEN and any future ophthalmic products or product candidates.

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

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

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

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 size, cash resources and greater development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable products or product candidates include the following:

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

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

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

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

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

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

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

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

While we have not experienced any such cyber-related fraud, system failure, accident or security breach to date 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.

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

In addition, the loss of clinical trial data for our product candidates or our post-market studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions or security breaches of our internal information technology systems or our vendors' technology systems could adversely affect or result in the loss of, misappropriation of, unauthorized access to, use of, disclosure of or the prevention of access to our confidential information, including trade secrets or other intellectual property, proprietary business information and personal information of our employees and patients in studies conducted on our behalf, which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access to, use of or disclosure of personal information, including personal information regarding our employees or information we may have regarding patients, could harm our reputation directly, compel us to comply with federal and state breach notification laws and foreign law equivalents, subject us to mandatory corrective action and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

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

We anticipate that in the near term our ability to generate revenues will depend almost entirely on our ability to continue the successful commercialization of ILUVIEN, both in the U.S. and abroad. We launched ILUVIEN in Germany and the U.K. in 2013; in the U.S. and Portugal in 2015; in Ireland and Austria in 2017; in the Middle East, Italy and Spain in 2018; in France in

2019; and in the Netherlands in 2020. A commercial launch of ILUVIEN is a significant undertaking that requires substantial financial and managerial resources. As of February 1, 2021, we had 140 employees. 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 products include:

- our inability to recruit and retain adequate numbers of effective personnel;
- the departure of our employees to work for a competitor;
- the inability of sales personnel to obtain access to or persuade adequate numbers of ophthalmologists to prescribe our products;
- the lack of complementary products or additional labeled indications for ILUVIEN to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating a commercial organization.

If we are not successful in recruiting and retaining sales and marketing personnel or in maintaining our sales and marketing infrastructure or if we do not successfully enter into additional collaboration arrangements with third parties, we will have difficulty commercializing ILUVIEN or any future products or product candidates, which would adversely affect our business, operating results and financial condition. As an indication of the risks we face, in the first six months of 2019 our revenues in the U.S. market were negatively affected by a competitor's hiring some of our key sales personnel.

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

The NEW DAY Study may fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early diabetic macular edema (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 in the early stages of conducting our NEW DAY clinical trial, 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 (afilbercept) injections. The NEW DAY Study is planned to enroll approximately 300 treatment-naïve, or almost naïve, DME patients in approximately 42 sites around the U.S. The NEW DAY Study may (a) fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early diabetic macular edema (DME), (b) fail to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, (c) take longer or be more costly to complete than we currently anticipate, and (d) fail to change physician prescribing practices despite a successful result. The occurrence of any of these events could materially and adversely affect our business, financial condition and cash flows, and results of operations.

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

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing ILUVIEN-based business, including adding new products in the ophthalmic field. 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. We cannot assure that, following an acquisition, we will achieve the revenues or specific net income that justifies the acquisition.

The U.K.'s leaving the EU, or "Brexit," could have a material adverse effect on us.

On June 23, 2016, the U.K. held a referendum and voted in favor of leaving the European Union (Brexit). The U.K. formally left the EU on January 31, 2020, subject to a transition period that ended on December 31, 2020. The process of preparing for Brexit has created political and economic uncertainty, particularly in the U.K. and the EEA, and this uncertainty may last for years, even though the U.K. has now left the EU. Our business in the U.K., the EEA and in other parts of the world could be adversely affected by Brexit in many ways, only some of which we can identify.

Because the regulatory framework for pharmaceutical products in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the U.K. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the U.K. These possible negative impacts, and others resulting from the U.K.'s withdrawal from the EU, may adversely affect our operating results and growth prospects as well as the manner in which we conduct our business operations in Europe.

We currently operate in Europe through two subsidiary companies, one based in the U.K. and the other based in the Republic of Ireland. The two subsidiary companies work very closely to cover our operations in Europe as a whole, which provides us with certain operational and other benefits when conducting business in the EEA. Nevertheless, the U.K.'s withdrawal from the EU could adversely affect our ability to realize those benefits, and we may incur costs and suffer disruptions in our European operations as a result, including changing our base of operations or part of our operations from the U.K. to another country in the EEA.

Brexit may continue to cause significant volatility in global financial markets, including in global currency and debt markets. This volatility could cause a slowdown in economic activity in the U.K., Europe or globally, which could adversely affect our operating results and growth prospects. Our business could be negatively affected by new trade agreements between the U.K. and other countries, including the U.S., and by the possible imposition of trade or other regulatory barriers in the U.K. These possible negative impacts, and others resulting from the U.K.'s withdrawal from the EU, may adversely affect our operating results and growth prospects.

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

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

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

- extended collection timelines for accounts receivable and greater working capital requirements;
- multiple legal systems and unexpected changes in legal requirements;
- tariffs, export restrictions, trade barriers and other regulatory or contractual limitations on our ability to sell or develop our products in certain foreign markets;
- 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;
- political instability, including war and terrorism or the threat of war and terrorism; and
- adverse economic conditions, including 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.

We rely on third parties for several important aspects of our business.

We rely heavily upon our third-party contractors, suppliers and distributors. Especially during challenging and uncertain times like the present, there may be disruptions or delays in the performance of these third parties. We rely entirely on third parties to manufacture, assemble and test our ILUVIEN applicators, as described in the following section. We also rely on distributors for a majority of our sales of ILUVIEN. We sell to two large pharmaceutical distributors in the U.S., which accounted for 49% of our consolidated revenues in 2020. Internationally, our distributors produced approximately 37% of our international sales in 2020. If one or more of our key third-party contractors, suppliers and distributors are unable to satisfy their commitments to us, our business and results of operations could be adversely affected.

MANUFACTURING RISKS

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

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

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

If any of these third-party manufacturers (a) breaches its agreement, (b) is unable to meet its contractual or quality requirements or (c) becomes unwilling to perform for any reason, we may be unable, or may be unable in a timely manner, to locate alternative acceptable manufacturers or testing facilities, as applicable, enter into favorable agreements with them and ensure that they are approved by the applicable regulatory authorities, such as the U.S. Food and Drug Administration (FDA). Further, all of our manufacturers rely on additional third parties for the manufacture of component parts. Any inability to acquire sufficient quantities of the active pharmaceutical ingredient, the ILUVIEN implants or the ILUVIEN applicator in a timely manner from these third parties could delay commercial production of ILUVIEN and adversely affect our ability to fulfill demand for ILUVIEN, which could in turn adversely affect our revenue, operations and cash flow.

In the first quarter of 2020, we were unable to obtain a sufficient number of ILUVIEN units to meet end user demand in the ordinary course of business (a stock-out) due to greater than anticipated demand in the fourth quarter of 2019 and an equipment issue within our third-party manufacturing facility. Although we rectified the equipment issue, any recurrence, for whatever reason, could have a material adverse effect on our revenues, reputation and relationships with our distributors and end users.

Our third-party manufacturing partners have been stressed by the COVID-19 pandemic. These difficulties stem from lockdown regulations that can affect the ability of staff to get to work and also the difficulties employing replacement staff to cover attrition. In a situation where manufacturing requires training and expertise, such as with ILUVIEN, the potential loss of trained personnel is a risk to manufacturing that is made worse during the pandemic.

We may fail to effect the transition of the manufacturing of essential component parts of our ILUVIEN applicator by our new contract manufacturer before we exhaust our current inventory of those parts.

Under the Flextronics Agreement dated March 2, 2012, Flextronics agreed to manufacture the component parts of the ILUVIEN applicator (the components) for us. As we reported in a Current Report on Form 8-K dated March 28, 2019, we received notice from Flextronics on that date that it intended to terminate the Flextronics Agreement on September 30, 2020. The Flextronics Agreement terminated in accordance with the notice on September 30, 2020. Before the Flextronics Agreement expired, Flextronics manufactured a supply of components that has served and is serving as a safety stock until the components can be supplied by the replacement manufacturer.

On October 30, 2020, we entered into a Manufacturing Services Agreement with Cadence, Inc., to manufacture the components used in the ILUVIEN applicator. Cadence is in the final stages of process qualification and is expected to begin manufacturing production components during the second quarter of 2021. We have filed with European Regulatory Agencies for the necessary approvals needed for Cadence to manufacture components to be used in ILUVIEN sold in Europe, and we anticipate receiving European approval in April 2021. We will be filing a Prior Approval Supplement (PAS) with the FDA in the next one-to-two months. We believe we have sufficient safety stock produced by Flextronics to meet the anticipated demand of our distributors and end users until FDA approval is obtained and throughout 2021. Until the transition to Cadence is complete, however, there can be no assurances that Cadence will manufacture the components in a timely and otherwise acceptable manner.

Significant disruption in this transition, or unanticipated costs related to the transition, could materially and adversely affect our business, financial condition and cash flows, and results of operations.

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

We rely on our manufacturers to purchase materials from third-party suppliers necessary to produce ILUVIEN. Suppliers may not sell these materials to our manufacturers when needed or on commercially reasonable terms. We do not have any control over the process or timing of our manufacturers' acquisition of these materials. If our manufacturers are unable to obtain these materials in sufficient amounts, our sales of ILUVIEN would be hampered or there would be a shortage in supply, which would materially affect our ability to generate the revenues from the sale of ILUVIEN that we expect. Moreover, although we have agreements with our suppliers for the supply of the active pharmaceutical ingredient in ILUVIEN, the commercial production of the ILUVIEN implant and the commercial production of the ILUVIEN applicator, the suppliers may be unable to meet their contractual or quality requirements or choose not to supply us in a timely manner or in the minimum guaranteed quantities. If our manufacturers are unable to obtain these essential supplies, their ability to manufacture ILUVIEN and thus our supply of ILUVIEN for sale would be delayed, which could significantly reduce our sales of ILUVIEN and have an adverse impact on our business.

Financial Risks

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

As of December 31, 2020, we had approximately $11.2 million in cash and cash equivalents. Whether this amount will be sufficient to fund our operations and support our growth will be determined by many factors, some of which are beyond our control, and we may need additional capital to fund our operations and support our growth sooner than we might anticipate. These factors include:

- the level of continued success of the commercialization of ILUVIEN in the U.S., and in our international markets,
- expenses relating to the commercialization of ILUVIEN;
- our research, development and general and administrative expenses;
- the timing of approvals, if any, of ILUVIEN for additional indications or in additional jurisdictions;
- the extent to which we enter into, maintain and derive revenues from licensing agreements, including agreements to license ILUVIEN in additional countries or regions; research and other collaborations; joint ventures; and other business arrangements;
- the extent to which we acquire, and our success in integrating, technologies or companies;
- regulatory changes and technological developments in our markets; 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 (a) we may be unable to do so on commercially reasonable terms, (b) the terms on which we obtain the capital may restrict our operations and (c) 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. In addition, our ability to raise additional capital may depend upon obtaining stockholder approval. There can be no assurance that we will be able to obtain stockholder approval for a capital raise if it is necessary under applicable Nasdaq rules that require capital raises over a certain size to be approved by stockholders. 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.

If we raise additional funds by selling shares of our capital stock, the ownership interest of our current stockholders will be diluted. 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 Solar Capital would permit such debt, which would be subordinated to the debt outstanding under the 2019 Solar Loan Agreement), 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.

The terms of the 2019 Solar Loan Agreement require us to meet certain operating covenants and restrict our operating and financial flexibility.

The 2019 Solar Loan Agreement contains certain operating covenants and restricts our operating and financial flexibility. The 2019 Solar Loan Agreement is secured by a lien covering all of our U.S. assets (and certain ownership interests in one of our foreign subsidiaries), other than our intellectual property. The 2019 Solar 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 Solar Loan Agreement occurs, Solar Capital may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to raise additional financing, renegotiate the 2019 Solar Loan Agreement on terms less favorable to us or immediately cease operations. Any declaration by Solar Capital of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline significantly after we publicly disclose that event. Further, if we are liquidated, Solar Capital's right to repayment would be senior to the rights of our stockholders.

We have incurred operating losses in each year since our inception and expect to continue to incur losses in 2021.

To date we have incurred recurring losses and negative cash flow from operations, and we have accumulated a deficit of $392.9 million from our inception through December 31, 2020. Our ability to achieve profitability and positive cash flow depends on our ability to maintain revenue and contain our expenses. We are uncertain if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to maintain and increase revenue and achieve profitability depends on our ability to continue to successfully market and sell ILUVIEN in the geographic areas where we or our distributors offer ILUVIEN. We cannot assure you that we will be profitable even if we successfully commercialize ILUVIEN or future products or product candidates. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

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

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. In that regard, the audit report issued by our independent registered public accounting firm for the audit of our 2020 financial statements includes an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern.

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

Our quarterly operating results and cash flows may 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 effects of the COVID-19 pandemic as described above;
- the ongoing commercial success of ILUVIEN (or lack thereof);
- inconsistent timing and ordering patterns from our U.S. distributors;
- seasonality caused by insurance renewals for patients in the U.S. and by doctor and or patient absences due to holidays and vacations;
- sales, marketing and medical affairs expenses;
- the timing and amount of royalties, milestone payments or product purchases by our distributors;
- our ability to obtain regulatory approval of ILUVIEN in additional jurisdictions or for additional indications;
- regulatory developments affecting ILUVIEN, our future product candidates or our competitors' products;
- the emergence of products or treatments that compete with ILUVIEN;
- variations in the level of expenses related to our products or future development programs;
- the status of our clinical development programs;
- our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- any lawsuit or intellectual property infringement in which we are or may become involved; and
- the timing and recognition of stock-based compensation expense.

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.

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

Approximately 51% of our net revenues in 2020 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.

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

As of December 31, 2020, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately $131.4 million and $96.2 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 2020 and 2040. Under the Tax Cuts and Jobs Act of 2017, U.S. federal NOLs and some state NOLs generated after 2017 will carry forward indefinitely. These NOLs may be subject to further limitation based upon the final results of our Internal Revenue Code sections 382 and 383 analyses. Sections 382 and 383 of the Internal Revenue Code limit the annual use of NOL carry-forwards and tax credit carry-forwards, respectively, following an ownership change. NOL carry-forwards may be subject to annual limitations under Section 382 (or comparable provisions of state law) if certain changes in ownership of our company were to occur. In general, an ownership change occurs for purposes of Section 382 if there is a more than 50% change in ownership of a company over a 3-year testing period. We have determined that a Section 382 change in ownership occurred in December of 2015. As a result of this change in ownership, we estimated that approximately $18.6 million of our federal NOLs and approximately $382,000 of federal tax credits generated prior to the change in ownership will not be utilized in the future. We are currently in the process of refining and finalizing these calculations, and upon finalization, will determine if a write-off is necessary. The reduction to our NOL deferred tax asset due to the annual Section 382 limitation and the NOL carryforward period would result in an offsetting reduction in valuation allowance recorded against the NOL deferred tax asset. Therefore, the limitation does not affect the statements of operations for the periods presented. Any future changes in our ownership or sale of our stock could further limit the use of our NOLs in the future. If we need to obtain alternative or additional financing to meet our liquidity requirements under the 2019 Solar Loan Agreement and we raise those funds by selling additional equity, this could further limit the use of our NOLs in the future.

The term loan under the 2019 Solar Loan Agreement matures on July 1, 2024, and our interest rate is based on LIBOR. As a result, we are exposed to the risks associated with the planned discontinuation of LIBOR before that date.

The term loan under the 2019 Solar Loan Agreement matures on July 1, 2024, and our interest rate is based on LIBOR. The U.K. Financial Conduct Authority (the authority that regulates LIBOR) has announced its intention to phase out the use of LIBOR by the end of 2021. On November 30, 2020, however, the Intercontinental Exchange, Inc. (ICE) announced that the ICE Benchmark Administration Limited, a wholly owned subsidiary of ICE and the administrator of LIBOR, announced its plan to extend the date that most U.S. LIBOR values would cease being computed and announced from December 31, 2021 to June 30, 2023. This announcement is viewed as an effective extension of the end of USD LIBOR. It is unclear if after this date LIBOR will cease to exist or if new methods of calculating LIBOR will be established such that it continues to exist. It is also unclear whether the COVID-19 pandemic will have further effect on LIBOR transition plans. We have exposure to LIBOR, including in the 2019 Solar Loan Agreement, which includes fallback language that seeks to facilitate an agreement with our lenders on a replacement rate for LIBOR in the event of its discontinuance. We cannot predict what reference rate would be agreed upon or what the impact of any such replacement rate would be to our interest expense, but such changes could result in increased interest expense related to the 2019 Solar Loan Agreement, and increased borrowing costs in the future. Although the impact is uncertain at this time, the elimination of LIBOR could have an adverse impact on our business, results of operations, or financial condition.

We may not be entitled to forgiveness of our PPP Loan.

On April 22, 2020, we received an approximately $1,778,000 loan (the PPP Loan) under the Paycheck Protection Program established by the U.S. Small Business Administration (the SBA). The PPP Loan is unsecured and is evidenced by a note (the Note) in favor of HSBC Bank USA, National Association (HSBC) as the lender. The Note has a two-year term. The Paycheck Protection Program provides for forgiveness of up to the full amount borrowed as long as we use the loan proceeds during the 24-week period following disbursement for eligible purposes as described in the CARES Act and related guidance. Under the

CARES Act, loan forgiveness is generally available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the 24-week period. We used all of the proceeds from the PPP Loan to pay expenses during the applicable period that we believe were for eligible purposes. On July 21, 2020, we submitted an application to HSBC for forgiveness of the PPP Loan. As of the date of this filing, the application for forgiveness is still pending review.

Under the revised rules for the PPP Loan program, we will not have to begin principal and interest payments before the date on which the SBA remits the loan forgiveness amount to HSBC (or notifies HSBC that no loan forgiveness is allowed). If no loan forgiveness is allowed, the Company will be required to pay HSBC equal monthly payments of principal and interest based on the principal amount outstanding on the PPP Loan, plus interest outstanding at the end of the deferment period, and taking into account any reductions in the principal amount due to forgiveness, if any. We cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP Loan will ultimately be forgiven by the SBA.

Regulatory Risks

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

Regulatory agencies generally approve products for particular indications, or the conditions that make a particular treatment or procedure advisable. If a regulatory agency approves ILUVIEN for only a limited indication, the size of our potential market for ILUVIEN will be reduced. ILUVIEN has received marketing authorization in numerous countries in the EEA and elsewhere in the world for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. In the U.S., Australia, Canada, Kuwait, Lebanon and the United Arab Emirates, the indication for ILUVIEN is different, as ILUVIEN is indicated for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. Either of these indications or future indications may limit the use of ILUVIEN to a narrower segment of the DME population than we believe is warranted. As a result, our potential revenues are now and may be in the future less that they would be with broader indications for ILUVIEN.

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

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

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

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

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

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

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

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

In the U.S., the Medicare and Medicaid programs currently provide reimbursement for ILUVIEN, but the reimbursement amount for ILUVIEN could be modified in the future, and the types of patients for whom ILUVIEN is reimbursed could be reduced to a smaller subset of patients. In addition, in some states, Medicare reimburses physicians for less than the cost of ILUVIEN. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the U.S. healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. As already noted, the new presidential administration may seek further reform of the Medicare program and the U.S. healthcare system. Some of these changes and reforms could result in reduced reimbursement rates for ILUVIEN and our future product candidates, which would adversely affect our business strategy, operations and financial results. Our business could also be adversely affected if retinal specialists are not reimbursed for the cost of the procedure in which they administer ILUVIEN at a level that is satisfactory to them. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Our business could be materially adversely affected if the Federal Medicare program, or local Medicare carriers (MACS) or fiscal intermediaries were to make such a determination and deny or limit the reimbursement of ILUVIEN. If the local contractors that administer the Medicare program are slow to reimburse retinal specialists for ILUVIEN, that delay could ultimately affect the timing of payments to us, which would in turn adversely affect our working capital.

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

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

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

In the EEA and the U.K., each country has a different reviewing body that evaluates reimbursement dossiers submitted by marketing authorization holders of new drugs and then makes recommendations as to whether or not the drug should be reimbursed. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval. For example, in February 2017 we announced that the Italian government had published a change in the reimbursement status of ILUVIEN, allowing ILUVIEN to be hospital-administered and that ILUVIEN should be fully reimbursed for pseudophakic patients. The negotiation for this reimbursement change took more than 15 months. 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. For example, in 2019 we gained pricing approval in France that is lower than our current established price in Portugal. Subsequently, the Portuguese government reduced the published price for ILUVIEN. Such 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 (a) limit the indications for reimbursement approval to a smaller subset than we believe ILUVIEN is effective in treating or (b) 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.

Regulatory approval for any approved product is limited by the regulatory authorities to those specific indications for which clinical safety and efficacy have been demonstrated.

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. In

addition to approval required for new formulations, any new indication for an approved product also requires regulatory approval. If we are unable to obtain regulatory approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our opportunity for future growth could be limited.

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.

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

ILUVIEN has received marketing authorization in the U.S., in numerous countries in Europe and in other places in the world as described above in "Business – Overview." We sell ILUVIEN directly in the U.S., Germany, the U.K., Portugal and Ireland and expect to launch directly into Denmark, Finland, Norway and Sweden in 2021. Our distributors will continue to sell ILUVIEN in the Middle East, Austria, France, the Netherlands, Italy and Spain in 2021, and we expect further progress to be made towards the launch through distributors in the Czech Republic, Belgium and Luxembourg in 2021. When we received marketing authorization in the remaining countries in the EEA, those marketing authorizations required that we sell at least one ILUVIEN in those countries within three years or our license in those countries could be revoked unless we negotiate to extend the deadline. We intend to either sell one ILUVIEN in each of those countries or negotiate to extend the deadline, but we may not be able to make such a sale or extend the deadline, in which case our license in that country could be revoked. If our license in any of these countries is revoked, we will need to pursue marketing authorization again for that country, and we may be unsuccessful in that effort.

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

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

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

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

Risks Related to Intellectual Property and Other Legal Matters

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

The patent rights relating to ILUVIEN licensed to us from EyePoint include five U.S. patents that expired between April 2020 and June 2020, one U.S. patent that will expire in August 2027, two European patents that expire in April 2021 and October 2024 and counterpart filings to these patents in a number of other jurisdictions. No patent term extension will be available for any of these U.S. patents, European patents or any of our licensed U.S. or European pending patent applications. After these patents expire in August 2027 in the U.S. and October 2024 in Europe, we will not be able to block others from marketing FAc in an implant similar to ILUVIEN.

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

As patents for certain of our products expire, we will or could face competition from lower priced generic or biosimilar products. The expiration or loss of patent protection for a product typically is followed promptly by substitutes that may significantly reduce sales for that 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. Our ability to pursue the development and commercialization of ILUVIEN depends upon the continuation of our license from EyePoint. This license 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 could revert to EyePoint if we:

(a) fail twice to cure our breach of an obligation to make certain payments to EyePoint following receipt of written notice of the breach;

(b) fail to cure other breaches of material terms of our agreement with EyePoint 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;

(c) 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 our property, file a petition under any bankruptcy or insolvency act or have any such petition filed against us and such proceeding remains undismissed or unstayed for a period of more than 60 days; or

(d) notify EyePoint in writing of our decision to abandon our license with respect to a certain product using EyePoint's proprietary delivery device.

If our license with EyePoint, or any other current or future material license agreement, were terminated, we would 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.

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

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

Under our license with EyePoint, EyePoint controls the filing, prosecution and maintenance of all patents. Our licensors may not successfully prosecute or continue to prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue

litigation against entities that are infringing upon these patents, or may pursue such litigation less aggressively than we ordinarily would. Without protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Moreover, FAc is an off-patent active ingredient that is commercially available in several forms, including the extended release ocular implant Retisert.

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

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

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

Several issued and pending U.S. patents claiming methods and devices for the treatment of eye diseases, including through the use of steroids, implants and injections into the eye, purport to cover aspects of ILUVIEN. For example, one of our potential competitors holds issued and pending U.S. patents and a pending European patent application with claims covering injecting an ocular implant into a patient's eye similar to the ILUVIEN applicator. There is also an issued U.S. patent with claims covering implanting a steroidal anti-inflammatory agent to treat an inflammation-mediated condition of the eye. If these or any other patents were held by a court of competent jurisdiction to be valid and to cover aspects of ILUVIEN, then the owners of such patents would be able to block our ability to commercialize ILUVIEN unless and until we obtain a license under such patents (which license might require us to pay royalties or grant a cross-license to one or more patents that we own), until those patents expire or unless we are able to redesign our product to avoid any such valid patents.

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

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

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

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

Further, the patent applications that we license or have filed may fail to result in issued patents. Patent examiners have rejected some claims in pending patent applications that we have filed or licensed. We may need to amend these claims. Even after amendment, a patent may not be permitted to issue. Further, the existing or future patents to which we have rights based on

our agreement with EyePoint may be too narrow to prevent third parties from developing or designing around these patents. Additionally, we may lose our rights to the patents and patent applications we license in the event of a breach or termination of our license agreement with EyePoint. Manufacturers may also seek to obtain approval to sell a generic version of ILUVIEN before the expiration of the relevant licensed patents. If the sufficiency of the breadth or strength of protection provided by the patents we license with respect to ILUVIEN or the patents we pursue related to ILUVIEN or any future product candidate is threatened, it could dissuade companies from collaborating with us to commercialize ILUVIEN and develop any future product candidates. Further, if we encounter delays in our clinical trials for any future product candidate, the period during which we could market those product candidates under patent protection would be reduced.

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

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

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

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

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If

securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

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

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

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

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

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

Certain Risks of Owning Our Common Stock

The Series A Convertible Preferred Stock contains covenants that may limit our business flexibility.

For so long as at least 37.5% of the shares of Series A Convertible Preferred Stock originally issued to the investors at the closing of our Series A Convertible Preferred Stock financing in October 2012 are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least 70% of the then outstanding shares of Series A Convertible Preferred Stock:

- increase or decrease the authorized number of shares of Series A Convertible Preferred Stock;
- authorize, create, issue or obligate us to issue (by reclassification, merger or otherwise) any security (or any class or series thereof) or any indebtedness, in each case that has any rights, preferences or privileges senior to, or on a parity with, the Series A Convertible Preferred Stock, or any security convertible into or exercisable for any such security or indebtedness, subject to limited exceptions for certain debt transactions;

- amend our certificate of incorporation or the certificate of designation of the Series A Convertible Preferred Stock, in each case in a manner that adversely affects the rights, preference or privileges of the Series A Convertible Preferred Stock;
- redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any shares of common stock or preferred stock; provided, however, that this restriction shall not apply to (A) the redemption of rights issued pursuant to any "poison pill" rights plan or similar plan we adopt in the future or (B) the repurchases of stock from former employees, officers, directors or consultants who performed services for us in connection with the cessation of such employment or service pursuant to the terms of existing agreements with such individuals;
- declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to (A) dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series A Convertible Preferred Stock is made pursuant to the certificate of designation or (B) dividends or distributions issued pro rata to all holders of capital stock (on an as-converted basis) in connection with our implementation of a "poison pill" rights plan or similar plan;
- authorize or approve any increase to the number of aggregate shares of capital stock reserved for issuance pursuant to stock option, stock purchase plans or other equity incentive plans such that the total aggregate number of shares issued under such plans and reserved for issuance under such plans (on an as-converted basis) exceeds the number of shares issued and reserved for issuance under such plans (on an as-converted basis) on the date of the closing of the Series A Convertible Preferred Stock financing by more than 20% (as adjusted for stock splits, combinations, stock dividends, recapitalizations and the like);
- issue stock or other equity securities of any subsidiary (other than to us or another of our wholly-owned subsidiaries);
- declare or pay any dividend or other distribution of cash, shares or other assets or redemption or repurchase of shares of any subsidiary; or
- incur any secured indebtedness other than certain limited debt transactions.

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

Holders of our Series A Convertible Preferred Stock have the ability to significantly influence the outcome of matters submitted for stockholder approval and may have interests that differ from those of our other stockholders.

The terms of the Series A Convertible Preferred Stock provide that certain corporate actions require the prior consent of the holders of at least 70% of the then outstanding shares of Series A Convertible Preferred Stock. As a result, there may be actions that management and the holders of a majority of our outstanding voting power may approve but that the holders of our Series A Convertible Preferred Stock may elect to block.

We have in the past failed to comply with the continued listing requirements of The Nasdaq Stock Market (Nasdaq). If we were to fail to comply again and were unable to regain compliance, our common stock could be delisted from The Nasdaq Global Market, which could materially reduce the liquidity of our common stock and have an adverse effect on its market price.

Our common stock trades on The Nasdaq Global Market, which we believe helps support and maintain liquidity for our stock. Companies whose shares are listed on The Nasdaq Global Market, however, are subject to various rules and requirements imposed by Nasdaq that a listed company must satisfy to continue having its stock listed on the exchange. In 2019 we received three different notices from Nasdaq informing us that we had failed on three occasions to meet the standards for continued listing on The Nasdaq Global Market. Although we regained compliance each time, we cannot provide any assurances that (a) we will not fail to comply in the future and (b) if that were to recur, we would be able to regain and maintain compliance with the continued listing standards.

If we were to fail to regain compliance with Nasdaq's continued listing requirements, our shares could be delisted from The Nasdaq Global Market, which could materially reduce the liquidity of our common stock and have an adverse effect on its market price. If our common stock is delisted from Nasdaq and we are unable to list our common stock on the NYSE American stock exchange, we would be forced to list our shares on the OTC Markets or another quotation medium, depending on our ability to meet the specific listing requirements of those quotation systems. As a result, an investor would likely find it more difficult to trade, or to obtain accurate price quotations for, our shares. Delisting would likely also reduce the visibility, liquidity and value of our common stock, including as a result of reduced institutional investor interest in our company, and may increase the volatility of our common stock. Delisting could also cause a loss of confidence of potential industry partners, lenders and employees, which could further harm our business and our future prospects.

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

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

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

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

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

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

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

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

We may sell our shares in registered public offerings. We also may elect to sell shares of our common stock through an at-the-market offering. Any sale of additional shares of common stock in the future, if we determine it is appropriate or necessary to do so, could cause a significant reduction in the market price of our common stock.

In addition to our outstanding common stock, as of February 1, 2021, we were obligated to issue: (a) a total of 1,125,711 shares of common stock upon the exercise of outstanding common stock options and (b) a total of 30,582 shares of common stock upon the exercise of outstanding common stock warrants. 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. The shares acquired upon exercise of warrants can be sold under Rule 144. If significant sales of these shares occur in short periods, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms.

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

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

To the extent we raise additional capital by issuing equity securities; our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, whether in public or private offerings, investors may be diluted by subsequent sales. Those sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders. In addition,

the Series A Convertible Preferred Stock is entitled to price-based anti-dilution protection in connection with certain financings, which has the potential to further dilute our other stockholders.

Pursuant to the 2019 Omnibus Incentive Plan, our board of directors is authorized to grant various types of equity-based awards, including stock options and RSUs, to our employees, directors and consultants. As of February 1, 2021, a total of 7,481 shares of our common stock were available for issuance under new awards granted under our 2019 Omnibus Incentive Plan. We are currently planning to seek stockholder approval at our 2021 annual stockholders meeting for an additional number of shares of our common stock to be authorized for awards under our 2019 Omnibus Incentive Plan.

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

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

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

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

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

General Risk Factors

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 and financial controls and changes in corporate governance practices. Our management and other personnel are required to devote a substantial amount of time to legal compliance.

If we fail to maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404), we are required to perform system and process evaluation and testing of our internal controls over financial reporting. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 requires us to incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group. Moreover, if we are unable to comply with the requirements of Section 404 in a timely manner or if we identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market

price of our stock could decline and we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities, which would require additional financial and management resources.

If the interpretations, estimates or judgments we use to prepare our financial statements prove to be incorrect, we may be required to restate our financial results, which could have a number of material adverse effects on us.

We are also subject to complex tax laws, regulations, accounting principles and interpretations thereof. The preparation of our financial statements requires us to interpret accounting principles and guidance and to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. We base our interpretations, estimates and judgments on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for the preparation of our financial statements. Generally accepted accounting principles presentation is subject to interpretation by the SEC, the Financial Accounting Standards Board and various other bodies formed to interpret and create appropriate accounting principles and guidance. If one of these bodies disagrees with our accounting recognition, measurement or disclosure or any of our accounting interpretations, estimates or assumptions, it may have a significant effect on our reported results and may retroactively affect previously reported results. Any restatement of our financial results could, among other potential adverse effects:

- result in us incurring substantial costs,
- affect our ability to timely file our periodic reports until the restatement is completed,
- divert the attention of our management and employees from managing our business,
- result in material changes to our historical and future financial results,
- result in investors losing confidence in our operating results,
- subject us to securities class action litigation, and
- cause our stock price to decline.

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. 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.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 2. *PROPERTIES*

In our U.S. segment, our U.S. headquarters are located in Alpharetta, Georgia, consisting of approximately 18,000 square feet of office space. We expect to relocate our U.S. headquarters under a lease for new office space we entered into on November 20, 2020. We have agreed to occupy approximately 14,900 feet of office space in a new office building that is currently under construction. The office building will be located in Halcyon, a new mixed-use development in Alpharetta. We expect to move to the new leased premises on or about October 1, 2021 after our current lease expires in September 2021. Our obligation to pay rent commences on October 1, 2022 at an annual rate of $447,000 and escalates gradually over the 11-year term of the lease to $583,000 in the final year.

In our international segment, we lease approximately 1,000 square feet of office space in each of Dublin, Ireland, Berlin, Germany, and Lisbon, Portugal, and approximately 6,000 square feet of office space in Aldershot, U.K. Our leases for these facilities in Ireland, Germany and Portugal expire in June 2022, June 2021 and March 2021, respectively. Our lease for the U.K. facility expires in December 2024. We anticipate that following the expiration of the leases, we will be able to lease additional or alternative space at commercially reasonable terms.

ITEM 3. *LEGAL PROCEEDINGS*

None.

ITEM 4. *MINE SAFETY DISCLOSURES*

Not applicable.

PART II

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

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

Stockholder Data

As of March 1, 2021, there were 28 holders of record of our common stock, and there were 5,753,434 shares of our common stock issued and outstanding.

Dividends

We have not declared or paid any cash dividends on our common stock since our inception. We do not plan to pay dividends in the foreseeable future. Further, the rights and preferences of our Series A Convertible Preferred Stock 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.

Sales of Unregistered Securities

In 2018, 2019 and 2020, 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 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" at the beginning of Part I of this Annual Report on Form 10-K.

Overview

Alimera Sciences, Inc., and its subsidiaries (we, our or us), is a pharmaceutical company that specializes in the commercialization and development of prescription ophthalmic pharmaceuticals. We presently focus on diseases affecting the back of the eye, or retina, because we believe these diseases are not well treated with current therapies and affect millions of people globally.

ILUVIEN

Our only product is ILUVIEN®, which has received marketing authorization and reimbursement in numerous countries for the treatment of DME. In the U.S. and certain other countries outside Europe, ILUVIEN is indicated for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. In 17 countries in Europe, ILUVIEN is indicated for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. ILUVIEN is also now indicated in 16 countries in Europe for prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye (NIU-PS). See Item 1, "Business - Overview" above.

We market ILUVIEN directly in the U.S., Germany, the U.K., Portugal, and Ireland, and we are planning to launch directly in the Nordic Region (Denmark, Finland, Norway and Sweden) with the support of an exclusive wholesaler. 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, France, Italy, Luxembourg, the Netherlands, Spain, Australia, New Zealand, Canada and several countries in the Middle East. As of December 31, 2020, we have recognized sales of ILUVIEN to our international distributors in the Middle East, Austria, France, Italy, Spain and the Netherlands.

Accumulated Deficit

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of December 31, 2020, we had accumulated a deficit of $392.9 million. We expect to incur additional expenses as we pursue our business strategy. See Item 1, “Business - Business Strategy” above.

As of December 31, 2020, we had approximately $11.2 million in cash and cash equivalents.

Effects of the COVID-19 Pandemic

The unprecedented events of the COVID-19 pandemic, and its unpredictable duration, in the regions where we have customers, employees and distributors have had an adverse effect on our sales of ILUVIEN and thus on our net revenues and may in the future have an adverse effect on our liquidity and financial condition. These adverse effects of the pandemic on us have resulted from the following, among other factors. Governments and private parties imposed limitations on in-person access to physicians, which adversely affects us in at least two ways. First, these limitations can affect patient access to treatment. Because ILUVIEN is administered only by an injection into the eye, telemedicine is not a viable substitute when administration of treatment is required. Second, limitations on in-person access to physicians also makes it difficult or impossible for our sales representatives (including those employed by our distributors) to meet with retina specialists and their staff to educate them about ILUVIEN.

Our business is also negatively affected by patients’ concerns in the current environment. Prior to the pandemic, most of our ILUVIEN sales were driven by the use of ILUVIEN to treat diabetic macular edema, or DME. Given that health authorities have cited diabetes as a factor that places a person at higher risk for severe illness from the COVID-19 pandemic, many DME patients are unwilling to visit their physicians in person (even if otherwise permitted) for fear of contracting the COVID-19 coronavirus.

In addition to the effects of limitations on in-person access to physicians, limitations on travel within and between the countries in which we market and sell ILUVIEN, as well as various types of “shelter in place” orders, have curtailed our in-person marketing activities.

These limitations and other effects of the COVID-19 pandemic have had an adverse impact on our revenues beginning late in the first quarter and continuing through the date of this report. We expect these factors to continue to adversely impact our revenue and capital resources, and the extent and duration of that impact is uncertain at this time, particularly in light of the emergence of COVID-19 variants that may increase the transmissibility of the coronavirus or be more deadly, or both. (See “Liquidity and Capital Resources – Current Cash Position” below.) As more and more people in our markets are vaccinated and as governmental restrictions are gradually lifted, however, we look forward to the prospect of a return to more normal conditions later this year and continuing the growth trends we saw prior to the COVID-19 pandemic. (Please refer to “Special Note Regarding Forward-Looking Statements and Projections” above.)

In response to these developments, we have implemented measures to mitigate the impact of the pandemic on our financial position and operations. These measures include the following:

- We are managing our cost structure, minimizing all non-payroll spending where possible to mitigate our anticipated loss of revenue and conserve our cash.
- We are decreasing our external spending on commercial and medical affairs activities related to the promotion of ILUVIEN.
- Because we believe that our employees are critical to both (a) serving our customers and patients through alternative forms of engagement as the pandemic-related restrictions continue, and (b) realizing the long-term value of ILUVIEN, we have maintained our staffing levels and do not currently have any plans to reduce them.

For more information about the effect of the COVID-19 pandemic on our business and the related risks we face, please see Item 1A, “Risk Factors – Risks Related to the Public Health Pandemic.”

License Agreement with EyePoint Pharmaceuticals US, Inc.

In July 2017, we amended and restated our license agreement with EyePoint Pharmaceuticals US, Inc. (EyePoint), formerly known as pSivida US, Inc., which was made effective July 1, 2017 (the New Collaboration Agreement). Under the New Collaboration Agreement, we have rights to the technology underlying ILUVIEN for the treatment of uveitis, including NIU-PS, 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. We began paying a 2% royalty on net revenues and other related consideration to EyePoint effective July 1, 2017. The royalty amount increased to 6% as of December 12, 2018. We will pay an additional 2% royalty on global net revenues and other related consideration in excess of $75.0 million in any year. During 2020 and 2019, we recognized approximately $2,064,000 and $2,158,000 of royalty expense, respectively.

Following the signing of the New Collaboration Agreement, we retained a right to offset $15.0 million of future royalty payments. In March 2019, pursuant to the New Collaboration Agreement, we forgave $5,000,000 of the Future Offset in connection with the approval of ILUVIEN for NIU-PS in the U.K. As of December 31, 2020, the balance of the Future Offset was approximately $7,874,000. (See Note 10 of our notes to consolidated financial statements below.)

Sources of Revenues

Our revenues for the fiscal years ended December 31, 2020 and 2019 were generated from product sales primarily in the U.S., Germany and the U.K. In the U.S., two large pharmaceutical distributors accounted for 49% and 60% of our consolidated revenues for the years ended December 31, 2020 and 2019, respectively. These U.S.-based distributors purchase ILUVIEN from us, maintain inventories of ILUVIEN and sell downstream to physician offices, pharmacies and hospitals. Internationally, in countries where we sell direct, our customers are hospitals, clinics and pharmacies. We sometimes refer to physician offices, pharmacies, hospitals and clinics as end users. In international countries where we sell to distributors, these distributors maintain inventory levels of ILUVIEN and sell to their customers.

Reclassifications

Within the operating expenses section of the consolidated statements of operations for the year ended December 31, 2019 as well as within the International segment, we reclassified $683,000 in sales and marketing expenses associated with our country managers in Europe from general and administrative expenses to sales and marketing expenses. We made this reclassification to align these expenses with the true nature of the activity being performed and to conform them to the current year presentation. These changes had no impact on previously reported consolidated balance sheets, net loss on our statements of operations, comprehensive loss, stockholders' deficit or cash flows.

Results of Operations - Year ended December 31, 2020 compared to year ended December 31, 2019

	Years Ended December 31,	
	2020	2019
	(In thousands, except share and per share data)	
NET REVENUE	$ 50,820	$ 53,943
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(6,941)	(6,626)
GROSS PROFIT	43,879	47,317
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	9,668	10,992
GENERAL AND ADMINISTRATIVE EXPENSES	11,652	13,271
SALES AND MARKETING EXPENSES	20,384	25,687
DEPRECIATION AND AMORTIZATION	2,676	2,641
OPERATING EXPENSES	44,380	52,591
LOSS FROM OPERATIONS	(501)	(5,274)
INTEREST EXPENSE AND OTHER	(5,380)	(4,869)
UNREALIZED FOREIGN CURRENCY GAIN (LOSS), NET	474	(84)
NET LOSS BEFORE TAXES	(5,407)	(10,227)
BENEFIT (PROVISION) FOR TAXES	68	(216)
NET LOSS	(5,339)	(10,443)
NET LOSS PER SHARE — Basic and diluted (Note 2)	$ (1.04)	$ (2.19)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	5,117,656	4,770,204

Revenue

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

Net revenue decreased by approximately $3.1 million, or 6%, to approximately $50.8 million for 2020, compared to approximately $53.9 million for 2019. The decrease was attributable to a $7.5 million revenue decrease in our U.S. business related to the impact of the COVID-19 pandemic. This decrease was offset by a $4.3 million revenue increase in our International segment, which was primarily due to expansion and growth into new and existing markets through our distributors. We also saw increased sales volume in the markets where we sell direct. These direct sales included sales for our uveitis indication.

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 $300,000, or 5%, to approximately $6.9 million for 2020, compared to approximately $6.6 million for 2019. The increase was primarily attributable to increased sales in our international segment, including to distributors, where costs of goods sold is a higher percentage of net revenue, and an increase in royalty expense payable on our global revenue as a result of the increased royalty percentage payable to EyePoint.

Gross profit decreased by approximately $3.4 million, or 7%, to approximately $43.9 million for 2020, compared to approximately $47.3 million for 2019. Gross margin was 86% and 88% for 2020 and 2019, respectively. As our revenues to our international distributors increase and our royalty expense payable to EyePoint increases, we expect our gross margin to decrease.

Research, Development and Medical Affairs Expenses

Currently, our research, development and medical affairs expenses are primarily focused on activities that support ILUVIEN and include salaries and related expenses for research and development and medical affairs personnel, including

medical science liaisons. Our research, development and medical affairs expenses also include costs related to the provision of medical affairs support, including symposia development for physician education, and costs related to compliance with FDA, EEA or other regulatory requirements. We expense both internal and external development costs as they are incurred.

Research, development and medical affairs expenses decreased by approximately $1.3 million, or 12%, to approximately $9.7 million for 2020, compared to approximately $11.0 million for 2019. The decrease was primarily attributable to decreases of approximately $650,000 in personnel costs, including international vacant positions, global bonus expenses and global stock-based compensation expenses; $620,000 in scientific communications expenses; $450,000 in travel expenses; and $420,000 in consulting costs. These decreases were offset by an increase of approximately $790,000 in clinical study costs, primarily consisting of costs associated with the NEW DAY Study.

General and Administrative Expenses

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

General and administrative expenses decreased by approximately $1.6 million, or 12%, to approximately $11.7 million for 2020, compared to approximately $13.3 million for 2019. The decrease was primarily attributable to decreases of approximately $700,000 in global stock-based compensation expenses and $470,000 in professional fees. Additionally, in 2020 we benefitted from a one-time cash refund of approximately $400,000 associated with recovery of previously paid VAT expense in Germany for the years 2014 through 2018.

Sales and Marketing Expenses

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

Sales and marketing expenses decreased by approximately $5.3 million, or 21%, to approximately $20.4 million for 2020, compared to approximately $25.7 million for 2019. The decrease was primarily attributable to a decrease of approximately $4.2 million in marketing costs related to cost controls we implemented to address the COVID-19 pandemic, the absence in 2020 of expenses we incurred in 2019 for the launch of our direct-to-patient advertising pilot program in the U.S., a decrease of $870,000 in travel expenses and a decrease of $400,000 in market access costs.

Operating Expenses

As a result of the changes in expenses described above, total operating expenses decreased by approximately $8.2 million, or 16%, to approximately $44.4 million for 2020, compared to approximately $52.6 million for 2019. The decrease was primarily attributable to decreases of approximately $5.3 million in sales and marketing expenses, $1.6 million in general and administrative expenses and $1.3 million in research, development and medical affairs expenses as described above.

Interest Expense and Other

On January 5, 2018, we entered into a $40.0 million loan and security agreement (the 2018 Solar Loan Agreement) with Solar Capital Ltd. (Solar Capital). On December 31, 2019, we refinanced the 2018 Solar Loan Agreement by entering into a $45.0 million loan and security agreement (the 2019 Solar Loan Agreement) with Solar Capital. For 2020 and 2019, interest expense consisted primarily of interest and amortization of deferred financing costs and debt discounts associated with our outstanding debt under the 2018 and 2019 Solar Loan Agreements. Interest income consisted primarily of interest earned on our cash, cash equivalents and investments.

Interest expense and other. Interest expense and other increased by approximately $500,000, or 10%, to approximately $5.4 million for 2020, compared to approximately $4.9 million for 2019. Interest expense consisted primarily of interest and amortization of deferred financing costs and debt discounts associated with our outstanding debt under the 2018 and 2019 Solar Loan Agreements with Solar Capital. For more detailed information, see Note 11 of our notes to consolidated financial statements below.

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

We follow FASB Accounting Standards Codification (ASC), *Earnings Per Share* (ASC 260), which requires the reporting of both basic and diluted earnings per share. Because our preferred stockholders participate in dividends equally with common

stockholders (if we were to declare and pay dividends), we use the two-class method to calculate EPS. However, our preferred stockholders are not contractually obligated to share in losses.

Basic EPS is computed by dividing net income (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.

Common stock equivalent securities that would potentially dilute basic EPS in the future, but were not included in the computation of diluted EPS because they were either classified as participating or would have been anti-dilutive, totaled approximately 1.6 million and 2.3 million for 2020 and 2019, respectively.

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.

We have a U.S. segment and an International segment, and we report Other to reconcile back to consolidated totals. Each segment is separately managed and is evaluated primarily upon segment income or loss from operations. Non-cash items including stock-based compensation expense, depreciation and amortization are categorized as Other. 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. There were no significant changes in our expense allocation methodology during 2020 or 2019.

U.S. Segment

	Years Ended December 31,	
	2020	2019
	(In thousands)	
NET REVENUE	$ 24,809	$ 32,283
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(2,858)	(3,487)
GROSS PROFIT	21,951	28,796
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	6,239	5,943
GENERAL AND ADMINISTRATIVE EXPENSES	7,971	8,449
SALES AND MARKETING EXPENSES	14,273	17,591
OPERATING EXPENSES	28,483	31,983
SEGMENT LOSS FROM OPERATIONS	$ (6,532)	$ (3,187)

U.S. Segment - Year ended December 31, 2020 compared to year ended December 31, 2019

Net Revenue. Net revenue decreased by approximately $7.5 million, or 23%, to approximately $24.8 million for 2020, compared to approximately $32.3 million for 2019. The decrease was primarily attributable to decreased sales due to the COVID-19 pandemic.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization decreased by approximately $600,000, or 17%, to approximately $2.9 million for 2020 compared to approximately $3.5 million for 2019. The decrease was primarily attributable to decreased sales.

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately $300,000, or 5%, to approximately $6.2 million for 2020, compared to approximately $5.9 million for 2019. The increase was primarily attributable to increases of approximately $1.0 million in clinical study costs, primarily consisting of costs associated with the NEW DAY Study and $280,000 in safety and quality expenses. These increases were offset by decreases of approximately $490,000 in scientific communications costs, $320,000 in consultant costs and $250,000 in travel expenses.

General and administrative expenses. General and administrative expenses decreased by approximately $400,000, or 5%, to approximately $8.0 million for 2020, compared to approximately $8.4 million for 2019. The decrease was primarily attributable to decreases in costs related to operating as a public company, including professional fees and shareholder relations costs.

Sales and marketing expenses. Sales and marketing expenses decreased by approximately $3.3 million, or 19%, to approximately $14.3 million for 2020, compared to approximately $17.6 million for 2019. The decrease was primarily attributable to a decrease of approximately $2.8 million in marketing costs related to cost controls we implemented to address the

COVID-19 pandemic, the absence in 2020 of expenses we incurred in 2019 for the launch of our direct-to-patient advertising pilot program in the U.S. and a decrease of $560,000 in travel expenses.

International Segment

	Years Ended December 31,	
	2020	2019
	(In thousands)	
NET REVENUE	$ 26,011	$ 21,660
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(4,083)	(3,139)
GROSS PROFIT	21,928	18,521
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	3,280	4,634
GENERAL AND ADMINISTRATIVE EXPENSES	2,812	3,261
SALES AND MARKETING EXPENSES	5,790	7,616
OPERATING EXPENSES	11,882	15,511
SEGMENT INCOME FROM OPERATIONS	$ 10,046	$ 3,010

International Segment - Year ended December 31, 2020 compared to year ended December 31, 2019

Net Revenue. Net revenue increased by approximately $4.3 million, or 20%, to approximately $26.0 million for 2020, compared to approximately $21.7 million for 2019. The increase was primarily attributable to the expansion and growth into new and existing markets through our distributors, partially offset by the effects of the COVID-19 pandemic. We also saw increased sales volume in the markets where we sell direct. These direct sales included sales for our uveitis indication.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately $1.0 million, or 32%, to approximately $4.1 million for 2020, compared to approximately $3.1 million for 2019. The increase was primarily attributable to our increased sales volume including increased sales to our international distributors, where costs of goods sold is a higher percentage of net revenue.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately $1.3 million, or 28%, to approximately $3.3 million for 2020, compared to approximately $4.6 million for 2019. The decrease was primarily attributable to decreases of approximately $550,000 in personnel and travel expenses, including savings associated with vacant positions; $350,000 in safety, quality and scientific communications expenses; $220,000 in costs associated with our 5-year open label registry study; and $130,000 in scientific communication costs.

General and administrative expenses. General and administrative expenses decreased by approximately $500,000, or 15%, to approximately $2.8 million for 2020, compared to approximately $3.3 million for 2019. We benefitted from a one-time cash refund of approximately $400,000 associated with recovery of previously paid VAT expense in Germany for the years 2014 through 2018.

Sales and marketing expenses. Sales and marketing expenses decreased by approximately $1.8 million, or 24%, to approximately $5.8 million for 2020, compared to approximately $7.6 million for 2019. The decrease was primarily attributable to decreases of approximately $1.4 million in marketing costs related to cost controls we implemented to address the COVID-19 pandemic; $310,000 in travel expenses due in part to medical congresses being cancelled or moved online; and $290,000 in market access costs.

Other

	Years Ended December 31,	
	2020	2019
	(In thousands)	
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	$ 149	$ 415
GENERAL AND ADMINISTRATIVE EXPENSES	869	1,561
SALES AND MARKETING EXPENSES	321	480
DEPRECIATION AND AMORTIZATION	2,676	2,641
OPERATING EXPENSES	4,015	5,097
SEGMENT LOSS FROM OPERATIONS	$ (4,015)	$ (5,097)

Other - Year ended December 31, 2020 compared to year ended December 31, 2019

Our CEO, who is our chief operating decision maker (CODM), manages and evaluates our U.S. and International segments based on net gain or loss from operations adjusted for certain non-cash items, such as stock-based compensation expense and depreciation and amortization. Therefore, these non-cash expenses included in research, development and

medical affairs expenses, general and administrative expenses, and sales and marketing expenses are classified within Other within our consolidated financial statements.

Operating expenses. Operating expenses in Other decreased by approximately $1.1 million, or 22%, to $4.0 million for 2020, compared to approximately $5.1 million for 2019. This decrease was primarily attributable to a decrease of $1.1 million in global stock-based compensation expenses.

Depreciation and amortization. Depreciation and amortization was approximately $2.7 million for 2020 and approximately $2.6 million for 2019.

Prospective Changes to Segment Presentation

Historically, we have had a U.S. segment and an International segment, and we report Other in order to reconcile to consolidated totals. Beginning in 2021, our chief operating decision maker (CODM) changed the way he analyzes the business and respective segments to provide increased transparency and comparability of the performance of the U.S. and International segments.

In future SEC filings and press releases relating to periods beginning January 1, 2021, our segments will consist of a U.S. segment, an International segment and an Operating Cost segment, and we will present Other to reconcile to consolidated totals. The amounts in each of the segment columns in the following tables have been adjusted to reflect our segment results as if the new approach had been in effect for the years ended December 31, 2020 and 2019. The amounts in the Consolidated column are unchanged from the segment information provided in Note 19 to our consolidated financial statements. Other than the Consolidated column, the information in the columns in the tables below differ from the segment information presented in Note 19 to our consolidated financial statements. For our segment presentation, please see Note 19.

Operating Cost consists largely of expenses not allocated to the U.S. or International segments, including expenses associated with centrally managed departments such as regulatory, clinical operations, quality and supply chain management and other corporate functions, including public company costs, executive management, legal and global insurance; costs related to global marketing; and costs related to our U.S. and European headquarters. Consistent with past practice, non-cash items including stock-based compensation expense, depreciation and amortization are still categorized in Other.

Our CODM will manage and evaluate each of our segments primarily based upon segment income or loss from operations. The objective of our change in segment reporting is to ensure comparability and consistency for our management and for investors and other users of the financial statements who assess our historical results and consider future cash flow prospects. We believe that the new segment structure will enable the CODM to better manage and monitor the business attributed to each segment.

Other than the Consolidated column, the information in the columns in the tables below differ from the segment information presented in Note 19 to our consolidated financial statements, to which you should refer for our segment information. The following tables reflect our segment results as if the new approach described above had been in effect for the years ended December 31, 2020 and 2019.

For our segment presentation, please see Note 19 to our consolidated financial statements.

	Year Ended December 31, 2020				
	U.S.	International	Operating Cost	Other	Consolidated
	(In thousands)				
NET REVENUE	$ 24,809	$ 26,011	$ —	$ —	$ 50,820
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(2,858)	(4,083)	—	—	(6,941)
GROSS PROFIT	21,951	21,928	—	—	43,879
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	3,137	2,996	3,386	149	9,668
GENERAL AND ADMINISTRATIVE EXPENSES	924	1,700	8,159	869	11,652
SALES AND MARKETING EXPENSES	13,784	5,790	489	321	20,384
DEPRECIATION AND AMORTIZATION	—	—	—	2,676	2,676
OPERATING EXPENSES	17,845	10,486	12,034	4,015	44,380
SEGMENT INCOME (LOSS) FROM OPERATIONS	4,106	11,442	(12,034)	(4,015)	(501)
OTHER INCOME AND EXPENSES, NET				(4,906)	(4,906)
NET LOSS BEFORE TAXES					$ (5,407)

For our segment presentation, please see Note 19 to our consolidated financial statements.

	Year Ended December 31, 2019				
	U.S.	International	Operating Cost	Other	Consolidated
			(In thousands)		
NET REVENUE	$ 32,283	$ 21,660	$ —	$ —	53,943
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(3,487)	(3,139)	—	—	(6,626)
GROSS PROFIT	28,796	18,521	—	—	47,317
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	4,264	4,439	1,874	415	10,992
GENERAL AND ADMINISTRATIVE EXPENSES	1,197	2,011	8,502	1,561	13,271
SALES AND MARKETING EXPENSES	17,129	7,616	462	480	25,687
DEPRECIATION AND AMORTIZATION	—	—	—	2,641	2,641
OPERATING EXPENSES	22,590	14,066	10,838	5,097	52,591
SEGMENT INCOME (LOSS) FROM OPERATIONS	6,206	4,455	(10,838)	(5,097)	(5,274)
OTHER INCOME AND EXPENSES, NET				(4,953)	(4,953)
NET LOSS BEFORE TAXES					$ (10,227)

Liquidity and Capital Resources

As explained above in “Effects of the COVID-19 Pandemic,” the unprecedented events of the COVID-19 pandemic, and its unpredictable duration, in the regions where we have customers, employees and distributors have had an adverse effect on our sales of ILUVIEN and thus on our net revenues and capital resources. The extent and duration of that impact is uncertain at this time, particularly in light of the emergence of COVID-19 variants that may increase the transmissibility of the coronavirus or be more deadly, or both.

Since January 2019, we have funded our operations through (a) cash received from our sales; (b) net proceeds of the 2018 and 2019 Solar Loan and Security Agreements that we obtained in January 2018 and December 2019, respectively; (c) a $1.0 million sale of common stock to a private investor in October 2019; and (d) an approximately $1,778,000 loan (the PPP Loan) we obtained in April 2020 under the Paycheck Protection Program established as part of the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act. Our loans do not include a revolving loan feature and have been fully advanced by the respective lenders. We currently have no additional borrowing capacity, and the 2019 Solar Loan Agreement generally prohibits any additional debt unless we obtain the prior consent of Solar Capital.

Indebtedness

2019 Solar Loan Agreement. On December 31, 2019, we refinanced our then existing $40.0 million loan and security agreement with Solar Capital and other lenders by entering into the $45.0 million 2019 Solar Loan Agreement with Solar Capital as Collateral Agent (Agent), and certain other lenders, including Solar Capital in its capacity as a lender. Under the 2019 Solar Loan Agreement, we borrowed $42.5 million on December 31, 2019 and $2.5 million on February 21, 2020 (the Solar Loan). The Solar Loan matures on July 1, 2024. We used the initial proceeds of the Solar Loan to pay off the previous $40.0 million 2018 Solar Capital loan, along with related prepayment, legal and other fees and expenses totaling approximately $2.3 million, which included $2.2 million in fees to Solar Capital. We used the remaining proceeds of the Solar Loan to provide additional working capital for general corporate purposes during 2020.

On May 1, 2020, we entered into a First Amendment (the Amendment) to the 2019 Solar Loan Agreement. The Amendment, among other things, requires that a minimum revenue covenant be measured at March 31, 2021 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 a plan we submitted to Agent in February 2021, and with such plan to be approved by our board of directors and Solar Capital in its sole discretion. The Amendment also included revised covenants that applied to our financial performance during 2020, all of which we met.

Paycheck Protection Program Loan. On April 22, 2020, we received an approximately $1,778,000 loan (the PPP Loan) under the Paycheck Protection Program established by the U.S. Small Business Administration (the SBA) as part of the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act. The PPP Loan is unsecured and is evidenced by a note (the Note) in favor of HSBC Bank USA, National Association (HSBC) as the lender.

The interest rate on the Note is 1.0% per annum. The Note has a two-year term and is payable in 18 equal monthly payments of principal and interest beginning on the 180th day following the disbursement of the loan proceeds, subject to possible full

forgiveness and a deferred commencement date for beginning payments as described below. The Paycheck Protection Program provides for forgiveness of up to the full amount borrowed and any accrued interest as long as we use the loan proceeds during the 24-week period following disbursement for eligible purposes as described in the CARES Act and related guidance. Under the CARES Act, loan forgiveness is generally available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the 24-week period. We used all of the proceeds from the PPP Loan to pay expenses during the applicable period that we believe were for eligible purposes. On July 21, 2020, we submitted an application to HSBC for forgiveness of the PPP Loan. As of the date of this filing, the application for forgiveness is still pending review.

Under the revised rules for the PPP Loan program, we will not have to begin principal and interest payments before the date on which the SBA remits the loan forgiveness amount to HSBC (or notifies HSBC that no loan forgiveness is allowed). If no loan forgiveness is allowed, the Company will be required to pay HSBC payments of principal and interest based on the principal amount outstanding on the PPP Loan, plus interest outstanding at the end of the deferment period, and taking into account any reductions in the principal amount due to forgiveness, if any.

Current Cash Position

As of December 31, 2020, we had approximately $11.2 million in cash and cash equivalents, compared to $9.4 million as of December 31, 2019 and $11.3 million as of September 30, 2020. We have historically experienced seasonality in our first quarter revenue each year. Given that seasonality and the ongoing effects of the COVID-19 pandemic, we anticipate a corresponding impact to our cash position as of March 31, 2021. In response to the effects of the COVID-19 pandemic, we have adjusted, and we expect to continue to adjust, our commercial spending to continue to operate with our existing cash resources. We may need to raise additional capital to fund our business strategy, including the continued commercialization of ILUVIEN and the retention of our current employees and staff. The actual amount of funds that we may need will depend on many factors, some of which are beyond our control. See “Effects of the COVID-19 Pandemic” in this Item 2 above for an explanation of our strategy to conserve our cash and otherwise mitigate the impact of the pandemic on our financial position and operations.

We cannot ensure that our commercial spending controls will be effective or will continue to be effective throughout the currently unknown duration of the pandemic. We cannot be sure that additional financing will be available when needed or that, if available, the additional financing could be obtained on terms that are not significantly detrimental to us or our stockholders. If we were to raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result, and the terms of any new equity securities could 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, (a) the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to achieve our business strategy; and (b) we would be required to obtain the permission or participation of Solar Capital, which we might not be able to obtain. Our recurring losses and any potential needs to raise capital create substantial doubt about our ability to continue as a going concern for the next 12 months following the issuance of the financial statements for the filing of this Form 10-K.

Sources and Uses of Cash in 2020 and 2019

For 2020, net cash used in our operations of $2.2 million was primarily due to our net loss of $5.3 million, a $1.6 million decrease in accounts payable, accrued expenses and other current liabilities, a $1.3 million increase in inventory, a $680,000 increase in prepaid expenses and other current assets and a $520,000 decrease in long-term liabilities. These decreases in cash were offset by $2.7 million of non-cash depreciation and amortization, a $2.6 million decrease in accounts receivable, $1.3 million of non-cash stock-based compensation expense and $1.0 million of non-cash interest expense associated with the amortization of our debt discount.

For 2019, net cash used in our operations of $4.2 million was primarily due to our net loss of $10.4 million, a $2.2 million increase in accounts receivable that was driven by increased revenue and an $830,000 increase in prepaid expenses and other current assets. These decreases in cash were offset by $2.6 million of non-cash depreciation and amortization, $2.5 million of non-cash stock-based compensation expense and $840,000 of non-cash interest expense associated with the amortization of our debt discount, a $1.4 million increase in accounts payable, accrued expenses and other current liabilities, a $450,000 decrease in deferred tax asset and a $390,000 increase in long-term liabilities.

For 2020, net cash used in our investing activities was approximately $620,000, which was primarily due to capital expenditures associated with the transfer of manufacturing to the facility at Cadence.

For 2019, net cash used in our investing activities was approximately $174,000, which was primarily due to the purchase of equipment and software.

For 2020, net cash provided by our financing activities was approximately $3.9 million, which was primarily due to borrowing the remaining $2.5 million under the 2019 Solar Loan Agreement and receiving the $1.8 million PPP Loan, offset by $430,000 of payments of finance lease obligations.

For 2019, net cash provided by our financing activities was approximately $869,000, which was primarily due to incurring $2.5 million of additional debt by entering into the $45.0 million 2019 Solar Loan Agreement and our sale of $1.0 million of common stock to Lincoln Park Capital Fund, LLC. These increases in cash were offset by payments of approximately $2.3 million, which included a $1.8 million fee to Solar Capital upon repayment of the 2018 Solar Loan that was previously accrued and a $400,000 prepayment fee to Solar Capital that was capitalized as deferred financing costs.

Critical Accounting Policies and 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. 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. We believe that the following 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.

Revenue Recognition

Net 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.

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

As of December 31, 2020 and 2019, we had received a total of $1.0 million of milestone payments in connection with our Canadian distributor that we have not recognized as revenue based on our analysis in connection with Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)*. These deferred revenues are included as a component of other non-current liabilities on our balance sheets.

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.

Additional Critical Accounting Policies and Estimates

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, 2020, we had federal NOL carry-forwards of approximately $131.4 million and state NOL carry-forwards of approximately $96.2 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 2020 and 2040. Under the Tax Cuts and Jobs Act of 2017, U.S. federal NOLs and some state NOLs generated after 2017 will carry forward indefinitely.

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

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

We considered our income tax positions for uncertainty in accordance with ASC 740. The balance of unrecognized tax benefits as of December 31, 2020 and December 31, 2019 are approximately $65,970 and $58,000, respectively. Both balances relate to research and development tax credits. In accordance with ASC 740-10, such attributes are reduced to the amount that is expected to be recognized in the future. We do not accrue interest or penalties, as there is no risk of additional tax liability due to significant NOLs available. We do not expect any decreases to the unrecognized tax benefits within the next twelve months due to any lapses in statute of limitations. Tax years from 2015 to 2018 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.

Off-Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, that would have been established to facilitate off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of SEC Regulation S-K) or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in those types of relationships. We enter into guarantees in the ordinary course of business related to the guarantee of our own performance and the performance of our subsidiaries.

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.

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 55 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, 2020.

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, 2020, 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, 2020.

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 2020 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.

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 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2020 (the 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 Proxy Statement and is incorporated herein by reference.

Equity Compensation Plan Information

The following table provides information, as of December 31, 2020, with respect to shares of our common stock that may be issued, subject to certain vesting requirements, under (a) existing awards under our 2010 Equity Incentive Plan (2010 Plan), and (b) existing and future awards under our 2019 Omnibus Incentive Plan (2019 Plan). The following table also provides information, as of December 31, 2020, 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	969,465 (1)	$ 26.72	258,325 (2)
Equity compensation plans not approved by security holders	—	—	—
Total	969,465	$ 26.72	258,325

(1) Of these shares, 713,460 were subject to stock options then outstanding under the 2010 Plan, 225,919 were subject to stock options then outstanding under the 2019 Plan, and 30,086 were outstanding but unvested shares of restricted stock then outstanding under the 2019 Plan.

(2) Represents 239,176 shares of common stock available for issuance under our 2019 Plan and 19,149 shares of common stock available for issuance under our ESPP. No shares are available for future issuance under the 2010 Plan. In addition, our ESPP provides for annual increases in the number of shares available for issuance thereunder equal to such number of shares necessary to restore the number of shares reserved thereunder to 32,961 shares of our common stock. As such, on January 1, 2021, an additional 13,812 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 2021 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 2021 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 4: Ratification of Selection of Independent Registered Public Accounting Firm - Independent Registered Public Accounting Firm’s Fees” in our 2021 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 4: Ratification of Selection of Independent Registered Public Accounting Firm - Pre-Approval Policies and Procedures of the Audit Committee” in our 2021 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, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, changes in stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Going concern
The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 5 to the consolidated financial statements, the Company has incurred recurring losses, negative cash flows from operations, and has an accumulated deficit of $392,909,000 as of December 31, 2020. These conditions, along with the other matters as set forth in Note 5, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 5. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

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

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

/s/ GRANT THORNTON LLP

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

Atlanta, Georgia
March 4, 2021

ALIMERA SCIENCES, INC.

CONSOLIDATED BALANCE SHEETS

AS OF DECEMBER 31, 2020 AND 2019

	December 31,	
	2020	2019
	(In thousands, except share and per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 11,208	$ 9,426
Restricted cash	34	33
Accounts receivable, net	17,200	19,331
Prepaid expenses and other current assets	3,718	2,565
Inventory (Note 6)	2,746	1,390
Total current assets	34,906	32,745
NON-CURRENT ASSETS:		
Property and equipment, net	1,638	940
Right of use assets, net	720	1,107
Intangible asset, net	12,838	14,783
Deferred tax asset	753	734
TOTAL ASSETS	$ 50,855	$ 50,309
CURRENT LIABILITIES:		
Accounts payable	$ 7,461	$ 7,077
Accrued expenses (Note 9)	3,197	4,716
Paycheck Protection Program (PPP) loan (Note 11)	1,481	—
Finance lease obligations	209	255
Total current liabilities	12,348	12,048
NON-CURRENT LIABILITIES:		
Notes payable (Note 11)	42,408	38,658
Finance lease obligations — less current portion	514	94
Other non-current liabilities	3,563	3,954
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' DEFICIT:		
Preferred stock, $.01 par value — 10,000,000 shares authorized at December 31, 2020 and 2019:		
Series A Convertible Preferred Stock, 1,300,000 authorized and 600,000 issued and outstanding at December 31, 2020 and 2019; liquidation preference of $24,000 at December 31, 2020 and 2019	19,227	19,227
Series C Convertible Preferred Stock, 10,150 authorized and zero issued and outstanding at December 31, 2020 and 10,150 authorized issued and outstanding at December 31, 2019; liquidation preference of $0 at December 31, 2020 and liquidation preference of $10,150 at December 31, 2019	—	11,117
Common stock, $.01 par value — 150,000,000 shares authorized, 5,719,367 shares issued and outstanding at December 31, 2020 and 4,965,949 shares issued and outstanding at December 31, 2019 (Note 2)	57	50
Additional paid-in capital	365,830	350,117
Common stock warrants	370	3,707
Accumulated deficit	(392,909)	(387,570)
Accumulated other comprehensive loss — foreign currency translation adjustments	(553)	(1,093)
TOTAL STOCKHOLDERS' DEFICIT	(7,978)	(4,445)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 50,855	$ 50,309

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED DECEMBER 31, 2020 AND 2019

	Years Ended December 31,	
	2020	2019
	(In thousands, except share and per share data)	
NET REVENUE	$ 50,820	$ 53,943
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(6,941)	(6,626)
GROSS PROFIT	43,879	47,317
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	9,668	10,992
GENERAL AND ADMINISTRATIVE EXPENSES	11,652	13,271
SALES AND MARKETING EXPENSES	20,384	25,687
DEPRECIATION AND AMORTIZATION	2,676	2,641
OPERATING EXPENSES	44,380	52,591
LOSS FROM OPERATIONS	(501)	(5,274)
INTEREST EXPENSE AND OTHER	(5,380)	(4,869)
UNREALIZED FOREIGN CURRENCY GAIN (LOSS), NET	474	(84)
NET LOSS BEFORE TAXES	(5,407)	(10,227)
BENEFIT (PROVISION) FOR TAXES	68	(216)
NET LOSS	(5,339)	(10,443)
NET LOSS PER SHARE — Basic and diluted (Note 2)	$ (1.04)	$ (2.19)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	5,117,656	4,770,204

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

FOR THE YEARS ENDED DECEMBER 31, 2020 AND 2019

	Years Ended December 31,	
	2020	2019
	(In thousands)	
NET LOSS	$ (5,339)	$ (10,443)
OTHER COMPREHENSIVE INCOME (LOSS)		
Foreign currency translation adjustments	540	(82)
TOTAL OTHER COMPREHENSIVE INCOME (LOSS)	540	(82)
COMPREHENSIVE LOSS	$ (4,799)	$ (10,525)

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT

FOR THE YEARS ENDED DECEMBER 31, 2020 AND 2019

	Common Stock		Series A Convertible Preferred Stock		Series C Convertible Preferred Stock		Additional Paid-In Capital	Common Stock Warrants	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount	Shares	Amount	Shares	Amount					
	(In thousands, except share data)										
BALANCE — December 31, 2018	4,671,921	$ 47	600,000	$ 19,227	10,150	$ 11,117	$346,762	$ 3,707	$ (377,127)	$ (1,011)	$ 2,722
Issuance of common stock, net of issuance costs	294,028	3	—	—	—	—	899	—	—	—	902
Stock-based compensation	—	—	—	—	—	—	2,456	—	—	—	2,456
Net loss	—	—	—	—	—	—	—	—	(10,443)	—	(10,443)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	(82)	(82)
BALANCE — December 31, 2019	4,965,949	50	600,000	19,227	10,150	11,117	350,117	3,707	(387,570)	(1,093)	(4,445)
Issuance of common stock, net issuance costs	76,745	—	—	—	—	—	49	—	—	—	49
Preferred stock conversion	676,673	7	—	—	(10,150)	(11,117)	11,110	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	1,331	—	—	—	1,331
Expiration of common warrants	—	—	—	—	—	—	3,337	(3,337)	—	—	—
Other	—	—	—	—	—	—	(114)	—	—	—	(114)
Net loss	—	—	—	—	—	—	—	—	(5,339)	—	(5,339)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	540	540
BALANCE — December 31, 2020	5,719,367	$ 57	600,000	$ 19,227	—	$ —	$365,830	$ 370	$ (392,909)	$ (553)	$ (7,978)

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2020 AND 2019

	Years Ended December 31,	
	2020	2019
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,339)	$ (10,443)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,676	2,641
Unrealized foreign currency transaction (gain) loss	(474)	84
Amortization of debt discount and deferred financing costs	972	837
Deferred tax expense	31	454
Stock compensation expense	1,331	2,456
Changes in assets and liabilities:		
Accounts receivable	2,631	(2,160)
Prepaid expenses and other current assets	(683)	(828)
Inventory	(1,259)	996
Accounts payable	106	779
Accrued expenses and other current liabilities	(1,664)	641
Other long-term liabilities	(521)	391
Net cash used in operating activities	(2,193)	(4,152)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(620)	(174)
Net cash used in investing activities	(620)	(174)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock, net of issuance costs	49	902
Issuance of debt	4,278	42,500
Payment of principal on notes payable	—	(40,000)
Payment of debt costs, including end of term payment	(19)	(2,227)
Payments on finance lease obligations	(426)	(306)
Net cash provided by financing activities	3,882	869
EFFECT OF EXCHANGE RATES ON CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	714	(159)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	1,783	(3,616)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH — Beginning of year	9,459	13,075
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH — End of year	$ 11,242	$ 9,459
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	$ 3,927	$ 4,041
Cash paid for income taxes	$ 110	$ 239
Supplemental schedule of noncash investing and financing activities:		
Property and equipment acquired under finance leases	$ 953	$ 154
Property and equipment acquired under operating leases	$ —	$ 676
Note payable end of term payment accrued but unpaid	$ 2,125	$ 2,125

The Company paid no dividends during the years ended December 31, 2020 and 2019.

See Notes to Consolidated Financial Statements.

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS

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

The Company presently focuses on diseases affecting the back of the eye, or retina, because the Company believes these diseases are not well treated with current therapies and affect millions of people globally. The Company's only product is ILUVIEN®, which has received marketing authorization and reimbursement in 24 countries for the treatment of diabetic macular edema (DME). In the U.S. and certain other countries outside Europe, ILUVIEN is indicated for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. In 17 countries in Europe, ILUVIEN is indicated for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. In addition, ILUVIEN has received marketing authorization in 16 European countries, and reimbursement in three countries, Germany, the Netherlands and the U.K., for the prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment (NIU-PS).

The Company markets ILUVIEN directly in the U.S., Germany, the U.K., Portugal and Ireland. In addition, the Company has entered into various agreements under which distributors are providing or will provide regulatory, reimbursement and sales and marketing support for ILUVIEN in Austria, Belgium, the Czech Republic, France, Italy, Luxembourg, the Netherlands, Spain, Australia, New Zealand, Canada and several countries in the Middle East. As of December 31, 2020, the Company has recognized sales of ILUVIEN to its international distributors in the Middle East, Austria, France, Italy, Spain and the Netherlands.

Effects of the COVID-19 Pandemic

The public health crisis caused by the COVID-19 pandemic and the measures being taken by governments, businesses, and the public at large to limit the COVID-19 pandemic's spread have had, and the Company expects will continue to have, certain negative effects on, and present certain risks to, the Company's business. These limitations and other effects of the COVID-19 pandemic have had an adverse impact on our revenues beginning late in the first quarter of 2020 and continuing through the fourth quarter of 2020. We expect these factors to continue to adversely impact our revenue, and the extent and duration of that impact is uncertain at this time, particularly in light of the emergence of COVID-19 variants that may increase the transmissibility of the coronavirus or be more deadly, or both. Depending on the duration of these limitations and the severity and duration of other effects of the COVID-19 pandemic, our liquidity and financial condition may be adversely affected in the future as well. This uncertainty could have an impact in future periods on certain estimates used in the preparation of the Company's quarterly financial results, including impairment of intangible assets, the income tax provision and realizability of certain receivables. Should the pandemic continue for an extended period, the impact on the Company's operations could have an adverse effect on the Company's revenue, financial condition and cash flows.

In response to the COVID-19 pandemic, the Company has implemented measures to mitigate the impact of the pandemic on its financial position and operations. These measures include the following:

- The Company is continuing to manage its cost structure, minimizing all non-payroll spending where possible to mitigate its anticipated loss of revenue and conserve our cash.
- The Company has decreased its external spending on commercial and medical affairs activities related to the promotion of ILUVIEN.
- Because the Company believes that its employees are critical to both (a) serving its customers and patients through alternative forms of engagement as the pandemic-related restrictions continue, and (b) realizing the long-term value of ILUVIEN, the Company has maintained its staffing levels and does not currently have any plans to reduce them.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Use of Estimates in Financial Statements

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

Principles of Consolidation

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

Reclassifications

Within the operating expenses section of the Consolidated Statements of Operations for the year ended December 31, 2019 as well as within the International segment (see Note 19), the Company reclassified $683,000 in sales and marketing expenses associated with its country managers in Europe from general and administrative expenses to sales and marketing expenses. The Company made this reclassification to provide additional transparency of the activity being performed and to conform them to the current year presentation. These changes had no impact on previously reported consolidated balance sheets, net loss on our statements of operations, comprehensive loss, stockholders' deficit or cash flows.

Modification of Income Taxes Footnote

The Company modified its income taxes footnote for the year ended December 31, 2019 and removed certain state NOL carry-forwards of approximately $4,169,000. This same amount was removed from the Company's valuation allowance, which resulted in no net change to the Company's total deferred tax assets or tax expense. The change was primarily driven by a shift in the Company's state apportionment. This change had no impact on previously reported consolidated balance sheets, net loss on our statements of operations, comprehensive loss, stockholders' deficit or cash flows.

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 and cash equivalents held at financial institutions are in excess of federally insured limits. Cash and cash equivalents were $11,242,000 and $9,426,000 as of December 31, 2020 and 2019, respectively, with approximately 39.0% and 57.0% of these balances, respectively, held in U.S.-based financial institutions.

Product Revenue

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

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are generated through sales primarily to major pharmaceutical distributors, pharmacies, hospitals and wholesalers. The Company does not require collateral from its customers for accounts receivable. The carrying amount of accounts receivable is reduced by an allowance for doubtful accounts that reflects management's best estimate of the amounts that will not be collected. In addition to reviewing delinquent accounts receivable, management considers many factors in estimating its general allowance, including historical data, experience, customer types, credit worthiness and economic trends. From time to time, management may adjust its assumptions for anticipated changes in any of those or other factors expected to affect collectability. A provision for doubtful accounts is charged to operations when management determines the accounts may become uncollectable. The Company writes off accounts receivable when management determines they are uncollectable and credits payments subsequently received on such receivables to bad debt expense in the period received. As of December 31, 2020 and 2019, the Company had no reserve for doubtful accounts.

Inventory

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

Intangible Assets

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

Property and Equipment

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

Impairment

Property and equipment and definite lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When indicators of impairment are present, the Company evaluates the carrying amount of such assets in relation to the operating performance and future estimated undiscounted net cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. The assessment of the recoverability of assets will be impacted if estimated future operating cash flows are not achieved. The Company recorded no impairment during the years ended December 31, 2020 and 2019.

Income Taxes

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

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

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses were $1,295,000 and $368,000 for 2020 and 2019, respectively.

Reverse Stock Split

On November 14, 2019, the Company filed a certificate of amendment to its restated certificate of incorporation with the Secretary of State of the State of Delaware, which effected a one-for-15 reverse stock split (the “reverse split”) of its issued and outstanding shares of common stock at 5:01 PM Eastern Time on that date. As a result of the reverse split, every 15 shares of common stock issued and outstanding were converted into one share of common stock. No fractional shares were issued in connection with the reverse split. Stockholders who would otherwise have been entitled to a fractional share of common stock instead received a cash payment equal to such fraction multiplied by the average of the closing sales prices of the common stock (as adjusted to give effect to the reverse split) on The Nasdaq Global Market for the five consecutive trading days immediately preceding the effective date.

The reverse split did not change the par value of the common stock or the authorized number of shares of common stock. The reverse split affected all stockholders uniformly and did not alter any stockholder’s percentage interest in equity (other than

as a result of the payment of cash in lieu of fractional shares). All outstanding options, preferred stock, restricted stock units, warrants and other securities entitling their holders to purchase or otherwise receive shares of Alimera's common stock have been adjusted as a result of the reverse split, as required by the terms of each security. The number of shares available to be awarded under the 2019 Omnibus Incentive Plan and the number of shares that are purchasable under the 2010 Employee Stock Purchase Plan have also been appropriately adjusted. The common stock began trading on The Nasdaq Global Market on a post-reverse split basis on November 15, 2019. The reverse split permitted the Company to regain compliance with Nasdaq's "minimum bid price" requirement for continued listing, which requires that the bid price of the stock of a listed company be at least $1.00 per share.

Stock-Based Compensation

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

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

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

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash and cash equivalents and current assets and liabilities approximate their fair value because of their short maturities. The weighted average interest rate of the Company's notes payable approximates the rate at which the Company could obtain alternative financing; therefore, the carrying amount of the note approximates the fair value. The Company uses the Black-Scholes option pricing model and assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value of options granted.

Foreign Currency Translation

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

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

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

Earnings Per Share (EPS)

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

Basic EPS is computed by dividing net (loss) income available to stockholders by the weighted average number shares outstanding for the period. Diluted EPS is calculated in accordance with ASC 260 by adjusting weighted average shares

outstanding for the dilutive effect of common stock options, restricted stock units and warrants. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be anti-dilutive.

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

	Years Ended December 31,	
	2020	2019
Series A convertible preferred stock	601,504	601,504
Series C convertible preferred stock	—	676,667
Common stock warrants	30,582	119,712
Stock options	939,379	871,472
Restricted stock units	—	36,763
Total	1,571,465	2,306,118

Reporting Segments

The Company determines segments in accordance with its internal operating structure. The Company's chief operating decision maker is the Chief Executive Officer (CEO). While the CEO is apprised of a variety of financial metrics and information, the business is principally managed and organized based upon geographic and regulatory environment. Each segment is separately managed and is evaluated primarily on segment income or loss from operations. The Company does not report balance sheet information by segment because it is not reviewed by the Company's chief operating decision maker. See Note 19.

Accounting Standards Issued but Not Yet Effective

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (ASC 326): Measurement of Credit Losses on Financial Instruments*. This ASU replaces the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. The standard becomes effective for the Company on January 1, 2023. The Company does not anticipate the adoption of this ASU will have a material impact on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12. *Income Taxes (ASC 740): Simplifying the Accounting for Income Taxes*. The standard eliminates the need for an organization to analyze whether the following apply in a given period: (1) exception to the incremental approach for intraperiod tax allocation; (2) exceptions to accounting for basis differences when there are ownership changes in foreign investments; and (3) exceptions in interim period income tax accounting for year-to-date losses that exceed anticipated losses. The ASU also is designed to improve financial statement preparers' application of income tax-related guidance and simplify GAAP for (1) franchise taxes that are partially based on income, (2) transactions with a government that result in a step-up in the tax basis of goodwill, (3) separate financial statements of legal entities that are not subject to tax and (4) enacted changes in tax laws in interim periods. The standard became effective for the Company on January 1, 2021. The Company does not expect the adoption of this ASU to have a material impact on its financial statements.

In March 2020, the FASB issued ASU 2020-04. *Reference Rate Reform (ASC 848) - Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. This standard provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The standard is available until December 31, 2022. The Company is currently assessing the impact of the optional guidance on the Company's consolidated financial statements and disclosures. The Company did not utilize the optional expedients and exceptions provided by ASU 2020-04 during the year ended December 31, 2020.

In August 2020, the FASB issued ASU 2020-06. *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* This standard simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The standard requires entities to provide expanded disclosures about the terms and features of convertible instruments and amends certain guidance in ASC 260 on the computation of EPS for convertible instruments and contracts on an entity's own equity. The standard becomes effective for the Company on January 1, 2022. The Company is currently assessing the impact of adoption of the ASU.

3. REVENUE RECOGNITION

Net 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. All of the Company's 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.

Currently, all of the Company's revenue is derived from product sales. The Company recognizes revenues from product sales at a point in time when the Customer obtains control, typically upon delivery. The Company accrues for fulfillment costs when the related revenue is recognized. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues.

As of December 31, 2020 and 2019, the Company had received a total of $1,000,000 of milestone payments in connection with the Company's Canadian distributor that it has not recognized as revenue based on the Company's analysis in connection with ASU 2014-09, *Revenue from Contracts with Customers (ASC 606)*. These deferred revenues are included as a component of other non-current liabilities within the Company's consolidated balance sheets.

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. To date, product returns have been minimal.

Other 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; development, regulatory and commercial milestone payments; payments for manufacturing supply services the Company provides; and a revenue share on net sales of licensed products. Each of these payments is recognized as other revenues.

As part of the accounting for these arrangements, the Company must develop estimates that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. Performance obligations are promises in a contract to transfer a distinct good or service to the Customer, and the Company recognizes revenue when, or as, performance obligations are satisfied. The Company uses key assumptions to determine the stand-alone selling price; these assumptions may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical, regulatory and commercial success.

Certain of these agreements include consideration in the form of milestone payments. At the inception of each arrangement that includes milestone payments, the Company evaluates the recognition of milestone payments. Typically, milestone payments are associated with events that are not entirely within the control of the Company or the licensee, such as regulatory approvals; are included in the transaction price; and are subject to a constraint until it is probable that there will not be a significant revenue reversal, typically upon achievement of the milestone. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. To date Other Revenue has been insignificant. Further, no Other Revenue was recognized in 2019 or 2020.

Customer Payment Obligations

The Company receives payments from its Customers based on billing schedules established in each contract, which vary across the Company’s locations, but generally range between 30 to 120 days. Occasionally, the Company offers extended payment terms or payment term discounts to certain customers. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation is that the Customer will pay for the product or services within one year or less of receiving those products or services.

4. LEASES

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

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

Operating Leases

The Company’s operating lease activities primarily consist of leases for office space in the U.S., the U.K., Ireland, Portugal and Germany. Most of these leases include options to renew, with renewal terms generally ranging from one to seven 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, 2020 for the Company's operating leases is as follows:

	(In thousands)
NON-CURRENT ASSETS:	
Right of use assets, net	$ 720
Total lease assets	$ 720
CURRENT LIABILITIES:	
Accrued expenses (Note 9)	$ 405
NON-CURRENT LIABILITIES:	
Other non-current liabilities	438
Total lease liabilities	$ 843

The Company's operating lease cost for the year ended December 31, 2020 was $454,000 and is included in general and administrative expenses in its consolidated statements of operations.

As of December 31, 2020, a schedule of maturity of lease liabilities under all of the Company's operating leases is as follows:

Years Ending December 31	(In thousands)
2021	$ 471
2022	168
2023	168
2024	168
Total	975
Less amount representing interest	(132)
Present value of minimum lease payments	843
Less current portion	(405)
Non-current portion	$ 438

Cash paid for operating leases was $611,000 during the year ended December 31, 2020. No right of use assets were obtained in exchange for operating leases for the year ended December 31, 2020.

As of December 31, 2020, the weighted average remaining lease terms of the Company's operating leases was 3.0 years. The weighted average discount rate used to determine the lease liabilities was 10.1%. 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 at January 1, 2019.

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, 2020 and December 31, 2019 for the Company's finance leases is as follows:

	December 31,	
	2020	2019
	(In thousands)	
NON-CURRENT ASSETS:		
Property and equipment, net	$ 810	$ 414

Total lease assets	$ 810	$ 414
CURRENT LIABILITIES:		
Finance lease obligations	$ 209	$ 255
NON-CURRENT LIABILITIES:		
Finance lease obligations — less current portion	514	94
Total lease liabilities	$ 723	$ 349

Depreciation expense associated with property and equipment under finance leases was approximately $404,000 and $314,000 for the years ended December 31, 2020 and 2019, respectively. Interest expense associated with finance leases was $51,000 and $33,000 for the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, 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)
2021	369
2022	269
2023	129
Total	767
Less amount representing interest	(44)
Present value of minimum lease payments	723
Less current portion	(209)
Non-current portion	$ 514

Cash paid for finance leases was $629,000 during the year ended December 31, 2020. The Company acquired $953,000 of property and equipment in exchange for finance leases during the year ended December 31, 2020.

As of December 31, 2020, the weighted average remaining lease terms of the Company's financing leases was 2.0 years. The weighted average discount rate used to determine the financing lease liabilities was 9.4%. When available, the Company uses the rate implicit in the lease or sublease to discount lease payments to present value; however, most of the Company's leases do not provide a readily determinable implicit rate. Therefore, the Company must estimate its incremental borrowing rate to discount the lease payments based on information available at lease commencement. The incremental borrowing rate is defined as the rate of interest that the Company would have to pay to borrow, on a collateralized basis and over a similar term, an amount equal to the lease payments in a similar economic environment. In using the Company's incremental borrowing rate, management has elected to utilize a portfolio approach and applies the rates to a portfolio of leases with similar underlying assets and terms.

5. GOING CONCERN

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

To date the Company has incurred recurring losses, negative cash flow from operations and has accumulated a deficit of $392,909,000 from the Company's inception through December 31, 2020. As of December 31, 2020, the Company had approximately $11,242,000 in cash and cash equivalents. The Company's ability to achieve profitability and positive cash flow depends on its ability to increase revenue and contain its expenses.

Further, the Company must maintain compliance with the debt covenants of its $45,000,000 Loan and Security Agreement dated December 31, 2019 with Solar Capital Ltd. (see Note 11). In management's opinion, the uncertainty regarding future revenues raises substantial doubt about the Company's ability to continue as a going concern without access to additional debt and/or equity financing, over the course of the next twelve months.

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

6. INVENTORY

Inventory consisted of the following:

	December 31,	
	2020	2019
	(In thousands)	
Component parts (1)	$ 623	$ 389
Work-in-process (2)	1,221	399
Finished goods	902	602
Total inventory	$ 2,746	$ 1,390

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

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

7. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31,	
	2020	2019
	(In thousands)	
Furniture and fixtures	$ 392	$ 392
Office equipment	547	543
Finance leases	1,117	890
Software	1,308	1,301
Leasehold improvements	486	471
Manufacturing equipment	1,735	1,154
Total property and equipment	5,585	4,751
Less accumulated depreciation and amortization	(3,947)	(3,811)
Property and equipment — net	$ 1,638	$ 940

Depreciation and amortization expense associated with property and equipment totaled $731,000 and $701,000 for the years ended December 31, 2020 and 2019, respectively.

8. INTANGIBLE ASSET

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

The gross carrying amount of the intangible asset is $25,000,000, which is being amortized over approximately 13 years from the acquisition date. The net book value of the intangible asset was $12,838,000 and $14,783,000 as of December 31, 2020 and 2019, respectively, and amortization expense was $1,946,000 and $1,940,000 for the years ended December 31, 2020 and 2019, respectively.

The estimated remaining amortization as of December 31, 2020 is as follows (in thousands):

Years Ending December 31	
2021	$ 1,940
2022	1,940
2023	1,940
2024	1,946
2025	1,940
Thereafter	3,132
Total	$ 12,838

9. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
	2020	2019
	(In thousands)	
Accrued clinical investigator expenses	$ 25	$ 576
Accrued compensation expenses	1,372	2,159
Accrued rebate, chargeback and other revenue reserves	1,116	766
Accrued lease liabilities (note 4)	405	469
Other accrued expenses	279	746
Total accrued expenses	$ 3,197	$ 4,716

10. LICENSE AGREEMENTS

EyePoint Agreement

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

Second Amended and Restated Collaboration Agreement

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

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

The New Collaboration Agreement converted the Company's obligation to share 20% of its net profits to a royalty payable on global net revenues of ILUVIEN. The Company began paying a 2% royalty on net revenues and other related consideration to EyePoint on July 1, 2017. This royalty amount increased to 6% effective December 12, 2018. Pursuant to the New Collaboration Agreement the Company is required to pay an additional 2% royalty on global net revenues and other related consideration in excess of $75,000,000 in any year. During 2020 and 2019, the Company recognized approximately $2,064,000 and $2,158,000 of royalty expense, respectively, which is included in cost of goods sold, excluding depreciation and amortization. As of December 31, 2020, approximately $583,000 of this royalty expense was included in the Company's accounts payable.

In connection with a previous agreement with EyePoint, the Company was entitled to recover commercialization costs that were incurred prior to profitability of ILUVIEN and offset a portion of future payments owed to EyePoint in connection with sales of ILUVIEN with those accumulated commercialization costs. (The Company's future rights to recover these amounts from EyePoint are referred to as the Future Offset.) Following the signing of the New Collaboration Agreement, the Company retained a right to recover up to $15,000,000 of the Future Offset. Due to the uncertainty of future net profits, the Company has fully reserved the Future Offset in the accompanying consolidated financial statements. In March 2019, pursuant to the New Collaboration Agreement, the Company forgave $5,000,000 of the Future Offset in connection with the approval of ILUVIEN for NIU-PS in the U.K. As of December 31, 2020, the balance of the Future Offset was approximately $7,874,000. The Company will be able to recover the balance of the Future Offset as a reduction of future royalties that would otherwise be owed to EyePoint as follows:

From December 12, 2018 through December 12, 2020, the royalty was reduced from 6% to 4%; and

Beginning December 13, 2020, the royalty was reduced from 6% to 5.2% for net revenues and other related consideration up to $75,000,000 annually and from 8% to 6.8% for net revenues and other related consideration in excess of $75,000,000 on an annual basis.

Possible Reversion of the Company's License Rights to EyePoint

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

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

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

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

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

11. LOAN AGREEMENTS

Hercules Warrants

In April 2014, Alimera Sciences Limited (Alimera UK), a subsidiary of the Company, entered into a $35,000,000 loan and security agreement (Hercules Loan Agreement) with Hercules Capital, Inc. (Hercules). On January 5, 2018, the Company paid off the Hercules Loan on behalf of Alimera UK. In connection with Alimera UK entering into the Hercules Loan Agreement, the Company issued a warrant that granted Hercules the right to purchase up to 19,002 shares of the Company's common stock at an exercise price of $92.10 per share (the 2014 Warrant). The Company amended the 2014 Warrant a number of times to increase the number of shares issuable upon exercise to 83,933 and decrease the exercise price to $20.85 per share. The right to exercise this warrant expired on November 2, 2020. In connection with Alimera UK entering into an amendment to the Hercules Loan Agreement on October 20, 2016, the Company agreed to issue a new warrant to Hercules (the 2016 Warrant) that granted Hercules the right to purchase up to 30,582 shares of the Company's common stock at an exercise price of $16.35 per share. The right to exercise this warrant expires on October 20, 2021.

Solar Capital Loan Agreements

2018 Solar Capital Loan Agreement

On January 5, 2018, the Company entered into a $40,000,000 Loan and Security Agreement (the 2018 Solar Loan Agreement) with Solar Capital Ltd. (Solar Capital) and certain other lenders. Under the 2018 Solar Loan Agreement, the Company borrowed the entire $40,000,000 as a term loan (the 2018 Solar Loan) that was scheduled to mature on July 1, 2022. The Company repaid the 2018 Solar Loan on December 31, 2019 with a new loan agreement with Solar Capital as described below. The Company used the proceeds of the 2018 Solar Loan to extinguish (prepay) the Hercules Loan Agreement and pay related expenses. The Company used the remaining loan proceeds to provide additional working capital for general corporate purposes. Interest on the 2018 Solar Loan was payable at one-month LIBOR plus 7.65% per annum. The 2018 Solar Loan Agreement provided for interest only payments through the date of repayment. As of the final interest payment on the 2018 Solar Loan, the interest rate was approximately 9.3%.

2018 Exit Fee Agreement

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

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

- first, if the Company achieves revenues of $80,000,000 or more from the sale of its ILUVIEN product in the ordinary course of business to third party customers, measured on a trailing 12-month basis during the term of the agreement, tested at the end of each month; and
- second, if the Company achieves revenues of $100,000,000 or more from the sale of its ILUVIEN product in the ordinary course of business to third party customers, measured in the same manner.

2019 Solar Capital Loan Agreement

On December 31, 2019, the Company entered into a $45,000,000 Loan and Security Agreement (the 2019 Solar Loan Agreement) with Solar Capital, as Agent, and the parties signing the Loan Agreement from time to time as Lenders, including Solar Capital in its capacity as a Lender (collectively, the Lenders). Under the 2019 Solar Loan Agreement, the Company borrowed $42,500,000 on December 31, 2019 and subsequent to December 31, 2019, the Company borrowed the remaining $2,500,000 on February 21, 2020 (the two borrowings totaling $45,000,000 are referred to as the Solar Loan). The Solar Loan matures on July 1, 2024.

As noted above, the Company used the initial proceeds of the Solar Loan to pay off the 2018 Solar Loan, along with related prepayment, legal and other fees and expenses of approximately $2,278,000, which included a $1.8 million fee to Solar Capital upon repayment of the 2018 Solar Loan that was previously accrued and a $400,000 prepayment fee to Solar Capital that was capitalized as deferred financing costs. The Company expects to use the remaining loan proceeds to provide additional working capital for general corporate purposes.

Interest on the Solar Loan is payable at the greater of (i) one-month LIBOR or (ii) 1.78%, plus 7.65% per annum. As of December 31, 2019, the Solar Loan's interest rate is 9.43%. The Solar Loan provides for interest only payments until January 1, 2023. If the Company meets certain revenue thresholds and no event of default shall have occurred and is continuing, the Company can extend the interest only period an additional six months, ending on June 30, 2023, followed by one year of monthly payments of principal and interest.

The Company paid the Lenders a non-refundable facility fee in the amount of $25,000 on February 21, 2020. In addition, the Company is obligated to pay a $2,250,000 fee upon repayment of the Solar Loan.

The Company may elect to prepay not less than $10,000,000 of the outstanding principal balance of the Solar Loan. The Company must pay a prepayment premium upon any prepayment of the Solar Loan before its maturity date, whether by mandatory or voluntary prepayment, acceleration or otherwise, equal to:

- 2.00% of the principal amount prepaid for a prepayment made on or after December 31, 2019 through and including December 31, 2020;
- 1.00% of the principal amount prepaid for a prepayment made after December 31, 2020 through and including December 31, 2021; and
- 0.50% of the principal amount prepaid for a prepayment made after December 31, 2021 and greater than 30 days before the maturity date.

2019 Exit Fee Agreement

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

If the Company has not already paid the $675,000 fee under the 2019 Exit Fee Agreement, the Company is also obligated to pay a fee of $337,500 on achieving each of the following milestones:

- first, if the Company achieves revenues of $75,000,000 or more from the sale of ILUVIEN in the ordinary course of business to third party customers, measured on a trailing 12-month basis during the term of the 2019 Exit Fee Agreement, tested at the end of each month; and
- second, if the Company achieves revenues of $95,000,000 or more from the sale of ILUVIEN in the ordinary course of business to third party customers, measured in the same manner.

In no event, however, will the Company be obligated to pay more than a total of $675,000 in fees under the 2019 Exit Fee Agreement. The 2018 Exit Fee Agreement under the 2018 Solar Loan Agreement remains in effect, has a term ending January 5, 2028 and is further described above.

No warrants were issued in connection with the 2018 Solar Loan Agreement or the 2019 Solar Loan Agreement.

The Company agreed, for itself and its subsidiaries, to customary affirmative and negative covenants and events of default in connection with the 2019 Solar Loan Agreement. The occurrence of an event of default could result in the acceleration of the Company's obligations under the 2019 Solar Loan Agreement and an increase to the applicable interest rate and would permit the Agent to exercise remedies with respect to the collateral under the 2019 Solar Loan Agreement.

The Company's obligations to the Agent and the Lenders under the 2019 Solar Loan Agreement are secured by a first priority security interest in substantially all of the assets, excluding intellectual property, of the Company and its wholly owned subsidiary, Alimera Sciences (DE), LLC (Alimera DE), which is a guarantor of the loan, provided that only 65% of the voting interests in the foreign subsidiaries owned by the Company and Alimera DE are pledged to the Lenders, and no assets or equity interests in the direct or indirect subsidiaries of such foreign subsidiaries are subject to the Lenders' security interests. The Lenders do, however, maintain a negative pledge on the property of the Company and all of its subsidiaries, including the Company's intellectual property, requiring the Lenders' consent for any liens (other than typical permitted liens) on or the sale of such property.

First Amendment to 2019 Solar Capital Loan Agreement

On May 1, 2020, the Company entered into a First Amendment (the Amendment) to the 2019 Solar Loan Agreement. The Amendment, among other things, requires that a revenue covenant be measured at March 31, 2021 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 a plan we submitted to Agent in February 2021, and with such plan to be approved by our board of directors and Solar Capital in its sole discretion. The Amendment also included revised covenants that applied to our financial performance during 2020, all of which we met.

Modification of Debt

In accordance with the guidance in ASC 470-50, *Debt*, the Company entered into and accounted for the 2019 Solar Loan Agreement as a modification and capitalized approximately $427,000 of costs as additional deferred financing costs and expensed approximately $76,000 of costs incurred with third parties within the consolidated statements of operations for the year ended December 31, 2019. In connection with entering into this loan, the Company was obligated to pay a $1.8 million fee upon repayment of the 2018 Solar Loan that was previously accrued and a $400,000 prepayment fee.

In accordance with the guidance in ASC 470-50, *Debt*, the Company entered into and accounted for the Amendment as a modification and expensed, as they were incurred, an insignificant amount of legal costs associated with third parties as costs of modification. The Company did not capitalize any additional costs associated with the Amendment.

Paycheck Protection Program

On April 22, 2020, the Company received an approximately $1,778,000 loan (the PPP Loan) under the Paycheck Protection Program established by the U.S. Small Business Administration (the SBA) as part of the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act. The PPP Loan is unsecured and is evidenced by a note (the Note) in favor of HSBC Bank USA, National Association (HSBC) as the lender.

The interest rate on the Note is 1.0% per annum. The Note has a two-year term and is payable in 18 equal monthly payments of principal and interest beginning on the 180th day following the disbursement of the loan proceeds, subject to possible full forgiveness and a deferred commencement date for beginning payments as described below. The Paycheck Protection Program provides for forgiveness of up to the full amount borrowed as long as the Company uses the loan proceeds during the 24-week period following disbursement for eligible purposes as described in the CARES Act and related guidance. Under the CARES Act, loan forgiveness is generally available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the 24-week period. The Company used all of the proceeds from the PPP Loan to pay expenses during the applicable period that the Company believes were for eligible purposes. On July 21, 2020, the Company submitted an application to HSBC for forgiveness of the PPP Loan. As of the date of this filing, the application for forgiveness is still pending review.

Under the revised rules for the PPP Loan program, the Company will not have to begin principal and interest payments before the date on which the SBA remits the loan forgiveness amount to HSBC (or notifies HSBC that no loan forgiveness is allowed). If no loan forgiveness is allowed, the Company will be required to pay HSBC equal monthly payments of principal and interest based on the principal amount outstanding on the PPP Loan, plus interest outstanding at the end of the deferment period, and taking into account any reductions in the principal amount due to forgiveness, if any. Interest accrued during the deferment period will be capitalized as principal.

In connection with the PPP Loan, the Company entered into a Consent to Loan and Security Agreement (the Consent) under the 2019 Solar Loan Agreement. In the Consent, Solar Capital consented as Collateral Agent and a Lender, and the other Lenders consented as Lenders, to the indebtedness incurred under the PPP Loan, subject to certain conditions, including the Company's covenant to comply with specified provisions of the CARES Act, the Company's confirmation of the accuracy of its representations and warranties in the 2019 Solar Loan Agreement and related documents and a release in favor of the Collateral Agent and the Lenders.

The Company has accounted for the PPP Loan in the same manner as it has for its other loan agreements. Payments that are due within 12 months of balance sheet dates are shown as current liabilities and payments due thereafter are shown as non-current liabilities. The Company incurred and capitalized insignificant costs with third parties as deferred financing costs associated with the PPP Loan and is expensing these costs to interest expense over the life of the loan using the effective interest method. If the Company's application for forgiveness is approved, the Company will recognize a gain on extinguishment of debt at the time of forgiveness.

Fair Value of Debt

The weighted average interest rates of the Company's notes payable approximate the rate at which the Company could obtain alternative financing. Therefore, the carrying amount of the notes approximated their fair value at December 31, 2020 and 2019.

12. COMMITMENTS AND CONTINGENCIES

Solar Loan

Under the 2019 Solar Loan Agreement (see Note 11), as of December 31, 2020, the Company was obligated to make future minimum principal payments on the Solar Loan, excluding the $2,250,000 fee that will be due upon its repayment in full, as follows:

Years Ending December 31	(In thousands)
2021	—
2022	—
2023	20,769
2024	24,231
Total	45,000
Less unamortized debt discount and deferred financing costs	(2,881)
Less current portion	—
Non-current portion	$ 42,119

As of December 31, 2020 and 2019, the Company had no accrued or unpaid interest payable under the 2019 Solar Loan Agreement.

PPP Loan

Under the PPP Loan (see Note 11), as of December 31, 2020, if the Company's application for forgiveness of the PPP Loan were not approved, the Company would be obligated to make future minimum principal payments on the PPP, as follows:

Years Ending December 31	(In thousands)
2021	1,481
2022	297
Total	1,778
Less deferred financing costs	(8)
Less current portion	(1,481)
Non-current portion	$ 289

Significant Agreements

In February 2010, the Company entered into an agreement with a third-party manufacturer for the manufacture of the ILUVIEN implant, the assembly of the ILUVIEN applicator and the packaging of the completed ILUVIEN commercial product. The Company is responsible for supplying the ILUVIEN applicator and the active pharmaceutical ingredient. In accordance with

the terms of the agreement, the Company must order at least 80% of the ILUVIEN units required in the U.S., Canada and the EEA from the third-party manufacturer. This agreement had an initial term of six years. After that six-year term ended, the agreement automatically renewed for successive one-year periods. In February 2016, the Company and the third-party manufacturer amended and restated this agreement to extend the term by five years, at which point the agreement will automatically renew 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.

In October 2020, the Company entered into a Manufacturing Services Agreement (the Cadence Agreement) with Cadence, Inc., under which Cadence will manufacture certain component parts of the ILUVIEN applicator (the components) at its facility near Pittsburgh, Pennsylvania. Under the Cadence Agreement, the Company 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.

In January 2020, the Company entered into an agreement with the first of two contract research organizations (CROs) for clinical and data management services to be performed in connection with a multicenter, single masked, randomized and controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its advantages over using the current standard of care of repeat anti-VEGF injections (the NEW DAY Study). The NEW DAY Study is planned to enroll 320 treatment-naïve, or almost naïve, DME patients in approximately 42 sites around the U.S. For the year ended December 31, 2020, the Company incurred $1,291,000 of expense associated with the NEW DAY Study. As of December 31, 2020, the Company expects to incur approximately an additional $12,000,000 of expense associated with the study through December 31, 2024.

Employment Agreements

The Company is party to employment agreements with four executives. The agreements generally provide for annual salaries, bonuses and benefits and for the “at-will” employment of such executives. Effective January 1, 2021, the Company is party to five agreements with annual salaries ranging from $300,000 to $550,000. If any of the agreements are terminated by the Company without cause, or by the employee for good reason, as defined in the agreements, the Company will be liable for one year to 18 months of salary and benefits. Certain other employees have general employment contracts that include stipulations regarding confidentiality, Company property, severance in an event of change of control and miscellaneous items.

13. PREFERRED STOCK

Series A Convertible Preferred Stock

On October 2, 2012, the Company closed its preferred stock financing in which it sold units consisting of 1,000,000 shares of Series A Convertible Preferred Stock (Series A Preferred Stock) and warrants (which expired on October 1, 2017) to purchase 300,000 shares of Series A Preferred Stock for gross proceeds of $40,000,000, prior to the payment of approximately $560,000 of related issuance costs. The powers, preferences and rights of the Series A Preferred Stock are set forth in the certificate of designation for the Series A Preferred Stock filed by the Company with the Delaware Secretary of State as part of the Company’s certificate of incorporation. Each share of Series A Preferred Stock is convertible into shares of the Company’s common stock at any time at the option of the holder at the rate equal to $40.00 divided by $39.90 (Conversion Price). Each share of Series A Preferred Stock shall automatically be converted into shares of common stock at the then-effective Conversion Price upon the date on which the Company consummates an equity financing transaction pursuant to which the Company sells to one or more third party investors either (a) shares of common stock or (b) other equity securities that are convertible into shares of common stock and that have rights, preference or privileges, senior to or on a parity with, the Series A Preferred Stock, in each case having an as-converted per share of common stock price of not less than $150.00 and that results in total gross proceeds to the Company of at least $30,000,000. The rights and preferences of Series A Preferred Stock also place limitations on the Company’s ability to declare or pay any dividend or distribution on any shares of capital stock. Each share of Series A Preferred Stock is entitled to one vote per share of common stock underlying the Series A Preferred Stock on an as-converted basis based on a deemed conversion price of $44.25 per share.

In 2014, the Company issued 6,015,037 shares of common stock pursuant to the conversion of 400,000 shares of Series A Preferred Stock. As of December 31, 2020, there were 600,000 shares of Series A Convertible Preferred Stock issued and outstanding.

Series B Convertible Preferred Stock and Series C Convertible Preferred Stock

On September 4, 2018, the Company entered into and closed a Series B Preferred Stock Exchange Agreement (Exchange Agreement) with the holders of all of its then outstanding approximately 8,416 shares of Series B Convertible Preferred Stock, par value $0.01 per share (Series B Preferred Stock). Under the Exchange Agreement, the holders of such Series B Preferred Stock exchanged those shares for an aggregate of 10,150 shares of Series C Convertible Preferred Stock, par value $0.01 per share (Series C Preferred Stock). The 10,150 issued and outstanding shares of Series C Preferred Stock had an aggregate stated value of $10,150,000 and were convertible into shares of the Company's common stock at $15.00 per share, or 676,667 shares of the Company's common stock in total, at any time at the option of the holder, subject to certain limitations. The holders of all of the outstanding shares of Series C Preferred Stock converted them into shares of the Company's common stock in the third and fourth quarters of 2020.

There were no shares of Series B Preferred Stock or Series C Preferred Stock issued and outstanding at December 31, 2020.

14. STOCK INCENTIVE PLANS

The Company has stock option and stock incentive plans that provide for grants of shares to employees and grants of options to employees and directors to purchase shares of the Company's common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. Awards that can be granted under these plans include stock options, restricted stock units (RSUs) and restricted stock. The Company also has an employee stock purchase plan (see Note 18). Options granted to employees typically become exercisable over a four-year vesting period and have a ten-year contractual term. Initial options granted to directors typically vest over a four-year period and have a ten-year contractual term. Annual option grants to directors typically vest immediately and have a ten-year contractual term. Upon the exercise of stock options, the Company may issue the required shares out of authorized but unissued common stock or out of treasury stock at management's discretion.

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

	Years Ended December 31,			
	2020		2019	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options outstanding at beginning of period	871,472	$ 35.46	830,100	$ 39.41
Grants	200,081	6.69	128,283	13.36
Forfeitures	(132,174)	54.06	(86,911)	40.49
Exercises	—	—	—	—
Options outstanding at year end	939,379	26.72	871,472	35.46
Options exercisable at year end	701,725	32.46	674,952	41.25
Weighted average per share fair value of options granted during the year	$ 4.16		$ 8.28	

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, 2020:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value (In thousands)
Outstanding	939,379	$ 26.72	5.92 years	$ —
Exercisable	701,725	32.46	5.02 years	—
Outstanding, vested and expected to vest	911,509	27.26	5.84 years	—

The Company estimated the fair value of options granted using the Black-Scholes option pricing model. Use of a valuation model requires the Company to make certain assumptions with respect to selected model inputs. Changes in these input variables would affect the amount of expense associated with equity-based compensation. Expected volatility is based on the historical volatility of the Company's common shares over the expected term of the stock option grant. To estimate the expected term, the Company utilizes the "simplified" method for "plain vanilla" options as discussed within the SEC's Statement of Accounting Bulletin 107. The Company intends to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior will be more widely available. The risk-free interest rate is based on U.S. Treasury Daily Treasury Yield Curve Rates corresponding to the expected life assumed at the date of grant. Dividend yield is zero as there are no payments of dividends made or expected. The weighted-average assumptions used for option grants were as follows:

	Years Ended December 31,	
	2020	2019
Risk-free interest rate	1.47%	2.39%
Volatility factor	69.20%	67.29%
Grant date fair value of common stock options	$ 4.16	$ 8.28
Weighted-average expected life	6.02 years	6.03 years
Assumed forfeiture rate	10.00%	10.00%

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

	Years Ended December 31,	
	2020	2019
	(In thousands)	
Sales and marketing	$ 244	$ 339
Research, development and medical affairs	116	328
General and administrative	719	1,240
Total employee stock-based compensation expense related to stock options	$ 1,079	$ 1,907

As of December 31, 2020, there was approximately $1,388,000 of total unrecognized compensation cost related to outstanding stock option awards that will be recognized over a weighted average period of 2.19 years. The total fair value of shares vested during 2020 was approximately $1,225,000.

The total estimated fair value of options granted during the years ended December 31, 2020 and 2019 was $831,000 and $1,063,000, respectively. There were no options exercised for the years ended December 31, 2020 and 2019.

Restricted Stock and Restricted Stock Units

A summary of restricted stock and restricted stock units (RSU) transactions under the plans are as follows:

	Years Ended December 31,			
	2020		2019	
	Restricted Stock & RSUs	Weighted Average Grant Date Fair Value	RSUs	Weighted Average Grant Date Fair Value
Restricted stock & RSUs outstanding at beginning of period	36,763	$ 13.15	60,041	$ 17.30
Grants of restricted stock & RSUs	30,086	3.12	36,763	13.15
Vested shares of restricted stock & RSUs	(36,763)	13.15	(59,341)	17.30
Forfeitures	—	—	(700)	17.40
Restricted stock & RSUs outstanding at year end	30,086	3.12	36,763	13.15

As of December 31, 2020, there was approximately $25,000 of total unrecognized compensation cost related to outstanding restricted stock that will be recognized during the first quarter of 2021.

Employee stock-based compensation expense related to restricted stock and RSUs recognized in accordance with ASC 718 was $192,000 and $517,000 for the years ended December 31, 2020, and 2019, respectively.

15. COMMON STOCK WARRANTS

Historically, the Company has issued warrants to purchase common stock to various lenders.

In connection with Alimera UK entering into the Hercules Loan Agreement (Note 11), the Company entered into the 2014 Warrant, which granted Hercules the right to purchase up to 19,002 shares of the Company's common stock at an exercise price of $92.10 per share. The Company amended the 2014 Warrant a number of times to increase the number of shares issuable upon exercise to 83,933 and decreased the exercise price to $20.85 per share. The right to exercise this warrant expired on November 2, 2020.

In connection with Alimera UK entering into the Fourth Loan Amendment with Hercules, the Company agreed to issue the 2016 Warrant, which granted Hercules the right to purchase up to 30,582 shares of the Company's common stock at an exercise price of $16.35 per share. The right to exercise this warrant expires on October 20, 2021.

Warrants to purchase a total of 119,712 shares of common stock were outstanding at December 31, 2019, and warrants to purchase a total of 30,582 shares of common stock were outstanding as of December 31, 2020. As of December 31, 2020, the exercise price of the outstanding warrants was $16.35 per share.

16. CONCENTRATIONS AND CREDIT RISK

For the years ended December 31, 2020 and 2019, there were three customers within the U.S. segment. Two of these customers, which are large pharmaceutical distributors, accounted for approximately 49% and 60%, respectively, of the Company's total consolidated revenues. These two customers accounted for approximately 67% and 68% of the Company's consolidated accounts receivable as of December 31, 2020 and 2019, respectively.

For the year ended December 31, 2020, one of the Company's third-party manufacturers of ILUVIEN comprised approximately 13.6% of the Company's total purchases, and there were no other vendors that comprised more than 10% of the Company's total purchases. For the year ended December 31, 2019, no vendor comprised more than 10% of the Company's total purchases. The Company relies on a single manufacturer for ILUVIEN, a single manufacturer for the ILUVIEN applicator and a single active pharmaceutical ingredient manufacturer for ILUVIEN's active pharmaceutical ingredient.

17. INCOME TAXES

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security ("CARES") Act was enacted and signed into law. In addition to other provisions, the CARES Act contains modifications to Net Operating Loss (NOL) carryback rules. For the twelve months ended December 31, 2020, there was no impact to the tax provision related to the CARES Act. The Company is currently evaluating the provisions of the CARES Act and how other elections may impact our financial position, results of operations, and disclosures, if needed.

The components of net loss before taxes are as follows:

	Years Ended December 31,	
	2020	2019
	(In thousands)	
United States	$ (5,535)	$ (1,840)
Foreign	128	(8,387)
Loss before provision for income taxes	$ (5,407)	$ (10,227)

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

The provision for income taxes consists of the following components:

	Years Ended December 31,	
	2020	2019
	(In thousands)	
Current expense (benefit):		
Federal	$ —	$ —
State	—	—
Foreign	(37)	(238)
Current income tax benefit	(37)	(238)
Deferred expense (benefit):		
Federal	(1,084)	(34)
State	(350)	4,743
Foreign	(31)	448
	(1,465)	5,157
Valuation allowance	1,434	(4,703)
Deferred income tax (benefit) expense	(31)	454
Total income tax (benefit) expense	$ (68)	$ 216

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

	Years Ended December 31,	
	2020	2019
	(In thousands)	
Valuation allowance at beginning of period	$ (37,448)	$ (42,151)
(Increase) decrease in valuation allowance	(1,434)	4,703
Valuation allowance at end of period	$ (38,882)	$ (37,448)

Worldwide net deferred tax assets and liabilities are as follows:

	December 31,	
	2020	2019
Deferred tax assets	(In thousands)	
Depreciation and amortization	$ 69	$ 61
Other deferred tax assets	948	662
NOL carry-forwards	31,832	30,361
Research and development costs	—	203
Equity compensation	4,902	4,774
Collaboration agreement receivable reserves	1,884	2,121
Valuation allowance	(38,882)	(37,448)
Total deferred tax assets	$ 753	$ 734

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

	Years Ended December 31,			
	2020		2019	
	Amount	Percent	Amount	Percent
	(in thousands, except percentages)			
Federal tax benefit at statutory rate	$ (1,135)	21.0%	$ (2,148)	21.0%
State tax — net of federal benefit	(350)	6.5	4,743	(46.4)
Permanent items and other	151	(2.8)	278	(2.7)
Foreign rate differential	52	(1.0)	1,898	(18.6)
Deferred rate change	6	(0.1)	(15)	0.1
Tax credits and true-ups	(226)	4.1	163	(1.5)
Increase (decrease) in valuation allowance	1,434	(26.5)	(4,703)	46.0
Total tax (benefit) expense	$ (68)	1.2%	$ 216	(2.1)%

The Company modified its income taxes footnote for the year ended December 31, 2019 and removed certain state NOL carry-forwards of approximately $4,169,000. This same amount was removed from the Company's valuation allowance, which resulted in no net change to the Company's total deferred tax assets. The change was primarily driven by a shift in the Company's state apportionment. This change had no impact on previously reported consolidated balance sheets, net loss on our statements of operations, comprehensive loss, stockholders' deficit or cash flows.

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

	Years Ended December 31,	
	2020	2019
	(In thousands)	
Balance of uncertain tax positions at beginning of period	$ 58	$ 68
Gross increases - tax positions in current period	10	3
Gross increases - tax positions in prior period	—	—
Gross decreases - tax positions in prior period	(3)	(13)
Settlements	—	—
Lapse of statute of limitations	—	—
Balance of uncertain tax positions at end of period	$ 65	$ 58

Included in the balance of unrecognized tax benefits as of December 31, 2020 and 2019 are approximately $65,970 and $58,000, respectively, of tax benefits related to research and development tax credits. In accordance with ASC 740-10, such attributes are reduced to the amount that is expected to be recognized in the future. The Company does not accrue interest or penalties, as there is no risk of additional tax liability due to significant NOLs available. The Company does not expect any decreases to the unrecognized tax benefits within the next twelve months due to any lapses in statute of limitations. Tax years from 2016 to 2019 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, 2020 and 2019, the Company had federal net operating loss (NOL) carry-forwards of approximately $131.4 million and $126.2 million, and state NOL carry-forwards of approximately $96.2 million and $92.2 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 2038, 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 2020 and 2040.

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

As of December 31, 2020, the Company had cumulative book losses in foreign subsidiaries of approximately $136.5 million. The Company has not recorded a deferred tax asset for the excess of tax over book basis in the stock of its foreign subsidiaries. The Company anticipates that its foreign subsidiaries will be profitable and have earnings in the future. Once the

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

18. EMPLOYEE BENEFIT PLANS

The Company has a salary deferral 401(k) plan that covers substantially all U.S. employees of the Company. The Company matches participant contributions subject to certain plan limitations. Compensation expense associated with the Company's matching plan totaled $248,000 and $195,000 for the years ended December 31, 2020 and 2019, respectively. The Company may also make an annual discretionary profit-sharing contribution. No such discretionary contributions were made during the years ended December 31, 2020 and 2019, respectively.

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

The ESPP was effective upon the completion of the Company's initial public offering in 2010, at which time a total of 32,961 shares of the Company's common stock were made available for sale. As of January 1 of each year, the number of available shares is automatically restored to the original level. A total of 13,812 and 5,655 shares of the Company's common shares were acquired through the ESPP during the years ended December 31, 2020 and 2019, respectively. As such, on January 1, 2021 and 2020, respectively, an additional 13,812 and 5,655 shares became available for future issuance under the ESPP. In accordance with ASC 718-50, the ability to purchase stock at 85% of the lower of the fair market value of a share of common stock on the offering date or the exercise date represents an option. The Company estimates the fair value of such options at the inception of each offering period using the Black-Scholes valuation model. In connection with the ESPP, the Company recorded $60,000 and $32,000 of compensation expense for the years ended December 31, 2020 and 2019, respectively.

19. SEGMENT INFORMATION

For the years ended December 31, 2020 and 2019, two customers within the U.S. segment that are large pharmaceutical distributors accounted for 49% and 60% of the Company's consolidated revenues for the years ended December 31, 2020 and 2019, respectively. These same two customers within the U.S. segment accounted for approximately 67% and 68% of the Company's consolidated accounts receivable at December 31, 2020 and 2019, respectively.

The Company's chief operating decision maker is the Chief Executive Officer (CEO). While the CEO is apprised of a variety of financial metrics and information, the business is principally managed and organized based upon geographic and regulatory environment. Each of the Company's segments – U.S. and International– is separately managed. Other is presented to reconcile to consolidated totals. The Company does not report balance sheet information by segment because the Company's chief operating decision maker does not review that information.

Each of the Company's U.S. and International segments is separately managed and is evaluated primarily upon segment income or loss from operations. The Company allocates certain operating expenses between 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, 2020 and 2019:

	Year Ended December 31, 2020			
	U.S.	International	Other	Consolidated
	(In thousands)			
NET REVENUE	$ 24,809	$ 26,011	$ —	$ 50,820
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(2,858)	(4,083)	—	(6,941)
GROSS PROFIT	21,951	21,928	—	43,879
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	6,239	3,280	149	9,668
GENERAL AND ADMINISTRATIVE EXPENSES	7,971	2,812	869	11,652
SALES AND MARKETING EXPENSES	14,273	5,790	321	20,384
DEPRECIATION AND AMORTIZATION	—	—	2,676	2,676
OPERATING EXPENSES	28,483	11,882	4,015	44,380
SEGMENT (LOSS) INCOME FROM OPERATIONS	(6,532)	10,046	(4,015)	(501)
OTHER INCOME AND EXPENSES, NET			(4,906)	(4,906)
NET LOSS BEFORE TAXES				$ (5,407)

	Year Ended December 31, 2019			
	U.S.	International	Other	Consolidated
	(In thousands)			
NET REVENUE	$ 32,283	$ 21,660	$ —	53,943
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(3,487)	(3,139)	—	(6,626)
GROSS PROFIT	28,796	18,521	—	47,317
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	5,943	4,634	415	10,992
GENERAL AND ADMINISTRATIVE EXPENSES	8,449	3,261	1,561	13,271
SALES AND MARKETING EXPENSES	17,591	7,616	480	25,687
DEPRECIATION AND AMORTIZATION	—	—	2,641	2,641
OPERATING EXPENSES	31,983	15,511	5,097	52,591
SEGMENT (LOSS) INCOME FROM OPERATIONS	(3,187)	3,010	(5,097)	(5,274)
OTHER INCOME AND EXPENSES, NET			(4,953)	(4,953)
NET LOSS BEFORE TAXES				$ (10,227)

EXHIBIT INDEX

Exhibit Number	Exhibit Title
3.1	Restated Certificate of Incorporation of Registrant, as amended on various dates (filed as Exhibit 3.1 to the Registrant's Annual Report on Form 10-K, as filed on March 2, 2020, and incorporated herein by reference)
3.2	Amended and Restated Bylaws of the Registrant, as amended (filed as Exhibit 3.2 to the Registrant's Annual Report on Form 10-K, as filed on March 2, 2020, and incorporated herein by reference)
4.1	Irrevocable Waiver of Rights to Designate Series A Director dated May 16, 2014 (filed as Exhibit 4.11 to the Registrant's Current Report on Form 8-K, as filed on May 16, 2014, and incorporated herein by reference)
4.2	Warrant Agreement dated October 20, 2016 by and among the Registrant and Hercules Capital, Inc. f/k/a Hercules Technology Growth Capital, Inc. (filed as Exhibit 4.16 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 4, 2016, and incorporated herein by reference)
4.3*	Description of Securities
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	Office Lease by and between Rubicon, L.C. and Alimera Sciences, Inc., dated as of May 27, 2003, as amended on various dates through August 14, 2014 (filed as Exhibit 10.11 to the Registrant's Annual Report on Form 10-K, as filed on February 25, 2019, and incorporated herein by reference)
10.3.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)
10.3.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)
10.3.C†	Form of Notice of Stock Unit Award and Stock Unit Agreement under 2010 Equity Incentive Plan (filed as Exhibit 10.34 to Registrant's Annual Report on Form 10-K, as filed on March 30, 2012, and incorporated herein by reference)
10.3.D†	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)
10.3.E†	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)
10.3.F†	Form of France Sub-Plan of the 2010 Equity Incentive Plan of Alimera Sciences, Inc. (filed as Exhibit 10.21 to the Registrant's Annual Report on Form 10-K, as filed on March 15, 2016, and incorporated herein by reference)
10.3.G†	(2017) UK Sub-Plan of the 2010 Equity Incentive Plan of Alimera Sciences, Inc. (filed as Exhibit 10.46 to the Registrant's Annual Report on Form 10-K, as filed on March 3, 2017, and incorporated herein by reference)
10.3.H†	Forms of Notice of Restricted Stock Unit Award and restricted Stock Unit Agreement under 2010 Equity Incentive Plan for the U.S., Germany, Portugal and the U.K. (filed as Exhibit 10.47 to the Registrant's Annual Report on Form 10-K, as filed on March 3, 2017, and incorporated herein by reference)

10.4.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)
10.4.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)
10.4.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)
10.5.A†	Alimera Sciences, Inc. 2019 Omnibus Incentive Plan (filed as Exhibit 10.60 to the Registrant's Current Report on Form 8-K, as filed on June 19, 2019, and incorporated herein by reference)
10.5.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)
10.5.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)
10.5.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)
10.6†	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)
10.7.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)
10.7.B†	Succession and Consulting Agreement, dated as of November 28, 2018, by and between Alimera Sciences, Inc. and C. Daniel Myers (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed November 29, 2018, and incorporated herein by reference)
10.7.C†	Amended and Restated Succession and Consulting Agreement, dated as of March 27, 2019, by and between Alimera Sciences, Inc. and Kenneth Green, Ph.D. (filed as Exhibit 10.57 to the Registrant's Current Report on Form 8-K, as filed May 7, 2019, and incorporated herein by reference)
10.7.D†	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)
10.7.E†	First Amendment to Restricted Stock Unit Award Agreement under 2010 Equity Incentive Plan of Richard S. Eiswirth, Jr. (filed as Exhibit 10.3.I to the Registrant's Quarterly Report on Form 10-Q, as filed May 6, 2020, and incorporated herein by reference)
10.7.F†	Employment Agreement, dated as of January 2, 2019, by and between Alimera Sciences, Inc. and J. Philip Jones (filed as Exhibit 10.59 to the Registrant's Current Report on Form 8-K, as filed May 8, 2019, and incorporated herein by reference)
10.7.G†	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)
10.7.H†	Employment Agreement, dated as of July 27, 2020, by and between Alimera Sciences, Inc. and Samer E. Kaba, M.D. (filed as Exhibit 10.8.F to the Registrant's Quarterly Report on Form 10-Q, as filed November 3, 2020, and incorporated herein by reference)
10.9.A	Securities Purchase Agreement dated July 17, 2012 (filed as Exhibit 10.36 to the Registrant's Current Report, as filed on July 18, 2012, and incorporated herein by reference)
10.9.B	Amendment No. 1 to Securities Purchase Agreement dated September 21, 2012 (filed as Exhibit 10.37 to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
10.10‡	Manufacturing Services Agreement by and between the Registrant and Flextronics Medical Sales and Marketing, Ltd. (filed as Exhibit 10.35 to Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2012, and incorporated herein by reference)
10.11‡	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)
10.12**	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)

10.13‡	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)
10.14.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)
10.14.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)
10.14.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)
10.14.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)
10.14.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)
10.15.A	U.S. Small Business Administration Note dated April 21, 2020 of Alimera Sciences, Inc. in favor of HSBC Bank USA, National Association as the Lender (filed as Exhibit 10.16 to the Registrant's Current Report on Form 8-K, as filed April 23, 2020, and incorporated herein by reference)
10.15.B	Loan Agreement dated April 21, 2020 between HSBC Bank USA, National Association and Alimera Sciences, Inc. (filed as Exhibit 10.17 to the Registrant's Current Report on Form 8-K, as filed April 23, 2020, 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
101	The following financial information from The Registrant's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in iXBRL (Inline Extensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2020 and 2019, (ii) Consolidated Statements of Operations for the years ended December 31, 2020 and 2019, (iii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2020 and 2019, (iv) Consolidated Statements of Changes in Stockholders' Deficit for the years ended December 31, 2020 and 2019, and (v) Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019
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 not material and would be competitively harmful if publicly disclosed.

* 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 4, 2021.

ALIMERA SCIENCES, INC.

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

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 4, 2021
/s/ J. Philip Jones J. Philip Jones	Chief Financial Officer (Principal Financial and Accounting Officer)	March 4, 2021
/s/ C. Daniel Myers C. Daniel Myers	Chairman of the Board of Directors	March 4, 2021
/s/ James Largent James Largent	Lead Independent Director	March 4, 2021
/s/ Brian K. Halak Brian K. Halak, Ph.D.	Director	March 4, 2021
/s/ Garheng Kong Garheng Kong, M.D., Ph.D.	Director	March 4, 2021
/s/ Peter J. Pizzo, III Peter J. Pizzo, III	Director	March 4, 2021
/s/ John Snisarenko John Snisarenko	Director	March 4, 2021
/s/ Mary T. Szela Mary T. Szela	Director	March 4, 2021

Exhibit 4.3

DESCRIPTION OF SECURITIES

Unless the context otherwise requires, throughout this exhibit, the words “we,” “us,” or “our” refer to Alimera Sciences, Inc. and its subsidiaries (as applicable).

Common Stock

We currently have authorized 150,000,000 shares of common stock, par value $0.01 per share. As of March 1, 2021, there were 5,753,434 shares of the registrant’s common stock issued and outstanding. Holders of our common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of our common stock are fully paid and nonassessable.

The following summary of the terms of our common stock is subject to and qualified in its entirety by reference to our restated certificate of incorporation and bylaws, copies of which are on file with the SEC as exhibits to previous SEC filings.

Voting Rights. The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders, including, without limitation, the election of our board of directors. Our stockholders have no right to cumulate their votes in the election of directors.

Dividends. Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive ratably those dividends declared from time to time by the board of directors.

Rights Upon Liquidation. Subject to preferences that may apply to shares of preferred stock outstanding at the time, in the event of liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in assets remaining after payment of liabilities.

Anti-Takeover Effects of Our Restated Certificate of Incorporation, Bylaws and Delaware Law. Some provisions of Delaware law and our restated certificate of incorporation and bylaws could make the following transactions more difficult: our acquisition by means of a tender offer; our acquisition by means of a proxy contest or otherwise; or removal of our incumbent officers and directors.

Section 203 of the Delaware General Corporation Law is applicable to takeovers of Delaware corporations. Subject to exceptions enumerated in Section 203, Section 203 provides that a corporation shall not engage in any business combination with any “interested stockholder” for a three-year period following the date that the stockholder becomes an interested stockholder unless:

- prior to that date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, though some shares may be excluded from the calculation; and
- on or subsequent to that date, the business combination is approved by the board of directors of the corporation and by the affirmative votes of holders of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Except as specified in Section 203, an interested stockholder is generally defined to include any person who, together with any affiliates or associates of that person, beneficially owns, directly or indirectly, 15% or more of the outstanding voting stock of the corporation, or is an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of the corporation, any time within three years immediately prior to the relevant date. Under certain circumstances, Section 203 makes it more difficult for an interested stockholder to effect various business combinations with a corporation for a three-year period, although the stockholders may elect not to be governed by this section, by adopting an amendment to the certificate of incorporation or bylaws, effective 12 months after adoption. Our restated certificate of incorporation and bylaws do not opt out from the restrictions imposed under Section 203. We anticipate that the provisions of Section 203 may encourage companies interested in acquiring us to negotiate in advance with the board because the stockholder approval requirement would be avoided if a majority of the directors then in office excluding an interested stockholder approve either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder. These provisions may have the effect of deterring hostile takeovers or delaying changes in control, which could depress the market price of our common stock and deprive stockholders of opportunities to realize a premium on shares of common stock held by them.

In addition to our board of directors’ ability to issue shares of preferred stock, our restated certificate of incorporation and bylaws contain provisions that 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 the 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;
- limit who may call special meetings of stockholders;
- prohibit stockholder action by written consent, requiring all actions 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.

Transfer Agent and Registrar. The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company LLC.

Listing. Our common stock is listed on The Nasdaq Global Market under the symbol “ALIM.”

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 B.V.	The Netherlands	Alimera Sciences B.V.
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 reports dated March 4, 2021 with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of Alimera Sciences, Inc. on Form 10-K for the year ended December 31, 2020. We consent to the incorporation by reference of said reports in the Registration Statements of Alimera Sciences, Inc. on Forms S-8 (File No. 333-166822, File No. 333-173095, File No. 333-180567, File No. 333-187600, File No. 333-194381, File No. 333-201606, File No. 333-209035, File No. 333-215451, File No. 333-222508, File No. 333-229280, File No. 333-232206, and File No. 333-249811) and on Form S-3 (File No. 333-249804).

/s/ GRANT THORNTON LLP

Atlanta, Georgia
March 4, 2021

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 4, 2021

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

Exhibit 31.2

CERTIFICATION

I, J. Philip Jones, 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 4, 2021

/s/ J. Philip Jones
J. Philip Jones
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, 20 20 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 Company, and J. Philip Jones, Chief Financial Officer, 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 4, 2021

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

Date: March 4, 2021

/s/ J. Philip Jones
J. Philip Jones
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.